

were in effect pursuant to section 706 [now 721] of the basic Act [this section], shall be deemed to be regulations under such section 706 [now 721, this section] as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 [now 721] as in effect prior to the enactment date [July 12, 1960] shall be available for the purposes specified in such section 706 [now 721, this section] as so amended.

“(B) If the Secretary, by regulation—

“(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

“(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action, any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

“(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act [section 371(f) of this title] except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

“(D) On and after the enactment date [July 12, 1960], regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 [now 721] of the basic Act [this section]. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706(b) or (c) [now 721(b), (c)] of the basic Act [subsec. (b) or (c) of this section].

“(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1)(A) and (C) of this subsection with respect to color additives

deemed provisionally listed, he shall, as soon as practicable after enactment of this Act [July 12, 1960], afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date [July 12, 1960] with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1)(C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

“SEC. 204. [EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS INSPECTION ACTS.] Nothing in this Act [amending this section and sections 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, and 371 of this title and repealing sections 354 and 364 of this title] shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following) [see section 601 et seq. of this title] or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).”

#### EFFECTIVE DATE; ACCELERATION

This section was made “immediately effective” by act May 2, 1939, ch. 107, title I, § 1, 53 Stat. 631.

#### TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

#### REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

### PART C—FEES

#### SUBPART 1—FREEDOM OF INFORMATION FEES

### § 379f. Recovery and retention of fees for freedom of information requests

#### (a) In general

The Secretary, acting through the Commissioner of Food and Drugs, may—

(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, to recover all reasonable costs incurred in processing requests made under section 552 of title 5 for records obtained or created under this chapter or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for such requests; and

(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

**(b) Use of fees**

The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1) of this section. Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this chapter.

**(c) Waiver of fees**

Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5.

(June 25, 1938, ch. 675, §731, formerly §711, as added Pub. L. 101-635, title II, §201, Nov. 28, 1990, 104 Stat. 4584; renumbered §731, Pub. L. 102-571, title I, §106(6), Oct. 29, 1992, 106 Stat. 4499.)

CODIFICATION

Section was formerly classified to section 379c of this title prior to renumbering by Pub. L. 102-571.

SUBPART 2—FEES RELATING TO DRUGS

TERMINATION OF SUBPART

*For termination of subpart by section 105 of Pub. L. 102-571, see Termination Date note set out under section 379g of this title.*

**§ 379g. Definitions**

For purposes of this subpart:

(1) The term “human drug application” means an application for—

(A) approval of a new drug submitted under section 355(b) of this title, or

(B) licensure of a biological product under subsection (a) or (k) of section 262 of title 42.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 262 of title 42, does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (B), of a large volume biological product intended for single dose injection for intravenous use or infusion.

(2) The term “supplement” means a request to the Secretary to approve a change in a human drug application which has been approved.

(3) The term “prescription drug product” means a specific strength or potency of a drug in final dosage form—

(A) for which a human drug application has been approved,

(B) which may be dispensed only under prescription pursuant to section 353(b) of this title, and

(C) which is on the list of products described in section 355(j)(7)(A) of this title (not including the discontinued section of such list) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 262 of title 42 (not including the discontinued section of such list).

Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 262 of title 42. Such term does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.

(4) The term “final dosage form” means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as capsules, tablets, or lyophilized products before reconstitution).

(5) The term “prescription drug establishment” means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form. For purposes of this paragraph, the term “manufactured” does not include packaging.

(6) The term “process for the review of human drug applications” means the following activities of the Secretary with respect to the review of human drug applications and supplements:

(A) The activities necessary for the review of human drug applications and supplements.

(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary’s review of pending human drug applications and supplements.

(D) Activities necessary for the review of applications for licensure of establishments subject to section 262 of title 42 and for the release of lots of biologics under such section.

(E) Monitoring of research conducted in connection with the review of human drug applications.

(F) Postmarket safety activities with respect to drugs approved under human 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).

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

(7) The term “costs of resources allocated for the process for the review of human drug applications” means the expenses incurred in connection with the process for the review of human drug applications for—

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

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

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

(D) collecting fees under section 379h of this title and accounting for resources allocated for the review of human drug applications and supplements.

(8) The term “adjustment factor” applicable to a fiscal year 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 1996.

(9) The term “person” includes an affiliate thereof.

(10) The term “active”, with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.

(11) 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.

(June 25, 1938, ch. 675, §735, as added Pub. L. 102-571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; amended Pub. L. 105-115, title I, §§102, 125(b)(2)(M), Nov. 21, 1997, 111 Stat. 2298, 2326; Pub. L. 107-188, title V, §503, June 12, 2002, 116

Stat. 688; Pub. L. 110-85, title I, §102, Sept. 27, 2007, 121 Stat. 825; Pub. L. 111-148, title VII, §7002(f)(3)(A), Mar. 23, 2010, 124 Stat. 818.)

#### AMENDMENT OF SECTION

*For termination of amendment by section 106(a) of Pub. L. 110-85, see Effective and Termination Dates of 2007 Amendment note below.*

*For termination of amendment by section 509 of Pub. L. 107-188, see Effective and Termination Dates of 2002 Amendment note below.*

*For termination of amendment by section 107 of Pub. L. 105-115, see Effective and Termination Dates of 1997 Amendment note below.*

#### TERMINATION OF SECTION

*For termination of section by section 105 of Pub. L. 102-571, see Termination Date note below.*

#### AMENDMENTS

2010—Par. (1)(B). Pub. L. 111-148 substituted “subsection (a) or (k) of section 262 of title 42” for “section 262 of title 42”.

2007—Pub. L. 110-85, §§102(1), 106(a), in introductory provisions, temporarily substituted “For purposes of this subpart” for “For purposes of this part”. See Effective and Termination Dates of 2007 Amendment note below.

Par. (1). Pub. L. 110-85, §§102(2)(D), 106(a), temporarily substituted “subparagraph (B)” for “subparagraph (C)” in concluding provisions. See Effective and Termination Dates of 2007 Amendment note below.

Par. (1)(A). Pub. L. 110-85, §§102(2)(A), 106(a), temporarily substituted “355(b) of this title, or” for “355(b)(1) of this title.”. See Effective and Termination Dates of 2007 Amendment note below.

Par. (1)(B), (C). Pub. L. 110-85, §§102(2)(B), (C), 106(a), temporarily redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: “approval of a new drug submitted under section 355(b)(2) of this title after September 30, 1992, which requests approval of—

“(i) a molecular entity which is an active ingredient (including any salt or ester of an active ingredient), or

“(ii) an indication for a use, that had not been approved under an application submitted under section 355(b) of this title, or”.

See Effective and Termination Dates of 2007 Amendment note below.

Par. (3)(C). Pub. L. 110-85, §§102(3), 106(a), temporarily substituted “355(j)(7)(A) of this title (not including the discontinued section of such list)” for “355(j)(7)(A) of this title” and inserted “(not including the discontinued section of such list)” before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Par. (4). Pub. L. 110-85, §§102(4), 106(a), temporarily inserted “(such as capsules, tablets, or lyophilized products before reconstitution)” before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Par. (6)(F). Pub. L. 110-85, §§102(5), 106(a), temporarily amended subpar. (F) generally. Prior to amendment, subpar. (F) read as follows: “In the case of drugs approved after October 1, 2002, under human drug applications or supplements: collecting, developing, and reviewing safety information on the drugs, including adverse event reports, during a period of time after approval of such applications or supplements, not to exceed three years.” See Effective and Termination Dates of 2007 Amendment note below.

Par. (8). Pub. L. 110-85, §§102(6), 106(a), temporarily substituted “October of the preceding fiscal year” for “April of the preceding fiscal year” and “October 1996” for “April 1997”. See Effective and Termination Dates of 2007 Amendment note below.

Pars. (9) to (11). Pub. L. 110-85, §§102(7), (8), 106(a), temporarily added pars. (9) and (10) and redesignated former par. (9) as (11). See Effective and Termination Dates of 2007 Amendment note below.

2002—Par. (1). Pub. L. 107-188, §§503(1), 509, temporarily substituted “licensure, as described in subparagraph (C)” for “licensure, as described in subparagraph (D)” in concluding provisions. See Effective and Termination Dates of 2002 Amendment note below.

Par. (3). Pub. L. 107-188, §§503(2)(D), 509, which directed the temporary amendment of concluding provisions of par. (3) by striking “section 262 of title 42” and all that follows through “biological product” and inserting “section 262 of title 42. Such term does not include a biological product”, was executed by striking language ending with “biological product” the first time appearing, thereby making the substitution for “section 262 of title 42, does not include a large volume parenteral drug product approved before September 1, 1992, does not include a biological product”, to reflect the probable intent of Congress. See Effective and Termination Dates of 2002 Amendment note below.

Par. (3)(C). Pub. L. 107-188, §§503(2)(A)–(C), 509, temporarily added subpar. (C). See Effective and Termination Dates of 2002 Amendment note below.

Par. (6)(F). Pub. L. 107-188, §§503(3), 509, temporarily added subpar. (F). See Effective and Termination Dates of 2002 Amendment note below.

Par. (8). Pub. L. 107-188, §§503(4), 509, temporarily struck out designations of subpars. (A) and (B) and text of subpar. (B) and concluding provisions, substituting definition of “adjustment factor” as the Consumer Price Index for definition of Index as the lower of the Consumer Price Index or the total of discretionary budget authority provided for programs in the domestic category for the immediately preceding fiscal year divided by such budget authority for fiscal year 1997. See Effective and Termination Dates of 2002 Amendment note below.

1997—Par. (1). Pub. L. 105-115, §§102(1), 107, in closing provisions, temporarily struck out “and” before “does not include an application” and substituted “September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion” for “September 1, 1992” before period at end. See Effective and Termination Dates of 1997 Amendment note below.

Par. (1)(B) to (D). Pub. L. 105-115, §125(b)(2)(M), inserted “or” at end of subpar. (B), redesignated subpar. (D) as (C), and struck out former subpar. (C) which read as follows: “initial certification or initial approval of an antibiotic drug under section 357 of this title, or”.

Par. (3). Pub. L. 105-115, §§102(2), 107, in closing provisions, temporarily struck out “and” before “does not include a large volume parenteral drug” and substituted “September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion” for “September 1, 1992” before period at end. See Effective and Termination Dates of 1997 Amendment note below.

Par. (4). Pub. L. 105-115, §§102(3), 107, temporarily substituted “without substantial further manufacturing” for “without further manufacturing”. See Effective and Termination Dates of 1997 Amendment note below.

Par. (5). Pub. L. 105-115, §§102(4), 107, temporarily amended first sentence generally. Prior to amendment, first sentence read as follows: “The term ‘prescription drug establishment’ means a foreign or domestic place of business which is—

“(A) at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more prescription drug products are manufactured in final dosage form, and  
“(B) under the management of a person that is listed as the applicant in a human drug application for a prescription drug product with respect to at least one such product.”

See Effective and Termination Dates of 1997 Amendment note below.

Par. (7)(A). Pub. L. 105-115, §§102(5), 107, temporarily substituted “contractors of the Food and Drug Administration,” for “employees under contract with the Food and Drug Administration who work in facilities owned or leased for the Food and Drug Administration,” and “and committees and to contracts with such contractors,” for “and committees,”. See Effective and Termination Dates of 1997 Amendment note below.

Par. (8)(A). Pub. L. 105-115, §§102(6)(A), 107, temporarily substituted “April of the preceding fiscal year” for “August of the preceding fiscal year” and “April 1997” for “August 1992”. See Effective and Termination Dates of 1997 Amendment note below.

Par. (8)(B). Pub. L. 105-115, §§102(6)(B), 107, temporarily substituted “section 254(c)” for “section 254(d)”, “fiscal year 1997” for “fiscal year 1992”, and “105th Congress, 1st Session” for “102d Congress, 2d Session”. See Effective and Termination Dates of 1997 Amendment note below.

Par. (9). Pub. L. 105-115, §§102(7), 107, temporarily added par. (9). See Effective and Termination Dates of 1997 Amendment note below.

#### EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Pub. L. 110-85, title I, §106(a), Sept. 27, 2007, 121 Stat. 842, provided that: “The amendments made by sections 102, 103, and 104 [enacting section 379h-1 of this title and amending this section and section 379h of this title] cease to be effective October 1, 2012.”

Pub. L. 110-85, title I, §107, Sept. 27, 2007, 121 Stat. 842, provided that: “The amendments made by this title [enacting sections 379h-1 and 379h-2 of this title and amending this section and sections 379h and 379j-11 of this title] shall take effect on October 1, 2007, or the date of the enactment of this Act [Sept. 27, 2007], whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] shall be assessed for all human drug applications received on or after October 1, 2007, regardless of the date of the enactment of this Act.”

#### EFFECTIVE AND TERMINATION DATES OF 2002 AMENDMENT

Amendment by Pub. L. 107-188 effective Oct. 1, 2002, see section 508 of Pub. L. 107-188, set out as an Effective Date of 2002 Amendment note under section 356b of this title.

Pub. L. 107-188, title V, §509, June 12, 2002, 116 Stat. 694, provided that: “The amendments made by sections 503 and 504 [amending this section and section 379h of this title] cease to be effective October 1, 2007, and section 505 [enacting provisions set out as a note below] ceases to be effective 120 days after such date.”

#### EFFECTIVE AND TERMINATION DATES OF 1997 AMENDMENT

Pub. L. 105-115, title I, §106, Nov. 21, 1997, 111 Stat. 2305, provided that: “The amendments made by this subtitle [subtitle A (§§101-107) of title I of Pub. L. 105-115, amending this section and section 379h of this title] shall take effect October 1, 1997.”

Pub. L. 105-115, title I, §107, Nov. 21, 1997, 111 Stat. 2305, provided that: “The amendments made by sections 102 and 103 [amending this section and section 379h of this title] cease to be effective October 1, 2002, and section 104 [enacting provisions formerly set out as a note below] ceases to be effective 120 days after such date.”

## TERMINATION DATE

Pub. L. 102-571, title I, §105, Oct. 29, 1992, 106 Stat. 4498, provided that: "The amendments made by section 103 [enacting this subpart] shall not be in effect after October 1, 1997 and section 104 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date."

## SAVINGS PROVISION

Pub. L. 110-85, title I, §108, Sept. 27, 2007, 121 Stat. 842, provided that: "Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note) [Pub. L. 107-188], and notwithstanding the amendments made by this title [enacting sections 379h-1 and 379h-2 of this title and amending this section and sections 379h and 379j-11 of this title], part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as in effect on the day before the date of the enactment of this title [Sept. 27, 2007], shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008."

Pub. L. 107-188, title V, §507, June 12, 2002, 116 Stat. 694, provided that: "Notwithstanding section 107 of the Food and Drug Administration Modernization Act of 1997 [section 107 of Pub. L. 105-115, set out as an Effective and Termination Dates of 1997 Amendment note above], and notwithstanding the amendments made by this subtitle A (§§501-509) of title V of Pub. L. 107-188, amending this section and sections 356b and 379h of this title], part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as in effect on the day before the date of the enactment of this Act [June 12, 2002], continues to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that, on or after October 1, 1997, but before October 1, 2002, were accepted by the Food and Drug Administration for filing and with respect to assessing and collecting any fee required by such Act for a fiscal year prior to fiscal year 2003."

Pub. L. 105-115, title I, §105, Nov. 21, 1997, 111 Stat. 2305, provided that: "Notwithstanding section 105 of the Prescription Drug User Fee Act of 1992 [section 105 of Pub. L. 102-571, set out above], the Secretary shall retain the authority to assess and collect any fee required by part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] for a human drug application or supplement accepted for filing prior to October 1, 1997, and to assess and collect any product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998."

## ACCOUNTABILITY AND REPORTS

Pub. L. 107-188, title V, §505, June 12, 2002, 116 Stat. 692, which required the Secretary of Health and Human Services to consult with various congressional committees and health care professionals and provide for public commentary when developing recommendations to Congress regarding review of human drug applications for fiscal years after 2007, and which required the Secretary to submit performance and fiscal reports on certain goals and fees beginning with fiscal year 2003, ceased to be effective 120 days after Oct. 1, 2007. See Effective and Termination Dates of 2002 Amendment note above.

## CONGRESSIONAL FINDINGS CONCERNING FEES RELATING TO DRUGS

Pub. L. 110-85, title I, §101(c), Sept. 27, 2007, 121 Stat. 825, provided that: "The Congress finds that the fees authorized by the amendments made in this title [enacting sections 379h-1 and 379h-2 of this title and amending this section and sections 379h and 379j-11 of this title] will be dedicated toward expediting the drug

development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 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."

Pub. L. 107-188, title V, §502, June 12, 2002, 116 Stat. 687, provided that: "The Congress finds that—

"(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

"(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of human drug applications and the assurance of drug safety;

"(3) the provisions added by the Prescription Drug User Fee Act of 1992 [see section 101(a) of Pub. L. 102-571, set out as a Short Title of 1992 Amendment note under section 301 of this title], as amended by the Food and Drug Administration Modernization Act of 1997 [see Short Title of 1997 Amendment note set out under section 301 of this title], have been successful in substantially reducing review times for human drug applications and should be—

"(A) reauthorized for an additional 5 years, with certain technical improvements; and

"(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration, including—

"(i) strengthening and improving the review and monitoring of drug safety;

"(ii) considering greater interaction between the agency and sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases; and

"(iii) developing principles for improving first-cycle reviews; and

"(4) the fees authorized by amendments made in this subtitle [subtitle A (§§501-509) of title V of Pub. L. 107-188, amending this section and sections 356b and 379h of this title] will be dedicated towards expediting the drug development process and the process for the review of human drug applications as set forth in the goals identified for purposes of part 2 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 Energy and Commerce of the House of Representatives and the chairman of the Committee on Health, Education, Labor and Pensions of the Senate, as set forth in the Congressional Record."

Pub. L. 105-115, title I, §101, Nov. 21, 1997, 111 Stat. 2298, provided that: "Congress finds that—

"(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

"(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

"(3) the provisions added by the Prescription Drug User Fee Act of 1992 [see section 101(a) of Pub. L. 102-571, set out as a Short Title of 1992 Amendment note under section 301 of this title] have been successful in substantially reducing review times for human drug applications and should be—

“(A) reauthorized for an additional 5 years, with certain technical improvements; and

“(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

“(4) the fees authorized by amendments made in this subtitle [subtitle A (§§101-107) of title I of Pub. L. 105-115, amending this section and section 379h of this title] will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 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 Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate, as set forth in the Congressional Record.”

Pub. L. 102-571, title I, §102, Oct. 29, 1992, 106 Stat. 4491, provided that: “The Congress finds that—

“(1) prompt approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

“(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications; and

“(3) the fees authorized by this title [see Short Title of 1992 Amendment note, set out under section 301 of this title] will be dedicated toward expediting the review of human drug applications as set forth in the goals identified in the letters of September 14, 1992, and September 21, 1992, from the Commissioner of Food and Drugs to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate, as set forth at 138 Cong. Rec. H9099-H9100 (daily ed. September 22, 1992).”

#### ANNUAL REPORTS

Pub. L. 105-115, title I, §104, Nov. 21, 1997, 111 Stat. 2304, which directed the Secretary of Health and Human Services to prepare and submit to Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, within 60 days after the end of each fiscal year during which fees are collected under this subpart, a report stating the Food and Drug Administration’s progress in achieving the goals identified in the letters described in section 101(4) of Pub. L. 105-115, set out above, during such fiscal year and the Administration’s future plans for meeting the goals, and within 120 days after the end of each fiscal year during which fees are collected, to prepare and submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Administration made of the fees collected during such fiscal year, ceased to be effective 120 days after Oct. 1, 2002. See section 107 of Pub. L. 105-115, set out as an Effective and Termination Dates of 1997 Amendment note above.

Pub. L. 102-571, title I, §104, Oct. 29, 1992, 106 Stat. 4498, which provided that the Secretary of Health and Human Services submit to Committee on Energy and Commerce of the House of Representatives and Committee on Labor and Human Resources of the Senate, within 60 days after the end of each fiscal year during which fees were collected under this subpart, a report stating the Food and Drug Administration’s progress in achieving the goals identified in section 102(3) of Pub. L. 102-571, set out as a note above, during such fiscal year and that agency’s future plans for meeting such goals, and within 120 days after the end of each fiscal

year during which such fees were collected, a report on the implementation of the authority for such fees during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year, ceased to be in effect 120 days after Oct. 1, 1997. See Termination Date note above.

#### ANIMAL DRUG USER FEE STUDY

Pub. L. 102-571, title I, §108, Oct. 29, 1992, 106 Stat. 4500, directed Secretary, in consultation with manufacturers of animal drug products and other interested persons, to undertake study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 360b of this title, and further provided for submission of study to Congress no later than Jan. 4, 1994.

### § 379h. Authority to assess and use drug fees

#### (a) Types of fees

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

#### (1) Human drug application and supplement fee

##### (A) In general

Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

(i) A fee established under subsection (c)(5) of this section for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(5) of this section for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required. Such fee shall be half of the amount of the fee established under clause (i).

##### (B) Payment

The fee required by subparagraph (A) shall be due upon submission of the application or supplement.

##### (C) Exception for previously filed application or supplement

If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person’s licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

##### (D) Refund of fee if application refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

**(E) Fees for applications previously refused for filing or withdrawn before filing**

A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

**(F) Exception for designated orphan drug or indication**

A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 360bb of this title shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 360bb of this title as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

**(G) Refund of fee if application withdrawn**

If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

**(2) Prescription drug establishment fee****(A) In general**

Except as provided in subparagraphs (B) and (C), each person that—

- (i) is named as the applicant in a human drug application; and
- (ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be assessed an annual fee established under subsection (c)(5) of this section for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before October 1 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the

establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

**(B) Exception**

If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

- (i) that did not manufacture the product in the previous fiscal year; and
- (ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.

**(C) Special rules for positron emission tomography drugs****(i) In general**

Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the application as producing positron emission tomography drugs under the approved application.

**(ii) Exception from annual establishment fee**

Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

- (I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and
- (II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

**(iii) Definition**

For purposes of this subparagraph, 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.

**(3) Prescription drug product fee****(A) In general**

Except as provided in subparagraph (B), each person who is named as the applicant in

a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(5) of this section. Such fee shall be payable on or before October 1 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

**(B) Exception**

A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b) or 355(j) of this title, under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

**(b) Fee revenue amounts**

**(1) In general**

For each of the fiscal years 2008 through 2012, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

(A) \$392,783,000; and

(B) an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).

**(2) Types of fees**

Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).

**(3) Modified workload adjustment factor for fiscal year 2007**

For purposes of paragraph (1)(B), the Secretary shall determine the modified workload adjustment factor by determining the dollar amount that results from applying the methodology that was in effect under subsection (c)(2) for fiscal year 2007 to the amount \$354,893,000, except that, with respect to the portion of such determination that is based on the change in the total number of commercial investigational new drug applications, the Secretary shall count the number of such applications that were active during the most recent 12-month period for which data on such submissions is available.

**(4) Additional fee revenues for drug safety**

**(A) In general**

For each of the fiscal years 2008 through 2012, paragraph (1)(A) shall be applied by substituting the amount determined under subparagraph (B) for “\$392,783,000”.

**(B) Amount determined**

For each of the fiscal years 2008 through 2012, the amount determined under this subparagraph is the sum of—

(i) \$392,783,000; plus

(ii)(I) for fiscal year 2008, \$25,000,000;

(II) for fiscal year 2009, \$35,000,000;

(III) for fiscal year 2010, \$45,000,000;

(IV) for fiscal year 2011, \$55,000,000; and

(V) for fiscal year 2012, \$65,000,000.

**(c) Adjustments**

**(1) Inflation adjustment**

For fiscal year 2009 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 reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established,

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia, or

(C) the average annual 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 5 years of the preceding 6 fiscal years.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

**(2) Workload adjustment**

For fiscal year 2009 and subsequent fiscal years, after the fee revenues established in subsection (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new

drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b) of this section, as adjusted for inflation under paragraph (1). Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities.

(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees and revenue amounts for fiscal year 2009 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2010 through 2012. The Secretary shall not make any adjustment for changes in review activities for any fiscal year after 2009 unless such study has been completed.

### (3) Rent and rent-related cost adjustment

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (b) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2006. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2006 for such fiscal year, and shall not exceed \$11,721,000 for any fiscal year.

### (4) Final year adjustment

#### (A) Increase in fees

For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), 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 carry-over user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2013. 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 2012. If the Secretary has carryover balances for such process in excess of 3 months of such operating re-

serves, the adjustment under this subparagraph shall not be made.

### (B) Decrease in fees

#### (i) In general

For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), decrease the fee revenues and fees established in subsection (b) by the amount determined in clause (ii), if, for fiscal year 2009 or 2010—

(I) the amount of the total appropriations for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriations for the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1); and

(II) the amount of the total appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1).

#### (ii) Amount of decrease

The amount determined in this clause is the lesser of—

(I) the amount equal to the sum of the amounts that, for each of fiscal years 2009 and 2010, is the lesser of—

(aa) the excess amount described in clause (i)(II) for such fiscal year; or

(bb) the amount specified in subsection (b)(4)(B)(ii) for such fiscal year; or

(II) \$65,000,000.

#### (iii) Limitations

##### (I) Fiscal year condition

In making the determination under clause (ii), an amount described in subclause (I) of such clause for fiscal year 2009 or 2010 shall be taken into account only if subclauses (I) and (II) of clause (i) apply to such fiscal year.

##### (II) Relation to subparagraph (A)

The Secretary shall limit any decrease under this paragraph if such a limitation is necessary to provide for the 3 months of operating reserves described in subparagraph (A).

### (5) Annual fee setting

The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2007, establish, for the next fiscal year, application, product, and establishment fees under subsection (a) of this section, based on the revenue amounts established under sub-

section (b) of this section and the adjustments provided under this subsection.

**(6) Limit**

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

**(d) Fee waiver or reduction**

**(1) In general**

The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) of this section where the Secretary finds that—

(A) such waiver or reduction is necessary to protect the public health,

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(C) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

(D) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

**(2) Considerations**

In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

**(3) Use of standard costs**

In making the finding in paragraph (1)(C), the Secretary may use standard costs.

**(4) Rules relating to small businesses**

**(A) "Small business" defined**

In paragraph (1)(D), the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

**(B) Waiver of application fee**

The Secretary shall waive under paragraph (1)(D) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

**(e) Effect of failure to pay fees**

A human drug application or supplement submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

**(f) Limitations**

**(1) In general**

Fees under subsection (a) of this section shall be refunded for a fiscal year beginning after fiscal year 1997 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 the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

**(2) Authority**

If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of paragraph (1) 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 human drug applications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.

**(g) 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. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

**(2) Collections and appropriation acts**

**(A) In general**

The fees authorized by this section—

(i) shall be retained 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 only be collected and available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and

Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

**(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 the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

**(3) Authorization of appropriations**

For each of the fiscal years 2008 through 2012, 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 subsection (c) and paragraph (4) of this subsection.

**(4) Offset**

If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.

**(h) Collection of unpaid fees**

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

**(i) Written requests for waivers, reductions, and refunds**

To qualify for consideration for a waiver or reduction under subsection (d) of this section, or for a refund of any fee collected in accordance with subsection (a) of this section, a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

**(j) Construction**

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory

committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

**(k) Orphan drugs**

**(1) Exemption**

A drug designated under section 360bb of this title for a rare disease or condition and approved under section 355 of this title or under section 262 of title 42 shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:

(A) The drug meets the public health requirements contained in this chapter as such requirements are applied to requests for waivers for product and establishment fees.

(B) The drug is owned or licensed and is marketed by a company that had less than \$50,000,000 in gross worldwide revenue during the previous year.

**(2) Evidence of qualification**

An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed \$50,000,000 for the preceding 12 months before the exemption was requested.

(June 25, 1938, ch. 675, § 736, as added Pub. L. 102-571, title I, § 103, Oct. 29, 1992, 106 Stat. 4494; amended Pub. L. 105-115, title I, § 103(a)-(g), Nov. 21, 1997, 111 Stat. 2299-2304; Pub. L. 107-109, § 5(a), Jan. 4, 2002, 115 Stat. 1413; Pub. L. 107-188, title V, § 504, June 12, 2002, 116 Stat. 689; Pub. L. 110-85, title I, § 103(a)-(h)(1), Sept. 27, 2007, 121 Stat. 826-832.)

AMENDMENT OF SECTION

*For termination of amendment by section 106(a) of Pub. L. 110-85, see Effective and Termination Dates of 2007 Amendment note below.*

*For termination of amendment by section 509 of Pub. L. 107-188, see Effective and Termination Date of 2002 Amendments note below.*

*For termination of amendment by section 107 of Pub. L. 105-115, see Effective and Termination Dates of 1997 Amendment note below.*

TERMINATION OF SECTION

*For termination of section by section 105 of Pub. L. 102-571, see Termination Date note below.*

REFERENCES IN TEXT

Section 357 of this title, referred to in subsec. (a)(3)(B), 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 subsec. (a)(3)(B), 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.

AMENDMENTS

2007—Subsec. (a). Pub. L. 110-85, §§ 103(a)(1), 106(a), temporarily substituted “2008” for “2003” in introductory provisions. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(1)(A). Pub. L. 110-85, §§ 103(g), 106(a), temporarily substituted “(c)(5)” for “(c)(4)” in cls. (i) and

(ii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(1)(D). Pub. L. 110–85, §§103(a)(2)(A), 106(a), temporarily inserted “or withdrawn before filing” after “refused for filing” in heading and “or withdrawn without a waiver before filing” before period at end of text. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(1)(E) to (G). Pub. L. 110–85, §§103(a)(2)(B), (C), 106(a), temporarily added subpar. (E) and redesignated former subpars. (E) and (F) as (F) and (G), respectively. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A). Pub. L. 110–85, §§103(a)(3)(A), (g), 106(a), temporarily substituted “subparagraphs (B) and (C)” for “subparagraph (B)” in introductory provisions and “(c)(5)” for “(c)(4)” in concluding provisions. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(C). Pub. L. 110–85, §§103(a)(3)(B), 106(a), temporarily added subpar. (C). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(3)(A). Pub. L. 110–85, §§103(g), 106(a), temporarily substituted “(c)(5)” for “(c)(4)”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (b). Pub. L. 110–85, §§103(b), 106(a), temporarily amended subsec. (b) generally, substituting provisions contained in pars. (1) to (4) relating to fee revenue amounts for fiscal years 2008 through 2012 for undesignated provisions relating to fee schedules for fiscal years 2003 to 2007. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(1). Pub. L. 110–85, §§103(c)(1), 106(a), temporarily amended par. (1) by substituting “For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)” for “The revenues established in subsection (b)” in introductory provisions, adding subpar. (C), and substituting “fiscal year 2008” for “fiscal year 2003” in concluding provisions. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2). Pub. L. 110–85, §§103(c)(2)(A), 106(a), temporarily substituted “For fiscal year 2009 and subsequent fiscal years,” for “Beginning with fiscal year 2004,” in introductory provisions. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2)(A). Pub. L. 110–85, §§103(c)(2)(B), 106(a), temporarily substituted “human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available.” for “human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary.” in first sentence. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2)(B). Pub. L. 110–85, §§103(c)(2)(C), 106(a), temporarily inserted at end “Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2)(C). Pub. L. 110–85, §§103(c)(2)(D), 106(a), temporarily added subpar. (C). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(3). Pub. L. 110–85, §§103(c)(3), 106(a), temporarily added par. (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(4). Pub. L. 110–85, §§103(c)(3)(A), (4), 106(a), temporarily redesignated par. (3) as (4) and amended it generally. Prior to amendment, text read as follows:

“For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) of this section if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of human drug applications for the first three months of fiscal year 2008. 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 2007. If the Secretary has carryover balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.” Former par. (4) redesignated (5). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(5). Pub. L. 110–85, §§103(c)(3)(A), (5), 106(a), temporarily redesignated par. (4) as (5) and substituted “2007” for “2002”. Former par. (5) redesignated (6). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(6). Pub. L. 110–85, §§103(c)(3)(A), 106(a), temporarily redesignated par. (5) as (6). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(1). Pub. L. 110–85, §§103(d)(1), 106(a), temporarily inserted “to a person who is named as the applicant in a human drug application” after “The Secretary shall grant” and “to that person” after “one or more fees assessed” in introductory provisions. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2), (3). Pub. L. 110–85, §§103(d)(2), (3), 106(a), temporarily added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(4). Pub. L. 110–85, §§103(d)(2), 106(a), temporarily redesignated par. (3) as (4). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(4)(A). Pub. L. 110–85, §§103(d)(4), 106(a), temporarily inserted before period at end “, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(1). Pub. L. 110–85, §§103(h)(1), 106(a), temporarily substituted “Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.” for “Fees collected for a fiscal year pursuant to subsection (a) of this section shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(3). Pub. L. 110–85, §§103(e)(1), 106(a), temporarily amended par. (3) generally. Prior to amendment, par. (3) authorized appropriations for fiscal years 2003 to 2007. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(4). Pub. L. 110–85, §§103(e)(2), 106(a), temporarily reenacted heading without change and amended text generally. Prior to amendment, text read as follows: “Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (k). Pub. L. 110–85, §§103(f), 106(a), temporarily added subsec. (k). See Effective and Termination Dates of 2007 Amendment note below.

2002—Subsec. (a). Pub. L. 107–188, §§504(a)(1), 509, temporarily substituted “fiscal year 2003” for “fiscal year

1998” in introductory provisions. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(1)(A)(i). Pub. L. 107-188, §§ 504(a)(2)(A), 509, temporarily substituted “under subsection (c)(4)” for “in subsection (b)”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(1)(A)(ii). Pub. L. 107-188, §§ 504(a)(2), 509, temporarily substituted “under subsection (c)(4)” for “in subsection (b)” and inserted “Such fee shall be half of the amount of the fee established under clause (i).” at end. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(1)(F), (G). Pub. L. 107-109 redesignated subpar. (G) as (F) and struck out heading and text of former subpar. (F). Text read as follows: “A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).”

Subsec. (a)(2)(A). Pub. L. 107-188, §§ 504(a)(3), 509, in concluding provisions, temporarily substituted “under subsection (c)(4)” for “in subsection (b)” and “payable on or before October 1” for “payable on or before January 31”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(3)(A). Pub. L. 107-188, §§ 504(a)(4)(A), 509, temporarily amended heading and text of subpar. (A) generally. Prior to amendment, text read as follows: “Except as provided in subparagraph (B), each person—

“(i) who is named as the applicant in a human drug application for a prescription drug product which has been submitted for listing under section 360 of this title, and

“(ii) who, after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall pay for each such prescription drug product the annual fee established in subsection (b) of this section. Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.” See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(3)(B). Pub. L. 107-188, §§ 504(a)(4)(B), 509, temporarily substituted “A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b)” for “The listing of a prescription drug product under section 360 of this title shall not require the person who listed such product to pay the fee prescribed by subparagraph (A) if such product is the same product as a product approved under an application filed under section 355(b)(2)”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (b). Pub. L. 107-188, §§ 504(b), 509, temporarily amended heading and text of subsec. (b) generally, substituting “Fee revenue amounts” for “Fee amounts” in heading and substituting fee schedules for fiscal years 2003 to 2007 for fee provisions relating to fiscal years 1998 to 2002. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(1). Pub. L. 107-188, §§ 504(c)(1)(A), (D), 509, temporarily substituted “revenues” for “fees and total fee revenues” in introductory provisions and “fiscal year 2003” for “fiscal year 1997” in concluding provisions. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(1)(A). Pub. L. 107-188, §§ 504(c)(1)(B), 509, temporarily struck out “during the preceding fiscal year” before “in the Consumer Price Index” and substituted “for the 12 month period ending June 30 preceding the fiscal year for which fees are being estab-

lished, or” for “, or”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(1)(B). Pub. L. 107-188, §§ 504(c)(1)(C), 509, temporarily substituted “for the previous fiscal year” for “for such fiscal year”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(2) to (5). Pub. L. 107-188, §§ 504(c)(2)-(4), 509, temporarily added pars. (2) and (3), redesignated former pars. (2) and (3) as (4) and (5), respectively, and amended heading and text of par. (4) generally. Prior to amendment, text of par. (4) read as follows: “Subject to the amount appropriated for a fiscal year under subsection (g) of this section, the Secretary shall, within 60 days after the end of each fiscal year beginning after September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b) of this section.” See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (d)(1)(C) to (E). Pub. L. 107-188, §§ 504(d)(1), 509, temporarily inserted “or” at end of subpar. (C), redesignated subpar. (E) as (D), and struck out former subpar. (D) which read as follows: “assessment of the fee for an application or a supplement filed under section 355(b)(1) of this title pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 355(b)(2) of this title could not be assessed fees under subsection (a)(1) of this section, or”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (d)(3)(A), (B). Pub. L. 107-188, §§ 504(d)(2), 509, temporarily substituted “paragraph (1)(D)” for “paragraph (1)(E)”. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (f). Pub. L. 107-188, §§ 504(e)(1), 509, temporarily substituted “Limitations” for “Assessment of fees” in heading. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (f)(1). Pub. L. 107-188, §§ 504(e)(2), 509, temporarily substituted “In general” for “Limitation” in heading and “Fees under subsection (a) of this section shall be refunded for a fiscal year beginning” for “Fees may not be assessed under subsection (a) of this section for a fiscal year beginning” in text. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (g)(1). Pub. L. 107-188, §§ 504(f)(1), 509, which directed the temporary amendment of par. (1) by striking “Fees collected for a fiscal year” and all that follows through “fiscal year limitation.” and inserting “Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.”, was not executed because the phrase “fiscal year limitation.” appeared in two places and because of the corrective amendment by Pub. L. 110-85, § 103(h)(1), which is effective as if included in Pub. L. 107-188, § 504. See 2007 Amendment note above and Effective and Termination Dates of 2002 Amendment note and Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 107-188, §§ 504(f)(2), 509, temporarily amended par. (2) by designating existing provisions as subpar. (A), inserting subpar. (A) heading, adding subpar. (B), redesignating former subpars. (A) and (B) as cls. (i) and (ii), respectively, of subpar. (A), substituting “shall be retained in each fiscal year in an amount not to exceed the amount specified” for “shall be collected in each fiscal year in an amount equal to the amount specified” in cl. (i), and realigning margin of cl. (ii). See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (g)(3)(A) to (E). Pub. L. 107-188, §§ 504(f)(3), 509, temporarily added subpars. (A) to (E) and struck out former subpars. (A) to (E) which read as follows:

- “(A) \$106,800,000 for fiscal year 1998;
- “(B) \$109,200,000 for fiscal year 1999;
- “(C) \$109,200,000 for fiscal year 2000;
- “(D) \$114,000,000 for fiscal year 2001; and
- “(E) \$110,100,000 for fiscal year 2002.”.

See Effective and Termination Dates of 2002 Amendment note below.

1997—Subsec. (a). Pub. L. 105–115, §§103(a)(1), 107, temporarily substituted “Beginning in fiscal year 1998” for “Beginning in fiscal year 1993” in introductory provisions. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(1)(B). Pub. L. 105–115, §§103(a)(2)(A), 107, temporarily amended heading and text of subpar. (B) generally. Prior to amendment, text read as follows:

“(i) FIRST PAYMENT.—50 percent of the fee required by subparagraph (A) shall be due upon submission of the application or supplement.

“(ii) FINAL PAYMENT.—The remaining 50 percent of the fee required by subparagraph (A) shall be due upon—

“(I) the expiration of 30 days from the date the Secretary sends to the applicant a letter designated by the Secretary as an action letter described in section 379g(6)(B) of this title, or

“(II) the withdrawal of the application or supplement after it is filed unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed.

The designation under subclause (I) or the waiver under subclause (II) shall be solely in the discretion of the Secretary and shall not be reviewable.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(1)(D). Pub. L. 105–115, §§103(a)(2)(B), 107, temporarily substituted “refused” for “not accepted” in heading and “75 percent” for “50 percent”, “subparagraph (B)” for “subparagraph (B)(i)”, and “refused” for “not accepted” in text. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(1)(E) to (G). Pub. L. 105–115, §§103(a)(2)(C), 107, temporarily added subpars. (E) to (G). See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(2). Pub. L. 105–115, §§103(a)(3), 107, temporarily reenacted heading without change and amended text generally. Prior to amendment, text read as follows: “Each person that—

“(A) owns a prescription drug establishment, at which is manufactured at least 1 prescription drug product which is not the, or not the same as a, product approved under an application filed under section 355(b)(2) or 355(j) of this title, and

“(B) after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be subject to the annual fee established in subsection (b) of this section for each such establishment, payable on or before January 31 of each year.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(3)(A). Pub. L. 105–115, §§103(a)(4)(A), 107, temporarily substituted, in cl. (i), “has been submitted for listing” for “is listed” and, in closing provisions, “Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.” for “Such fee shall be payable at the time of the first such listing of such product in each calendar year. Such fee shall be paid only once each year for each listed prescription drug product irrespective of the number of times such product is listed under section 360 of this title.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(3)(B). Pub. L. 105–115, §§103(a)(4)(B), 107, temporarily substituted “355(j) of this title, under an abbreviated application filed under section 357 of this

title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.” for “355(j) of this title.”. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (b). Pub. L. 105–115, §§103(b), 107, temporarily amended subsec. (b) generally. Prior to amendment, subsec. (b) related to fee amounts, including a schedule of fees in par. (1) and fee exceptions for certain small businesses in par. (2). See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (c). Pub. L. 105–115, §§103(c)(1), 107, temporarily substituted “Adjustments” for “Increases and adjustments” in heading. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (c)(1). Pub. L. 105–115, §§103(c)(2), 107, temporarily substituted “Inflation adjustment” for “Revenue increase” in heading, “The fees and total fee revenues established in subsection (b) of this section shall be adjusted by the Secretary” for “The total fee revenues established by the schedule in subsection (b)(1) of this section shall be increased by the Secretary” in introductory provisions, and “change” for “increase” after “total percentage” in subpars. (A) and (B), and inserted at end “The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (c)(2). Pub. L. 105–115, §§103(c)(3), 107, temporarily substituted “September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b) of this section.” for “October 1, 1992, adjust the fees established by the schedule in subsection (b)(1) of this section for the following fiscal year to achieve the total fee revenues, as may be increased under paragraph (1). Such fees shall be adjusted under this paragraph to maintain the proportions established in such schedule.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (c)(3). Pub. L. 105–115, §§103(c)(4), 107, temporarily substituted “this subsection” for “paragraph (2)”. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (d). Pub. L. 105–115, §§103(d), 107, temporarily struck out introductory provisions which read “The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) of this section where the Secretary finds that—” and closing provisions which read “In making the finding in paragraph (3), the Secretary may use standard costs.”, inserted designation, heading, and introductory provisions of par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, of par. (1), and added pars. (1)(E), (2), and (3). See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (f)(1). Pub. L. 105–115, §§103(e), 107, temporarily substituted “fiscal year 1997” for “fiscal year 1993” and “fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)” for “fiscal year 1992”. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (g)(1). Pub. L. 105–115, §§103(f)(1), 107, temporarily inserted at end “Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (g)(2)(A). Pub. L. 105-115, §§103(f)(2)(A), 107, temporarily substituted “Acts, or otherwise made available for obligation.” for “Acts”. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (g)(2)(B). Pub. L. 105-115, §§103(f)(2)(B), 107, temporarily substituted “over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997” for “over such costs for fiscal year 1992”. See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (g)(3), (4). Pub. L. 105-115, §§103(f)(3), 107, temporarily added pars. (3) and (4) and struck out heading and text of former par. (3). Text read as follows: “There are authorized to be appropriated for fees under this section—

- “(A) \$36,000,000 for fiscal year 1993,
- “(B) \$54,000,000 for fiscal year 1994,
- “(C) \$75,000,000 for fiscal year 1995,
- “(D) \$78,000,000 for fiscal year 1996, and
- “(E) \$84,000,000 for fiscal year 1997,

as adjusted to reflect increases in the total fee revenues made under subsection (c)(1) of this section.” See Effective and Termination Dates of 1997 Amendment note below.

Subsecs. (i), (j). Pub. L. 105-115, §§103(g), 107, temporarily added subsec. (i) and redesignated former subsec. (i) as (j). See Effective and Termination Dates of 1997 Amendment note below.

#### EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Pub. L. 110-85, title I, §103(h)(2), Sept. 27, 2007, 121 Stat. 832, provided that: “Paragraph (1) [amending this section] shall take effect as if included in section 504 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107-188; 116 Stat. 687) [amending this section].”

Amendment by Pub. L. 110-85 to cease to be effective Oct. 1, 2012, see section 106(a) of Pub. L. 110-85, set out as a note under section 379g of this title.

Amendment by Pub. L. 110-85 effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, see section 107 of Pub. L. 110-85, set out as a note under section 379g of this title.

#### EFFECTIVE AND TERMINATION DATES OF 2002 AMENDMENT

Amendment by Pub. L. 107-188 effective Oct. 1, 2002, see section 508 of Pub. L. 107-188, set out as an Effective Date of 2002 Amendment note under section 356b of this title.

Amendment by Pub. L. 107-188 to cease to be effective Oct. 1, 2007, see section 509 of Pub. L. 107-188, set out as a note under section 379g of this title.

#### EFFECTIVE AND TERMINATION DATES OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective Oct. 1, 1997, and ceases to be effective Oct. 1, 2002, see sections 106 and 107 of Pub. L. 105-115, set out as notes under section 379g of this title.

#### TERMINATION DATE

Section not in effect after Oct. 1, 1997, see section 105 of Pub. L. 102-571, set out as a note under section 379g of this title.

#### SPECIAL RULE FOR WAIVERS AND REFUNDS

Section 103(h) of Pub. L. 105-115 provided that: “Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) prior to the date of enactment of this Act [Nov. 21, 1997] shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establish-

ment fee required by such Act for a fiscal year prior to fiscal year 1998, shall be evaluated according to the terms of the Prescription Drug User Fee Act of 1992 [see section 101(a) of Pub. L. 102-571, set out as a Short Title of 1992 Amendment note under section 301 of this title] (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379g et seq.] (as in effect on September 30, 1997). The term “person” in such Acts shall continue to include an affiliate thereof.”

### § 379h-1. Fees relating to advisory review of prescription-drug television advertising

#### (a) Types of direct-to-consumer television advertisement review fees

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

##### (1) Advisory review fee

###### (A) In general

With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a “DTC advertisement”), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public dissemination shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

###### (B) Exception for required submissions

A DTC advertisement that is required to be submitted to the Secretary prior to initial public dissemination is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for advisory review.

###### (C) Notice to Secretary of number of advertisements

Not later than June 1 of each fiscal year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for advisory review in the next fiscal year. Notwithstanding the preceding sentence, for fiscal year 2008, the Secretary shall publish such a notice in the Federal Register not later than 30 days after September 27, 2007.

###### (D) Payment

###### (i) In general

The fee required by subparagraph (A) (referred to in this section as “an advisory review fee”) shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended to be submitted for advisory review, subject to subparagraph (F)(i). Notwithstanding the preceding sentence, the advisory review fee for any DTC advertisement that is intended to be submitted for advisory review during fiscal year 2008 shall be due not later than 120 days after September 27, 2007, or an earlier date as specified by the Secretary.

###### (ii) Effect of submission

Notification of the Secretary under subparagraph (C) of the number of DTC adver-

tisements a person intends to submit for advisory review is a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. Notwithstanding the preceding sentence, the commitment shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions for fiscal year 2008 by the date specified in clause (i).

**(iii) Notice regarding carryover submissions**

In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for advisory review in the fiscal year involved shall be subject to the advisory review fee.

**(E) Modification of advisory review fee**

**(i) Late payment**

If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) not later than November 1 of such fiscal year (or, in the case of such a notification submitted with respect to fiscal year 2008, not later than 150 days after September 27, 2007, or an earlier date specified by the Secretary), the fees shall be regarded as late and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this section. For such person, all advisory review fees for such fiscal year shall be due and payable 20 days before any direct-to-consumer advertisement is submitted to the Secretary for advisory review, and each such fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

**(ii) Exceeding identified number of submissions**

If a person submits a number of DTC advertisements for advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding any other provision of this section. For each such DTC advertisement, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

**(F) Limits**

**(i) Submissions**

For each advisory review fee paid by a person for a fiscal year, the person is entitled to acceptance for advisory review by the Secretary of one DTC advertisement and acceptance of one resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over not more than one paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

**(ii) No refunds**

Except as provided by subsections (d)(4) and (f), fees paid under this section shall not be refunded.

**(iii) No waivers, exemptions, or reductions**

The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

**(iv) Right to advisory review not transferable**

The right to an advisory review under this paragraph is not transferable, except to a successor in interest.

**(2) Operating reserve fee**

**(A) In general**

Each person that on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to fee<sup>1</sup> established under subsection (d)(2) (referred to in this section as an “operating reserve fee”) for the first fiscal year in which an advisory review fee is assessed to such person. The person is not subject to an operating reserve fee for any other fiscal year.

**(B) Payment**

Except as provided in subparagraph (C), the operating reserve fee shall be due no later than—

- (i) October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1); or
- (ii) for fiscal year 2008, 120 days after September 27, 2007, or an earlier date specified by the Secretary.

**(C) Late notice of submission**

If, in the first fiscal year of a person’s participation in the program under this section, that person submits any DTC advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (a)(1)(C), that person shall pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(E)(ii). Fees required by this subparagraph shall be in addition to any fees required by subparagraph (A). Fees

<sup>1</sup> So in original. Probably should be “the fee”.

under this subparagraph shall be due 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

**(D) Late payment**

**(i) In general**

Notwithstanding subparagraph (B), and subject to clause (ii), an operating reserve fee shall be regarded as late if the person required to pay the fee has not paid the complete operating reserve fee by—

(I) for fiscal year 2008, 150 days after September 27, 2007, or an earlier date specified by the Secretary; or

(II) in any subsequent year, November 1.

**(ii) Complete payment**

The complete operating reserve fee shall be due and payable 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

**(iii) Amount**

Notwithstanding any other provision of this section, an operating reserve fee that is regarded as late under this subparagraph shall be equal to 150 percent of the operating reserve fee that otherwise would have applied pursuant to subsection (d).

**(b) Advisory review fee revenue amounts**

Fees under subsection (a)(1) shall be established to generate revenue amounts of \$6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsections (c) and (g)(4).

**(c) Adjustments**

**(1) Inflation adjustment**

Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

(C) the average annual 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 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

**(2) Workload adjustment**

Beginning with fiscal year 2009, after the fee revenues established in subsection (b) are ad-

justed for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of DTC advertisements for advisory review prior to initial dissemination. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based upon the number of DTC advertisements identified pursuant to subsection (a)(1)(C) for the upcoming fiscal year, excluding allowable previously paid carry over submissions. The adjustment shall be determined by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by \$27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

**(3) Annual fee setting for advisory review**

**(A) In general**

Not later than August 1 of each fiscal year (or, with respect to fiscal year 2008, not later than 90 days after September 27, 2007), the Secretary shall establish for the next fiscal year the DTC advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under paragraphs (1) and (2), and the number of DTC advertisements identified pursuant to subsection (a)(1)(C), excluding allowable previously-paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of DTC advertisements so identified, excluding allowable previously-paid carry over submissions under subsection (a)(1)(F)(i).

**(B) Fiscal year 2008 fee limit**

Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for fiscal year 2008 may not be more than \$83,000 per submission for advisory review.

**(C) Annual fee limit**

Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

**(D) Limit**

The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

**(d) Operating reserves****(1) In general**

The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least \$6,250,000 in fiscal year 2008, to continue the program under this section in the event the fees collected in any subsequent fiscal year pursuant to subsection (a)(1) do not generate the fee revenue amount established for that fiscal year.

**(2) Fee setting**

The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of DTC advertisements identified by that person pursuant to subsection (a)(1)(C) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year, except that in no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the program under this section in fiscal year 2008.

**(3) Use of operating reserve**

The Secretary may use funds from the reserves only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsections (b) and (c) and the amount of fees actually collected for that fiscal year pursuant to subsection (a)(1), or to pay costs of ending the program under this section if it is terminated pursuant to subsection (f) or not reauthorized beyond fiscal year 2012.

**(4) Refund of operating reserves**

Within 120 days after the end of fiscal year 2012, or if the program under this section ends early pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the program under this section, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

**(e) Effect of failure to pay fees**

Notwithstanding any other requirement, a submission for advisory review of a DTC advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

**(f) Effect of inadequate funding of program****(1) Initial funding**

If on November 1, 2007, or 120 days after September 27, 2007, whichever is later, the Secretary has not received at least \$11,250,000 in advisory review fees and operating reserve fees combined, the program under this section shall not commence and all collected fees shall be refunded.

**(2) Later fiscal years**

Beginning in fiscal year 2009, if, on November 1 of the fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below \$9,000,000, adjusted for inflation (as described in subsection (c)(1)), the program under this section shall terminate, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and finally, unused advisory review fees from the relevant fiscal year.

**(g) 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. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

**(2) Collections and appropriation acts****(A) In general**

The fees authorized by this section—

(i) shall be retained 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 obligation only if the amounts appropriated as budget authority for such fiscal year are sufficient to support a number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.

**(B) Review employees**

For purposes of subparagraph (A)(ii), the term “full-time equivalent review employees” means the total combined number of full-time equivalent employees in—

(i) the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; and

(ii) the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, Food and Drug Administration.

**(3) Authorization of appropriations**

For each of the fiscal years 2008 through 2012, 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 pursuant to subsection (c) and paragraph (4) of this subsection, plus amounts collected for the reserve fund under subsection (d).

**(4) Offset**

Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

**(h) Definitions**

For purposes of this section:

(1) The term “advisory review” means reviewing and providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of this chapter prior to its initial public dissemination.

(2) The term “advisory review fee” has the meaning indicated for such term in subsection (a)(1)(D).

(3) The term “carry over submission” means a submission for an advisory review for which a fee was paid in one fiscal year that is submitted for review in the following fiscal year.

(4) The term “direct-to-consumer television advertisement” means an advertisement for a prescription drug product (as defined in section 379g(3) of this title) intended to be displayed on any television channel for less than 3 minutes.

(5) The term “DTC advertisement” has the meaning indicated for such term in subsection (a)(1)(A).

(6) The term “operating reserve fee” has the meaning indicated for such term in subsection (a)(2)(A).

(7) The term “person” includes an individual, partnership, corporation, and association, and any affiliate thereof or successor in interest.

(8) The term “process for the advisory review of prescription drug advertising” means the activities necessary to review and provide advisory comments on DTC advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

(9) The term “resources allocated for the process for the advisory review of prescription drug advertising” means the expenses incurred in connection with the process for the advisory review of prescription drug advertising 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 offi-

cers, employees, and committees, and to contracts with such contractors;

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

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

(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

(E) terminating the program under this section pursuant to subsection (f)(2) if that becomes necessary.

(10) The term “resubmission” means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary’s comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

(11) The term “submission for advisory review” means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

(June 25, 1938, ch. 675, §736A, as added Pub. L. 110-85, title I, §104, Sept. 27, 2007, 121 Stat. 832.)

**TERMINATION OF SECTION**

*For termination of section by section 106(a) of Pub. L. 110-85, see Effective and Termination Dates note below.*

**EFFECTIVE AND TERMINATION DATES**

Section effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, and ceases to be effective Oct. 1, 2012, see sections 106(a) and 107 of Pub. L. 110-85, set out as Effective and Termination Dates of 2007 Amendment notes under section 379g of this title.

**§ 379h-2. Reauthorization; reporting requirements**

**(a) Performance report**

Beginning with fiscal year 2008, 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 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

**(b) Fiscal report**

Beginning with fiscal year 2008, 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 the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, 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 regulated industry.

**(2) Prior public input**

Prior to beginning negotiations with the regulated 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
- (D) publish the comments on the Food and Drug Administration's Internet Web site.

**(3) Periodic consultation**

Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

**(4) Public review of recommendations**

After negotiations with the regulated industry, the Secretary shall—

- (A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;
- (B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

**(5) Transmittal of recommendations**

Not later than January 15, 2012, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

**(6) Minutes of negotiation meetings**

**(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

**(B) Content**

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §736B, as added Pub. L. 110-85, title I, §105, Sept. 27, 2007, 121 Stat. 840.)

TERMINATION OF SECTION

*For termination of section by section 106(b) of Pub. L. 110-85, see Effective and Termination Dates note below.*

REFERENCES IN TEXT

Section 101(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a), is section 101(c) of Pub. L. 110-85, which is set out as a note under section 379g of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 110-85, title I, §106(b), Sept. 27, 2007, 121 Stat. 842, provided that: "The amendment made by section 105 [enacting this section] ceases to be effective January 31, 2013."

Section effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, see section 107 of Pub. L. 110-85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379g of this title.

SUBPART 3—FEES RELATING TO DEVICES

TERMINATION OF SUBPART

*For termination of subpart by section 107 of Pub. L. 107-250, see Effective and Termination Dates note set out under section 379i of this title.*

**§ 379i. Definitions**

For purposes of this subpart:

- (1) The term "premarket application" means—

(A) an application for approval of a device submitted under section 360e(c) of this title or section 262 of title 42; or

(B) a product development protocol described in section 360e(f) of this title.

Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term “premarket report” means a report submitted under section 360e(c)(2) of this title.

(3) The term “premarket notification submission” means a report submitted under section 360(k) of this title.

(4)(A) The term “supplement”, with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

(i) an application or report has been approved under section 360e(d) of this title, or an application has been approved under section 262 of title 42; or

(ii) a notice of completion has become effective under section 360e(f) of this title.

(B) The term “panel-track supplement” means a supplement to an approved premarket application or premarket report under section 360e of this title that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term “180-day supplement” means a supplement to an approved premarket application or premarket report under section 360e of this title that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term “real-time supplement” means a supplement to an approved premarket application or premarket report under section 360e of this title that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term “efficacy supplement” means a supplement to an approved premarket application under section 262 of title 42 that requires substantive clinical data.

(5) The term “30-day notice” means a notice under section 360e(d)(6) of this title that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(6) The term “request for classification information” means a request made under section 360c(g) of this title for information respecting the class in which a device has been classified or the requirements applicable to a device.

(7) The term “annual fee”, for periodic reporting concerning a class III device, means the annual fee associated with periodic reports

required by a premarket application approval order.

(8) The term “process for the review of device applications” means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary’s review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 262 of title 42 for an investigational new drug application under section 355(i) of this title or for an investigational device exemption under section 360j(g) of this title and activities conducted in anticipation of the submission of such applications under section 355(i) or 360j(g) of this title.

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 360d of this title in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 360c or 360e(i) of this title in connection with the initial classification or reclassification of a device or under section 360e(b) of this title in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 360e of this title or a premarket application under section 262 of title 42.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

(9) The term “costs of resources allocated for the process for the review of device appli-

cations” means the expenses incurred in connection with the process for the review of device applications for—

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

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

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

(D) collecting fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

(10) The term “adjustment factor” applicable to a fiscal year 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 2001.

(11) The term “person” includes an affiliate thereof.

(12) The term “affiliate” means a business entity that has a relationship with a second business entity (whether domestic or international) 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.

(13) The term “establishment subject to a registration fee” means an establishment that is required to register with the Secretary under section 360 of this title and is one of the following types of establishments:

**(A) Manufacturer**

An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

**(B) Single-use device reprocessor**

An establishment that, within the meaning of section 321(l)(2)(A) of this title, performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

**(C) Specification developer**

An establishment that develops specifications for a device that is distributed under the establishment’s name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment’s name by a contract manufacturer.

(June 25, 1938, ch. 675, §737, as added Pub. L. 107-250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; amended Pub. L. 108-214, §2(a)(1), (d)(3)(A),

Apr. 1, 2004, 118 Stat. 572, 577; Pub. L. 110-85, title II, §211, Sept. 27, 2007, 121 Stat. 843.)

AMENDMENT OF SECTION

*For termination of amendment by section 217 of Pub. L. 110-85, see Effective and Termination Dates of 2007 Amendment note below.*

TERMINATION OF SECTION

*For termination of section by section 107 of Pub. L. 107-250, see Effective and Termination Dates note set out below.*

AMENDMENTS

2007—Pub. L. 110-85, §§211(1), 217, temporarily substituted “For purposes of this subpart” for “For purposes of this part” in introductory provisions. See Effective and Termination Dates of 2007 Amendment note below.

Pars. (5) to (9). Pub. L. 110-85, §§211(2), (3), 217, temporarily added pars. (5) to (7) and redesignated former pars. (5) and (6) as (8) and (9), respectively. Former pars. (7) and (8) redesignated (10) and (12), respectively. See Effective and Termination Dates of 2007 Amendment note below.

Par. (10). Pub. L. 110-85, §§211(2), (4), 217, temporarily redesignated par. (7) as (10) and substituted “October of the preceding fiscal year” for “April of the preceding fiscal year” and “October 2001” for “April 2002”. See Effective and Termination Dates of 2007 Amendment note below.

Par. (11). Pub. L. 110-85, §§211(5), 217, temporarily added par. (11). See Effective and Termination Dates of 2007 Amendment note below.

Par. (12). Pub. L. 110-85, §§211(2), 217, temporarily redesignated par. (8) as (12). See Effective and Termination Dates of 2007 Amendment note below.

Par. (13). Pub. L. 110-85, §§211(6), 217, temporarily added par. (13). See Effective and Termination Dates of 2007 Amendment note below.

2004—Pub. L. 108-214, §2(d)(3)(A), made technical correction to directory language of Pub. L. 107-250, §102(a), which enacted this section.

Par. (4)(B). Pub. L. 108-214, §2(a)(1)(A), substituted “and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness” for “and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness”.

Par. (4)(D). Pub. L. 108-214, §2(a)(1)(B), struck out “manufacturing,” after “software.”

Par. (5)(J). Pub. L. 108-214, §2(a)(1)(C), substituted “a premarket application or premarket report under section 360e of this title or a premarket application under section 262 of title 42.” for “a premarket application under section 360e of this title or section 262 of title 42.”

Par. (8). Pub. L. 108-214, §2(a)(1)(D), substituted “The term ‘affiliate’ means a business entity that has a relationship with a second business entity (whether domestic or international)” for “The term ‘affiliate’ means a business entity that has a relationship with a second business entity”.

EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Pub. L. 110-85, title II, §216, Sept. 27, 2007, 121 Stat. 852, provided that: “The amendments made by this subtitle [subtitle A (§§211-217) of title II of Pub. L. 110-85, enacting section 379j-1 of this title and amending this section and section 379j of this title] shall take effect on October 1, 2007, or the date of the enactment of this Act [Sept. 27, 2007], whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1,

2007, regardless of the date of the enactment of this Act.”

Pub. L. 110-85, title II, §217, Sept. 27, 2007, 121 Stat. 852, provided that: “The amendments made by this subtitle [subtitle A (§§211-217) of title II of Pub. L. 110-85, enacting section 379j-1 of this title and amending this section and section 379j of this title] cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-1] (regarding annual performance and financial reports) ceases to be effective January 31, 2013.”

#### EFFECTIVE AND TERMINATION DATES

Pub. L. 107-250, title I, §106, Oct. 26, 2002, 116 Stat. 1602, provided that: “The amendments made by this title [enacting this subpart] shall take effect on the date of the enactment of this Act [Oct. 26, 2002], except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2002, regardless of the date of enactment.”

Pub. L. 107-250, title I, §107, Oct. 26, 2002, 116 Stat. 1602, provided that: “The amendments made by this title [enacting this subpart] cease to be effective October 1, 2007, except that section 103 [set out as a note below] with respect to annual reports ceases to be effective January 31, 2008.”

#### SAVINGS PROVISION

Pub. L. 110-85, title II, §214, Sept. 27, 2007, 121 Stat. 852, provided that: “Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250) [set out as an Effective and Termination Dates note above], and notwithstanding the amendments made by this subtitle [subtitle A (§§211-217) of title II of Pub. L. 110-85, enacting section 379j-1 of this title and amending this section and section 379j of this title], part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle [Sept. 27, 2007], shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.”

#### FINDINGS

Pub. L. 110-85, title II, §201(c), Sept. 27, 2007, 121 Stat. 842, provided that: “The Congress finds that the fees authorized under the amendments made by this title [enacting section 379j-1 of this title and amending this section and sections 333, 360, 360i, 360m, 374, and 379j of this title] will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 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.”

Pub. L. 107-250, title I, §101, Oct. 26, 2002, 116 Stat. 1589, provided that: “The Congress finds that—

“(1) prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease;

“(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met; and

“(3) the fees authorized by this title [enacting this subpart and provisions set out as notes under this section and section 379j of this title] will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record.”

#### ANNUAL REPORTS

Pub. L. 107-250, title I, §103, Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 109-43, §2(b), Aug. 1, 2005, 119 Stat. 441, which directed the Secretary of Health and Human Services to submit annual reports to Congress on progress in achieving goals identified in section 101(3), set out above, and implementation of authority for and use of fees collected under the medical device user-fee program established under this subpart, ceased to be effective Jan. 31, 2008. See Effective and Termination Dates note above.

#### STUDY

Pub. L. 107-250, title I, §104(b), Oct. 26, 2002, 116 Stat. 1601, directed the Secretary of Health and Human Services to conduct a study for the purpose of making certain determinations regarding the medical device user-fee program established under the amendment made by section 102 of Pub. L. 107-250 and to submit a report to Congress by Jan. 10, 2007.

#### CONSULTATION

Pub. L. 107-250, title I, §105, Oct. 26, 2002, 116 Stat. 1601, provided that:

“(a) IN GENERAL.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications for fiscal years after fiscal year 2007, and for the reauthorization of sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379i, 379j], the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

“(b) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under subsection (a), after negotiations with the regulated industry; shall present such recommendations to the congressional committees specified in such paragraph; shall hold a meeting at which the public may present its views on such recommendations; and shall provide for a period of 30 days for the public to provide written comments on such recommendations.”

### § 379j. Authority to assess and use device fees

#### (a) Types of fees

##### (1) In general

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section.

##### (2) Premarket application, premarket report, supplement, and submission fee, and annual fee for periodic reporting concerning a class III device

###### (A) In general

Except as provided in subparagraph (B) and subsections (d) and (e) of this section, each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(1) of this section for the fiscal year involved in accordance with the following:

- (i) A premarket application.
- (ii) For a premarket report, a fee equal to the fee that applies under clause (i).
- (iii) For a panel track supplement, a fee equal to 75 percent of the fee that applies under clause (i).
- (iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).
- (v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).
- (vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).
- (vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).
- (viii) For a premarket notification submission, a fee equal to 1.84 percent of the fee that applies under clause (i).
- (ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).
- (x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

#### **(B) Exceptions**

##### **(i) Humanitarian device exemption**

An application under section 360j(m) of this title is not subject to any fee under subparagraph (A).

##### **(ii) Further manufacturing use**

No fee shall be required under subparagraph (A) for the submission of a premarket application under section 262 of title 42 for a product licensed for further manufacturing use only.

##### **(iii) State or Federal Government sponsors**

No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, or premarket notification submission submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

##### **(iv) Premarket notifications by third parties**

No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 360m of this title.

##### **(v) Pediatric conditions of use**

###### **(I) In general**

No fee shall be required under subparagraph (A) for a premarket application, premarket report, or premarket notification submission if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

###### **(II) Subsequent proposal of adult conditions of use**

In the case of a person who submits a premarket application or premarket re-

port for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

#### **(C) Payment**

The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 360e(c)(4) of this title shall pay such fees upon submission of the first portion of such applications.

#### **(D) Refunds**

##### **(i) Application refused for filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

##### **(ii) Application withdrawn before filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

##### **(iii) Application withdrawn before first action**

After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement.

##### **(iv) Modular applications withdrawn before first action**

The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 360e(c)(4) of this title that is withdrawn before a second portion is submitted and before a first action on the first portion.

##### **(v) Later withdrawn modular applications**

If an application submitted under section 360e(c)(4) of this title is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

##### **(vi) Sole discretion to refund**

The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

**(3) Annual establishment registration fee**

**(A) In general**

Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 360 of this title beginning with its registration for fiscal year 2008.

**(B) Exception**

No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance

Act<sup>1</sup> [25 U.S.C. 450 et seq.]), unless a device manufactured by the establishment is to be distributed commercially.

**(C) Payment**

The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 360 of this title.

**(b) Fee amounts**

Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application .....	\$185,000	\$200,725	\$217,787	\$236,298	\$256,384
Establishment Registration .....	\$1,706	\$1,851	\$2,008	\$2,179	\$2,364.

**(c) Annual fee setting**

**(1) In general**

The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, publish in the Federal Register fees under subsection (a) of this section.

**(2) Adjustment**

**(A) In general**

When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

**(B) Publication**

For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination.

**(3) Limit**

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications.

**(4) Supplement**

**(A) In general**

The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

**(B) Notice to Congress**

Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

**(d) Small businesses; fee waiver and fee reduction regarding premarket approval fees**

**(1) In general**

The Secretary shall grant a waiver of the fee required under subsection (a) of this section for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. For the purposes of this paragraph, the term "small business" means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

<sup>1</sup> See References in Text note below.

**(2) Rules relating to premarket approval fees****(A) Definition**

For purposes of this paragraph, the term “small business” means an entity that reported \$100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

**(B) Evidence of qualification****(i) In general**

An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

**(ii) Firms submitting tax returns to the United States Internal Revenue Service**

The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

**(iii) Firms not submitting tax returns to the United States Internal Revenue Service**

In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant’s or affiliate’s gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant’s firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

**(C) Reduced fees**

Where the Secretary finds that the applicant involved meets the definition under

subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or periodic reporting concerning a class III device; and

(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.

**(D) Request for fee waiver or reduction**

An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a) of this section. The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

**(e) Small businesses; fee reduction regarding premarket notification submissions****(1) In general**

For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) of this section may be paid at a reduced rate in accordance with paragraph (2)(C).

**(2) Rules relating to premarket notification submissions****(A) Definition**

For purposes of this subsection, the term “small business” means an entity that reported \$100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

**(B) Evidence of qualification****(i) In general**

An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

**(ii) Firms submitting tax returns to the United States Internal Revenue Service**

The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

**(iii) Firms not submitting tax returns to the United States Internal Revenue Service**

In the case of an applicant that has not previously submitted a Federal income tax

return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

**(C) Reduced fees**

For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

**(D) Request for reduction**

An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a) of this section. The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

**(f) Effect of failure to pay fees**

**(1) No acceptance of submissions**

A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

**(2) No registration**

Registration information submitted under section 360 of this title by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 360 of this title.

**(g) Conditions**

**(1) Performance goals; termination of program**

With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than \$205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

(B) fees were not assessed under subsection (a) for the previous fiscal year.

**(2) Authority**

If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) 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 premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

**(h) Crediting and availability of fees**

**(1) In general**

Fees authorized under subsection (a) of this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

**(2) Collections and appropriation acts**

**(A) In general**

The fees authorized by this section—

(i) shall be retained 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 only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal

year 2002 multiplied by the adjustment factor.

**(B) Compliance**

**(i) In general**

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 the process for the review of device applications—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

**(ii) More than 5 percent**

To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

**(3) Authorizations of appropriations**

There are authorized to be appropriated for fees under this section—

- (A) \$48,431,000 for fiscal year 2008;
- (B) \$52,547,000 for fiscal year 2009;
- (C) \$57,014,000 for fiscal year 2010;
- (D) \$61,860,000 for fiscal year 2011; and
- (E) \$67,118,000 for fiscal year 2012.

**(4) Offset**

If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.

**(i) Collection of unpaid fees**

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

**(j) Written requests for refunds**

To qualify for consideration for a refund under subsection (a)(2)(D) of this section, a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

**(k) Construction**

This section may not be construed to require that the number of full-time equivalent posi-

tions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(June 25, 1938, ch. 675, § 738, as added Pub. L. 107-250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591; amended Pub. L. 108-214, § 2(a)(2), (d)(2)(A), (B), (3)(A), Apr. 1, 2004, 118 Stat. 572, 576, 577; Pub. L. 109-43, § 2(a), Aug. 1, 2005, 119 Stat. 439; Pub. L. 110-85, title II, § 212, Sept. 27, 2007, 121 Stat. 844.)

AMENDMENT OF SECTION

*For termination of amendment by section 217 of Pub. L. 110-85, see Effective and Termination Dates of 2007 Amendment note below.*

TERMINATION OF SECTION

*For termination of section by section 107 of Pub. L. 107-250, see Effective and Termination Dates note set out under section 379i of this title.*

REFERENCES IN TEXT

The Indian Self Determination and Educational Assistance Act, referred to in subsec. (a)(3)(B), probably means the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to subchapter II (§ 450 et seq.) of chapter 14 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.

AMENDMENTS

2007—Subsec. (a)(1). Pub. L. 110-85, §§ 212(a)(1)(A), 217, temporarily substituted “Beginning in fiscal year 2008” for “Beginning on October 26, 2002”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2). Pub. L. 110-85, §§ 212(a)(1)(B), 217, temporarily amended heading generally. Prior to amendment, heading read as follows: “Premarket application, premarket report, supplement, and submission fee”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(iii). Pub. L. 110-85, §§ 212(a)(2)(A), 217, temporarily substituted “a fee equal to 75 percent of the fee that applies” for “a fee equal to the fee that applies”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(iv). Pub. L. 110-85, §§ 212(a)(2)(B), 217, temporarily substituted “15 percent” for “21.5 percent”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(v). Pub. L. 110-85, §§ 212(a)(2)(C), 217, temporarily substituted “7 percent” for “7.2 percent”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(vi), (vii). Pub. L. 110-85, §§ 212(a)(2)(D), (E), 217, temporarily added cl. (vi) and redesignated former cl. (vi) as (vii). Former cl. (vii) redesignated (viii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(viii). Pub. L. 110-85, §§ 212(a)(2)(D), (F), 217, temporarily redesignated cl. (vii) as (viii), substituted “1.84 percent” for “1.42 percent”, and struck out “, subject to any adjustment under subsection (e)(2)(C)(ii) of this section” before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(ix), (x). Pub. L. 110-85, §§ 212(a)(2)(G), 217, temporarily added cls. (ix) and (x). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(C). Pub. L. 110-85, §§ 212(a)(3), 217, temporarily amended subpar. (C) generally. Prior to

amendment, text read as follows: “The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, or premarket notification submission except that invoices for applications submitted between October 1, 2002, and October 26, 2002, shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 360e(c)(3) of this title shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 under this section shall include all fees payable from October 1, 2002, through September 30, 2003.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(D)(iii). Pub. L. 110-85, §§212(a)(4)(A), 217, temporarily struck out at end “The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(D)(iv) to (vi). Pub. L. 110-85, §§212(a)(4)(B), 217, temporarily added cls. (iv) to (vi). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(3). Pub. L. 110-85, §§212(a)(5), 217, temporarily added par. (3). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (b). Pub. L. 110-85, §§212(b), 217, temporarily amended subsec. (b) generally. Prior to amendment, text read as follows: “Except as provided in subsections (c), (d), (e), (g), and (h) of this section, the fees under subsection (a) of this section shall be established to generate the following revenue amounts: \$25,125,000 in fiscal year 2003; \$27,255,000 in fiscal year 2004; and \$29,785,000 in fiscal year 2005. If legislation is enacted after October 26, 2002, requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c). Pub. L. 110-85, §§212(c)(1)(A), 217, temporarily made technical amendment to heading. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(1). Pub. L. 110-85, §§212(c)(1)(B), 217, temporarily struck out at end “The fees established for fiscal year 2006 shall be based on a premarket application fee of \$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of \$281,600.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2), (3). Pub. L. 110-85, §§212(c)(2)(A), (B), 217, temporarily added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(4). Pub. L. 110-85, §§212(c)(2)(A), (C), 217, temporarily redesignated par. (3) as (4) and substituted in subpar. (A) “The Secretary” for “For fiscal years 2006 and 2007, the Secretary” and “for the first month of the next fiscal year” for “for the first month of fiscal year 2008”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(1). Pub. L. 110-85, §§212(d)(1), 217, temporarily struck out “, partners, and parent firms” after “affiliates” and substituted “clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)” for “clauses (i) through (vi) of subsection (a)(2)(A) of this section”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(A). Pub. L. 110-85, §§212(d)(2)(A), 217, temporarily struck out “, partners, and parent firms” before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B). Pub. L. 110-85, §§212(d)(2)(B)(i), (ii), 217, temporarily designated first sentence as cl. (i) and second to fourth sentences as cl. (ii) and inserted cl.

headings. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B)(ii). Pub. L. 110-85, §§212(d)(2)(B)(iii), (iv), 217, temporarily struck out “, partners, and parent firms” after “its affiliates” and after “such affiliates” and substituted “If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.” for “If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B)(iii). Pub. L. 110-85, §§212(d)(2)(B)(v), 217, temporarily added cl. (iii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(C). Pub. L. 110-85, §§212(d)(3), 217, temporarily amended subpar. (C) generally. Prior to amendment, text read as follows: “Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) of this section may be paid at a reduced rate of 38 percent of the fee established under such subsection for a premarket application, a premarket report, or a supplement.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(1). Pub. L. 110-85, §§212(e)(1), 217, temporarily substituted “2008” for “2004” and “(a)(2)(A)(viii)” for “(a)(2)(A)(vii)”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(A). Pub. L. 110-85, §§212(e)(2)(A), 217, temporarily struck out “, partners, and parent firms” before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(B). Pub. L. 110-85, §§212(e)(2)(B)(i), (ii), 217, temporarily inserted cl. headings and designated first sentence as cl. (i) and second to fourth sentences as cl. (ii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(B)(ii). Pub. L. 110-85, §§212(e)(2)(B)(iii), (iv), 217, temporarily struck out “, partners, and parent firms” after “its affiliates” and after “such affiliates” and substituted “If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.” for “If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(B)(iii). Pub. L. 110-85, §§212(e)(2)(B)(v), 217, temporarily added cl. (iii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(C). Pub. L. 110-85, §§212(e)(3), 217, temporarily amended subpar. (C) generally. Prior to amendment, subpar. (C) contained provisions, for fiscal year 2004 and each subsequent fiscal year, authorizing in cl. (i) a reduced fee for a premarket notification submission, and directing in cl. (ii) the Secretary how to determine an adjustment per fee revenue amount. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (f). Pub. L. 110-85, §§212(f), 217, temporarily amended subsec. (f) generally. Prior to amendment, text read as follows: “A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(1). Pub. L. 110-85, §§212(g)(1), 217, temporarily added par. (1) and struck out former par. (1). Prior to amendment, par. (1) related to performance goals for fiscal years 2003 through 2005, with respect to the amount appropriated under the salaries and expenses account of the Food and Drug Administration, for devices and radiological products, and termination of the program after fiscal year 2005. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 110-85, §§212(g)(2), 217, temporarily amended par. (2) generally. Prior to amendment,

text read as follows: “If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of subparagraph (C) or (D) of paragraph (1) 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 premarket applications, supplements, premarket reports, and premarket notification submissions, and at any time in such fiscal year, notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (h)(3). Pub. L. 110–85, §§212(h)(1), 217, temporarily amended par. (3) generally, substituting provisions authorizing appropriations for fiscal years 2008 to 2012 for provisions authorizing appropriations for fiscal years 2003 to 2007. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (h)(4). Pub. L. 110–85, §§212(h)(2), 217, temporarily amended par. (4) generally. Prior to amendment, text read as follows: “Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.” See Effective and Termination Dates of 2007 Amendment note below.

2005—Subsec. (a)(2)(A). Pub. L. 109–43, §2(a)(7), substituted “subsection (c)(1)” for “subsection (c)(5)”.

Subsec. (b). Pub. L. 109–43, §2(a)(1), inserted “and” after “2004;” and substituted “2005” for “2005; \$32,615,000 in fiscal year 2006, and \$35,000,000 in fiscal year 2007”.

Subsec. (c). Pub. L. 109–43, §2(a)(2)(A), substituted “Annual fee setting” for “Adjustments” in heading.

Subsec. (c)(1). Pub. L. 109–43, §2(a)(2)(B)–(D), redesignated par. (5) as (1), substituted “In general” for “Annual fee setting” in heading, “publish in the Federal Register fees under subsection (a) of this section. The fees” for “establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a) of this section, based on the revenue amounts established under subsection (b) of this section and the adjustment provided under this subsection and subsection (e)(2)(C)(ii) of this section, except that the fees”, “2006” for “2003”, and “\$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of \$281,600.” for “\$154,000.” in text, and struck out former par. (1) which required an annual inflation adjustment of the revenues established in subsec. (b).

Subsec. (c)(2). Pub. L. 109–43, §2(a)(2)(B), (C), redesignated par. (6) as (2) and struck out former par. (2) which required an annual adjustment of the fee revenues established in subsec. (b) to reflect changes in the workload of the Secretary for the process for the review of device applications.

Subsec. (c)(3). Pub. L. 109–43, §2(a)(2)(B), (E), added par. (3) and struck out former par. (3) which required an annual compensating adjustment of the fee revenues established in subsec. (b).

Subsec. (c)(4). Pub. L. 109–43, §2(a)(2)(B), struck out par. (4) which provided for a fiscal year 2007 adjustment of the fee revenues established in subsec. (b) to provide for operating reserves of carryover user fees.

Subsec. (c)(5), (6). Pub. L. 109–43, §2(a)(2)(C), redesignated pars. (5) and (6) as (1) and (2), respectively.

Subsec. (d)(1). Pub. L. 109–43, §2(a)(3)(A), inserted after first sentence “For the purposes of this paragraph, the term ‘small business’ means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.”

Subsec. (d)(2)(A). Pub. L. 109–43, §2(a)(3)(B), struck out cl. (i) designation and heading before “For purposes”, substituted “paragraph,” for “subsection,” and “\$100,000,000” for “\$30,000,000”, and struck out heading and text of clause (ii). Text read as follows: “The Sec-

retary may adjust the \$30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.”

Subsec. (d)(2)(C). Pub. L. 109–43, §2(a)(7), substituted “subsection (c)(1)” for “subsection (c)(5)”.

Subsec. (e)(2)(A). Pub. L. 109–43, §2(a)(4), substituted “\$100,000,000” for “\$30,000,000”.

Subsec. (e)(2)(C). Pub. L. 109–43, §2(a)(7), substituted “subsection (c)(1)” for “subsection (c)(5)” in cls. (i) and (ii).

Subsec. (g)(1)(B)(i). Pub. L. 109–43, §2(a)(5)(A)(i), added cl. (i) and struck out former cl. (i) which read as follows: “For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

“(I) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

“(II) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

“(III) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.”

Subsec. (g)(1)(B)(ii). Pub. L. 109–43, §2(a)(5)(A)(ii), added introductory provisions and struck out former introductory provisions which read as follows: “For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:”

Subsec. (g)(1)(C). Pub. L. 109–43, §2(a)(5)(B)(i), substituted “2005 and” for “2003 through” and inserted “more than 1 percent” after “years, is”.

Subsec. (g)(1)(C)(ii). Pub. L. 109–43, §2(a)(5)(B)(ii), substituted “amount that applies” for “sum that applies”.

Subsec. (g)(1)(D)(i). Pub. L. 109–43, §2(a)(5)(C), inserted “more than 1 percent” after “year, is”.

Subsec. (h)(3)(D), (E). Pub. L. 109–43, §2(a)(6), added subpar. (D) and struck out former subpars. (D) and (E) which read as follows:

“(D) \$32,615,000 for fiscal year 2006; and

“(E) \$35,000,000 for fiscal year 2007.”

2004—Pub. L. 108–214, §2(d)(3)(A), made technical correction to directory language of Pub. L. 107–250, §102(a), which enacted this section.

Subsec. (a). Pub. L. 108–214, §2(d)(2)(A), designated introductory provisions of subsec. (a) as par. (1), inserted heading, substituted “this section.” for “this section as follows:”, and redesignated former par. (1) as (2).

Subsec. (a)(1)(A). Pub. L. 108–214, §2(a)(2)(A)(i), substituted, in introductory provisions, “subsections (d) and (e)” for “subsection (d)”, in cl. (iv), “clause (i)” for “clause (i), subject to any adjustment under subsection (c)(3) of this section”, and, in cl. (vii), “clause (i), subject to any adjustment under subsection (e)(2)(C)(ii)” for “clause (i), subject to any adjustment under subsection (c)(3) of this section and any adjustment under subsection (e)(2)(C)(ii)”.

Subsec. (a)(1)(D)(i), (ii). Pub. L. 108–214, §2(a)(2)(A)(ii), substituted “application, report,” for “application”.

Subsec. (d)(1). Pub. L. 108–214, §2(d)(2)(B)(i), substituted “subsection (a)(2)(A)” for “subsection (a)(1)(A)” in last sentence.

Subsec. (d)(2)(B). Pub. L. 108–214, §2(a)(2)(B), substituted “firms, which show” for “firms, which show” in second sentence.

Subsec. (e)(1). Pub. L. 108–214, §2(a)(2)(C)(i), (d)(2)(B)(ii), substituted “For fiscal year 2004 and each subsequent fiscal year, where” for “Where” and “subsection (a)(2)(A)(vii)” for “subsection (a)(1)(A)(vii)”.

Subsec. (e)(2)(B). Pub. L. 108–214, §2(a)(2)(C)(ii)(I), substituted “firms, which show” for “firms, which show”.

Subsec. (e)(2)(C). Pub. L. 108-214, §2(a)(2)(C)(ii)(II), (d)(2)(B)(iii), substituted “For fiscal year 2004 and each subsequent fiscal year, where” for “Where” in cl. (i), “subsection (a)(2)(A)(vii)” for “subsection (a)(1)(A)(vii)” in cls. (i) and (ii), and “subsection (a)(2)(A)(i)” for “subsection (a)(1)(A)(i)” in cl. (ii).

Subsec. (f). Pub. L. 108-214, §2(a)(2)(D), struck out “for filing” after “accepted”.

Subsec. (h)(2)(B). Pub. L. 108-214, §2(a)(2)(E), designated existing provisions as cl. (i), inserted heading, redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i), redesignated former subcls. (I) and (II) of cl. (i) as items (aa) and (bb), respectively, of cl. (i)(II), and added cl. (ii).

Subsec. (j). Pub. L. 108-214, §2(d)(2)(B)(iv), substituted “subsection (a)(2)(D)” for “subsection (a)(1)(D)”.

EFFECTIVE AND TERMINATION DATES OF 2007  
AMENDMENT

Amendment by Pub. L. 110-85 effective Oct. 1, 2007, except for certain premarket fees under this subpart, and ceases to be effective Oct. 1, 2012, see sections 216 and 217 of Pub. L. 110-85, set out as notes under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 26, 2002, except for certain premarket fees, and ceases to be effective Oct. 1, 2007, see sections 106 and 107 of Pub. L. 107-250, set out as notes under section 379i of this title.

FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING  
PREMARKET REPORTS

Pub. L. 107-250, title I, §102(b), Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 108-214, §2(d)(2)(C), (3)(B), Apr. 1, 2004, 118 Stat. 577, provided that: “A person submitting a premarket report to the Secretary of Health and Human Services is exempt from the fee under section 738(a)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j(a)(2)(A)(ii)] (as added by subsection (a) of this section) if—

“(1) the premarket report is the first such report submitted to the Secretary by the person; and

“(2) before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.”

**§ 379j-1. Reauthorization; reporting requirements**

**(a) Reports**

**(1) Performance report**

For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

**(2) Fiscal report**

For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year

during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, 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 during such fiscal year for which the report is made.

**(3) Public availability**

The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

**(b) Reauthorization**

**(1) Consultation**

In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, 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 regulated industry.

**(2) Prior public input**

Prior to beginning negotiations with the regulated 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)(1);

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

(D) publish the comments on the Food and Drug Administration’s Internet Web site.

**(3) Periodic consultation**

Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

**(4) Public review of recommendations**

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

**(5) Transmittal of recommendations**

Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

**(6) Minutes of negotiation meetings**

**(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

**(B) Content**

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §738A, as added Pub. L. 110-85, title II, §213, Sept. 27, 2007, 121 Stat. 850.)

TERMINATION OF SECTION

*For termination of section by section 217 of Pub. L. 110-85, see Effective and Termination Dates note below.*

REFERENCES IN TEXT

Section 201(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a)(1), is section 201(c) of Pub. L. 110-85, which is set out as a note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 1, 2007, except for certain pre-market fees under this subpart, and ceases to be effective Jan. 31, 2013, see sections 216 and 217 of Pub. L. 110-85, set out as Effective and Termination Dates of 2007 Amendment notes under section 379i of this title.

SUBPART 4—FEES RELATING TO ANIMAL DRUGS

TERMINATION OF SUBPART

*For termination of subpart by section 5 of Pub. L. 108-130, see Termination Date note set out under section 379j-11 of this title.*

*For savings provisions, see section 106 of Pub. L. 110-316, set out as a note under section 379j-11 of this title.*

**§ 379j-11. Definitions**

For purposes of this subpart:

(1) The term “animal drug application” means an application for approval of any new animal drug submitted under section 360b(b)(1) of this title. Such term does not include either a new animal drug application submitted under section 360b(b)(2) of this title or a supplemental animal drug application.

(2) The term “supplemental animal drug application” means—

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 360b(c)(2) of this title for which data with respect to safety or effectiveness are required.

(3) The term “animal drug product” means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term “animal drug establishment” means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

(5) The term “investigational animal drug submission” means—

(A) the filing of a claim for an investigational exemption under section 360b(j) of this title for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(6) The term “animal drug sponsor” means either an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) The term “final dosage form” means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

(8) The term “process for the review of animal drug applications” means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental

animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.

(9) The term "costs of resources allocated for the process for the review of animal drug applications" means the expenses incurred in connection with the process for the review of animal drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

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

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

(D) collecting fees under section 379j-12 of this title and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(10) The term "adjustment factor" applicable to a fiscal year refers to the formula set forth in section 379g(8) of this title with the base or comparator month being October 2002.

(11) The term "person" includes an affiliate thereof.

(12) The term "affiliate" refers to the definition set forth in section 379g(11) of this title.

(June 25, 1938, ch. 675, § 739, as added Pub. L. 108-130, § 3, Nov. 18, 2003, 117 Stat. 1361; amended Pub. L. 110-85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110-316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510.)

#### AMENDMENT OF SECTION

*For termination of amendment by section 108(a) of Pub. L. 110-316, see Effective and Termination Dates of 2008 Amendment note below.*

#### TERMINATION OF SECTION

*For termination of section by section 5 of Pub. L. 108-130, see Termination Date note below.*

*For savings provisions, see section 106 of Pub. L. 110-316, set out as a note below.*

#### AMENDMENTS

2008—Par. (6). Pub. L. 110-316, §§ 102(1), 108(a), temporarily substituted "that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary" for " , except for an approved application for which all subject products have been removed from listing under section 360 of this title". See Effective and Termination Dates of 2008 Amendment note below.

Par. (8)(H). Pub. L. 110-316, §§ 102(2), 108(a), temporarily substituted "but not after such application has been approved" for "but not such activities after an animal drug has been approved". See Effective and Termination Dates of 2008 Amendment note below.

Par. (10). Pub. L. 110-316, §§ 102(3), 108(a), temporarily substituted "month being October 2002" for "year being 2003". See Effective and Termination Dates of 2008 Amendment note below.

Pars. (11), (12). Pub. L. 110-316, §§ 102(4), (5), 108(a), temporarily added par. (11) and redesignated former par. (11) as (12). See Effective and Termination Dates of 2008 Amendment note below.

2007—Pub. L. 110-85, § 109(a), substituted "subpart" for "part" in introductory provisions.

Par. (11). Pub. L. 110-85, § 109(b), substituted "379g(11)" for "379g(9)".

#### EFFECTIVE AND TERMINATION DATES OF 2008 AMENDMENT

Pub. L. 110-316, title I, § 107, Aug. 14, 2008, 122 Stat. 3514, provided that: "The amendments made by sections 102, 103, and 104 [enacting section 379j-13 of this title and amending this section and section 379j-12 of this title] shall take effect on October 1, 2008, and fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-11 et seq.], as amended by this title, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after such date, regardless of the date of the enactment of this title [Aug. 14, 2008]."

Pub. L. 110-316, title I, § 108, Aug. 14, 2008, 122 Stat. 3515, provided that:

"(a) AUTHORIZATION.—The amendments made by sections 102 and 103 [amending this section and section 379j-12 of this title] cease to be effective October 1, 2013.

"(b) REPORTING REQUIREMENTS.—The amendment made by section 104 [enacting section 379j-13 of this title] ceases to be effective January 31, 2014."

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110-85 effective Oct. 1, 2007, see section 107 of Pub. L. 110-85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379g of this title.

## TERMINATION DATE

Pub. L. 108-130, § 5, Nov. 18, 2003, 117 Stat. 1371, provided that: “The amendments made by section 3 [enacting this subpart] shall not be in effect after October 1, 2008, and section 4 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date.”

## SAVINGS PROVISIONS

Pub. L. 110-316, title I, § 106, Aug. 14, 2008, 122 Stat. 3514, provided that: “Notwithstanding section 5 of the Animal Drug User Fee Act of 2003 [Pub. L. 108-130] (21 U.S.C. 379j-11 note), and notwithstanding the amendments made by this title [enacting section 379j-13 of this title and amending this section and sections 360b and 379j-12 of this title], part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-11 et seq.), as in effect on the day before the date of the enactment of this title [Aug. 14, 2008], shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after September 1, 2003, but before October 1, 2008, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2009.”

## FINDINGS

Pub. L. 110-316, title I, § 101(b), Aug. 14, 2008, 122 Stat. 3509, provided that: “Congress finds that the fees authorized by the amendments made in this title [enacting section 379j-13 of this title and amending this section and sections 360b and 379j-12 of this title] will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-11 et seq.], in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.”

Pub. L. 108-130, § 2, Nov. 18, 2003, 117 Stat. 1361, provided that: “Congress finds as follows:

“(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

“(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of new animal drug applications.

“(3) The fees authorized by this Act [enacting this subpart and provisions set out as notes under this section and section 301 of this title] will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 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 Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.”

## ACCOUNTABILITY AND REPORTS

Pub. L. 108-130, § 4, Nov. 18, 2003, 117 Stat. 1370, which required the Secretary of Health and Human Services, after certain consultations, to develop recommendations relating to the review of animal drug applications after fiscal year 2008, to submit to congressional committees a report each fiscal year concerning the

progress of the Food and Drug Administration in achieving certain goals toward expediting the animal drug development process and the review of the animal drug applications and investigational animal drug submissions, and to submit a report for each fiscal year to congressional committees on the implementation of the authority for the fees collected under this subpart during the fiscal year and the use, by the Food and Drug Administration, of the fees collected, ceased to be effective 120 days after Oct. 1, 2008. See Termination Date note above.

**§ 379j-12. Authority to assess and use animal drug fees****(a) Types of fees**

Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

**(1) Animal drug application and supplement fee****(A) In general**

Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (b) of this section for an animal drug application, except an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title; and

(ii) A fee established in subsection (b), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

(I) a supplemental animal drug application for which safety or effectiveness data are required; and

(II) an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title.

**(B) Payment**

The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

**(C) Exception for previously filed application or supplement**

If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

**(D) Refund of fee if application refused for filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

**(E) Refund of fee if application withdrawn**

If an animal drug application or a supplemental animal drug application is with-

drawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

**(2) Animal drug product fee**

Each person—

(A) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 360 of this title, and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application;

shall pay for each such animal drug product the annual fee established in subsection (b) of this section. Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

**(3) Animal drug establishment fee**

Each person—

(A) who owns or operates, directly or through an affiliate, an animal drug establishment, and

(B) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 360 of this title, and

(C) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual fee established in subsection (b) of this section for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee shall be paid on or before January 31 of each year. The establishment shall be assessed only one fee per fiscal year under this section: *Provided, however*, that where a single establishment manufactures both animal drug products and prescription drug products, as defined in section 379g(3) of this title, such establishment shall

be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 379h(a)(2) of this title, within a single fiscal year.

**(4) Animal drug sponsor fee**

Each person—

(A) who meets the definition of an animal drug sponsor within a fiscal year; and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual fee established under subsection (b) of this section. The fee shall be paid on or before January 31 of each year. Each animal drug sponsor shall pay only one such fee each fiscal year.

**(b) Fee amounts**

Except as provided in subsection (a)(1) of this section and subsections (c), (d), (f), and (g) of this section, the fees required under subsection (a) of this section shall be established to generate fee revenue amounts as follows:

**(1) Total fee revenues for application and supplement fees**

The total fee revenues to be collected in animal drug application fees under subsection (a)(1)(A)(i) of this section and supplemental and other animal drug application fees under subsection (a)(1)(A)(ii) of this section shall be \$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.

**(2) Total fee revenues for product fees**

The total fee revenues to be collected in product fees under subsection (a)(2) of this section shall be \$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.

**(3) Total fee revenues for establishment fees**

The total fee revenues to be collected in establishment fees under subsection (a)(3) of this section shall be \$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.

**(4) Total fee revenues for sponsor fees**

The total fee revenues to be collected in sponsor fees under subsection (a)(4) of this section shall be \$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.

**(c) Adjustments**

**(1) Workload adjustment**

The fee revenues shall be adjusted each fiscal year after fiscal year 2009 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal

drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b) of this section.

**(2) Final year adjustment**

For fiscal year 2013, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2014. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2013.

**(3) Annual fee setting**

The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) of this section and the adjustments provided under this subsection.

**(4) Limit**

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

**(d) Fee waiver or reduction**

**(1) In general**

The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) of this section where the Secretary finds that—

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person,

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Fed-

eral Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation)),

(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication, or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

**(2) Use of standard costs**

In making the finding in paragraph (1)(B), the Secretary may use standard costs.

**(3) Rules for small businesses**

**(A) Definition**

In paragraph (1)(E), the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates.

**(B) Waiver of application fee**

The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

**(C) Certification**

The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

**(e) Effect of failure to pay fees**

An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 379j-11(5)(B) of this title that is submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

**(f) Assessment of fees**

**(1) Limitation**

Fees may not be assessed under subsection (a) of this section for a fiscal year beginning

after fiscal year 2003 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 the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

**(2) Authority**

If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of paragraph (1) 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 animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.

**(g) Crediting and availability of fees**

**(1) In general**

Fees authorized under subsection (a) of this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated 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 salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

**(2) Collections and appropriation acts**

**(A) In general**

The fees authorized by this section—

(i) shall be retained 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 only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

**(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 the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

**(3) Authorization of appropriations**

There are authorized to be appropriated for fees under this section—

- (A) \$15,260,000 for fiscal year 2009;
- (B) \$17,280,000 for fiscal year 2010;
- (C) \$19,448,000 for fiscal year 2011;
- (D) \$21,768,000 for fiscal year 2012; and
- (E) \$24,244,000 for fiscal year 2013;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

**(4) Offset**

If the sum of the cumulative amount of fees collected under this section for fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2013.

**(h) Collection of unpaid fees**

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

**(i) Written requests for waivers, reductions, and refunds**

To qualify for consideration for a waiver or reduction under subsection (d) of this section, or for a refund of any fee collected in accordance with subsection (a) of this section, a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

**(j) 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 the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

**(k) Abbreviated new animal drug applications**

The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications, and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

(June 25, 1938, ch. 675, §740, as added Pub. L. 108-130, §3, Nov. 18, 2003, 117 Stat. 1363; amended Pub. L. 110-316, title I, §103, Aug. 14, 2008, 122 Stat. 3510.)

## AMENDMENT OF SECTION

*For termination of amendment by section 108(a) of Pub. L. 110-316, see Effective and Termination Dates of 2008 Amendment note below.*

## TERMINATION OF SECTION

*For termination of section by section 5 of Pub. L. 108-130, see Termination Date note below.*

*For savings provisions, see section 106 of Pub. L. 110-316, set out as a note under section 379j-11 of this title.*

## AMENDMENTS

2008—Subsec. (a)(1)(A)(i). Pub. L. 110-316, §§103(a)(1), 108(a), temporarily inserted “, except an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title” after “for an animal drug application”. See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (a)(1)(A)(ii). Pub. L. 110-316, §§103(a)(2), 108(a), temporarily amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: “A fee established in subsection (b) of this section for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).” See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(1). Pub. L. 110-316, §§103(b)(1), 108(a), temporarily substituted “and supplemental and other animal drug application fees” for “and supplemental animal drug application fees” and “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.” for “\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.” See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(2). Pub. L. 110-316, §§103(b)(2), 108(a), temporarily substituted “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.” for “\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.” See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(3). Pub. L. 110-316, §§103(b)(3), 108(a), temporarily substituted “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.” for “\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.” See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(4). Pub. L. 110-316, §§103(b)(4), 108(a), temporarily substituted “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.” for “\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.” See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(1). Pub. L. 110-316, §§103(c)(1)–(3), 108(a), temporarily redesignated par. (2) as (1), substituted “The fee revenues shall be adjusted each fiscal year after fiscal year 2009” for “After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004” in introductory provisions, struck out “, as adjusted for inflation under paragraph (1)” before period in subpar. (B), and struck out former par. (1) relating to inflation adjustment. See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(2). Pub. L. 110-316, §§103(c)(2), (4), 108(a), temporarily redesignated par. (3) as (2) and substituted “2013” for “2008” in two places and “2014” for “2009”. Former par. (2) redesignated (1). See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(3) to (5). Pub. L. 110-316, §§103(c)(2), 108(a), temporarily redesignated pars. (4) and (5) as (3) and (4), respectively. Former par. (3) redesignated (2). See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(3)(A) to (E). Pub. L. 110-316, §§103(d), 108(a), temporarily amended subpars. (A) to (E) generally. Prior to amendment, subpars. (A) to (E) read as follows:

- “(A) \$5,000,000 for fiscal year 2004;
- “(B) \$8,000,000 for fiscal year 2005;
- “(C) \$10,000,000 for fiscal year 2006;
- “(D) \$10,000,000 for fiscal year 2007; and
- “(E) \$10,000,000 for fiscal year 2008;”.

See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(4). Pub. L. 110-316, §§103(e), 108(a), temporarily amended par. (4) generally. Prior to amendment, par. (4) read as follows: “Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.” See Effective and Termination Dates of 2008 Amendment note below.

## EFFECTIVE AND TERMINATION DATES OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2008, and ceases to be effective Oct. 1, 2013, see sections 107 and 108(a) of Pub. L. 110-316, set out as notes under section 379j-11 of this title.

## TERMINATION DATE

Section not effective after Oct. 1, 2008, see section 5 of Pub. L. 108-130, set out as a note under section 379j-11 of this title.

**§379j-13. Reauthorization; reporting requirements****(a) Performance report**

Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during 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 101(b) of the Animal Drug User Fee Amendments of 2008 toward expediting the animal drug development process and the review of the new and

supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

**(b) Fiscal report**

Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during 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 during such fiscal year for which the report is made.

**(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 the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2013, 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) veterinary professionals;
- (E) representatives of patient and consumer advocacy groups; and
- (F) the regulated industry.

**(2) Prior public input**

Prior to beginning negotiations with the regulated 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
- (D) publish the comments on the Food and Drug Administration's Internet Web site.

**(3) Periodic consultation**

Not less frequently than once every 4 months during negotiations with the regulated

industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

**(4) Public review of recommendations**

After negotiations with the regulated industry, the Secretary shall—

- (A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;
- (B) publish such recommendations in the Federal Register;
- (C) provide for a period of 30 days for the public to provide written comments on such recommendations;
- (D) hold a meeting at which the public may present its views on such recommendations; and
- (E) after consideration of such public views and comments, revise such recommendations as necessary.

**(5) Transmittal of recommendations**

Not later than January 15, 2013, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

**(6) Minutes of negotiation meetings**

**(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

**(B) Content**

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §740A, as added Pub. L. 110-316, title I, §104, Aug. 14, 2008, 122 Stat. 3511.)

TERMINATION OF SECTION

*For termination of section by section 108(b) of Pub. L. 110-316, see Effective and Termination Dates note below.*

REFERENCES IN TEXT

Section 101(b) of the Animal Drug User Fee Amendments of 2008, referred to in subsec. (a), is section 101(b) of Pub. L. 110-316, which is set out as a note under section 379j-11 of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or

after Oct. 1, 2008, and ceases to be effective Jan. 31, 2014, see sections 107 and 108(b) of Pub. L. 110-316, set out as Effective and Termination Dates of 2008 Amendment notes under section 379j-11 of this title.

SUBPART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

TERMINATION OF SUBPART

*For termination of subpart by section 204 of Pub. L. 110-316, see Termination Date notes set out under sections 379j-21 and 379j-22 of this title.*

**§ 379j-21. Authority to assess and use generic new animal drug fees**

**(a) Types of fees**

Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

**(1) Abbreviated application fee**

**(A) In general**

Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (b) for such an application.

**(B) Payment**

The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

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

If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

**(D) Refund of fee if application refused for filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

**(E) Refund of fee if application withdrawn**

If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

**(2) Generic new animal drug product fee**

Each person—

(A) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 360 of this title, and

(B) who, after September 1, 2008, had pending before the Secretary an abbreviated ap-

plication or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (b). Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

**(3) Generic new animal drug sponsor fee**

**(A) In general**

Each person—

(i) who meets the definition of a generic new animal drug sponsor within a fiscal year, and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual fee established under subsection (b). The fee shall be paid on or before January 31 of each year.

**(B) Amount of fee**

Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 6 approved abbreviated applications.

(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with 1 or fewer approved abbreviated applications.

**(b) Fee amounts**

Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

**(1) Total fee revenues for application fees**

The total fee revenues to be collected in abbreviated application fees under subsection (a)(1) shall be \$1,449,000 for fiscal year 2009, \$1,532,000 for fiscal year 2010, \$1,619,000 for fiscal year 2011, \$1,712,000 for fiscal year 2012, and \$1,809,000 for fiscal year 2013.

**(2) Total fee revenues for product fees**

The total fee revenues to be collected in generic new animal drug product fees under subsection (a)(2) shall be \$1,691,000 for fiscal year

2009, \$1,787,000 for fiscal year 2010, \$1,889,000 for fiscal year 2011, \$1,997,000 for fiscal year 2012, and \$2,111,000 for fiscal year 2013.

**(3) Total fee revenues for sponsor fees**

The total fee revenues to be collected in generic new animal drug sponsor fees under subsection (a)(3) shall be \$1,691,000 for fiscal year 2009, \$1,787,000 for fiscal year 2010, \$1,889,000 for fiscal year 2011, \$1,997,000 for fiscal year 2012, and \$2,111,000 for fiscal year 2013.

**(c) Adjustments**

**(1) Workload adjustment**

The fee revenues shall be adjusted each fiscal year after fiscal year 2009 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b).

**(2) Final year adjustment**

For fiscal year 2013, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2014. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2013.

**(3) Annual fee setting**

The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

**(4) Limit**

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of abbreviated applications for generic new animal drugs.

**(d) Fee waiver or reduction**

The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

**(e) Effect of failure to pay fees**

An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

**(f) Assessment of fees**

**(1) Limitation**

Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 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 the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor 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 because of paragraph (1) 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 abbreviated applications, generic new animal drug sponsors, and generic new animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

**(g) 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. Such fees are authorized to be appropriated 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 sal-

ary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

**(2) Collections and appropriation acts**

**(A) In general**

The fees authorized by this section—

(i) shall be retained 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 only be collected and available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

**(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 the process for the review of abbreviated applications for generic new animal drugs—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

**(3) Authorization of appropriations**

There are authorized to be appropriated for fees under this section—

(A) \$4,831,000 for fiscal year 2009;

(B) \$5,106,000 for fiscal year 2010;

(C) \$5,397,000 for fiscal year 2011;

(D) \$5,706,000 for fiscal year 2012; and

(E) \$6,031,000 for fiscal year 2013;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees.

**(4) Offset**

If the sum of the cumulative amount of fees collected under this section for the fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to the appropriation

account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2013.

**(h) Collection of unpaid fees**

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

**(i) Written requests for waivers, reductions, and refunds**

To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

**(j) 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 the process of the review of abbreviated applications for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

**(k) Definitions**

In this section and section 379j-22 of this title:

**(1) Abbreviated application for a generic new animal drug**

The terms “abbreviated application for a generic new animal drug” and “abbreviated application” mean an abbreviated application for the approval of any generic new animal drug submitted under section 360b(b)(2) of this title. Such term does not include a supplemental abbreviated application for a generic new animal drug.

**(2) Adjustment factor**

The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

(A) for purposes of subsection (f)(1), such Index for October 2002; and

(B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

**(3) Costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs**

The term “costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs” means the expenses incurred in connection with the process for the review of abbreviated applications for generic new animal drugs for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory

committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(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 this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

**(4) Final dosage form**

The term “final dosage form” means, with respect to a generic new animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

**(5) Generic new animal drug**

The term “generic new animal drug” means a new animal drug that is the subject of an abbreviated application.

**(6) Generic new animal drug product**

The term “generic new animal drug product” means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

**(7) Generic new animal drug sponsor**

The term “generic new animal drug sponsor” means either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

**(8) Investigational submission for a generic new animal drug**

The terms “investigational submission for a generic new animal drug” and “investigational submission” mean—

(A) the filing of a claim for an investigational exemption under section 360b(j) of this title for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

(B) the submission of information for the purpose of enabling the Secretary to evalu-

ate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

**(9) Person**

The term “person” includes an affiliate thereof (as such term is defined in section 379g(11) of this title).

**(10) Process for the review of abbreviated applications for generic new animal drugs**

The term “process for the review of abbreviated applications for generic new animal drugs” means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.

(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary’s review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the generic new animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

**(11) Supplemental abbreviated application for generic new animal drug**

The terms “supplemental abbreviated application for a generic new animal drug” and “supplemental abbreviated application” mean a request to the Secretary to approve a change in an approved abbreviated application.

(June 25, 1938, ch. 675, §741, as added Pub. L. 110-316, title II, §202(b), Aug. 14, 2008, 122 Stat. 3515.)

TERMINATION OF SECTION

*For termination of section by section 204(a) of Pub. L. 110-316, see Termination Date note below.*

## PRIOR PROVISIONS

A prior section 741 of act June 25, 1938, was renumbered section 745 and is classified to section 379k of this title.

## TERMINATION DATE

Pub. L. 110-316, title II, §204(a), Aug. 14, 2008, 122 Stat. 3524, provided that: “The amendments made by section 202 [enacting this section and amending sections 379k, 379l, and 379o of this title] shall cease to be effective October 1, 2013.”

## FINDINGS

Pub. L. 110-316, title II, §201(b), Aug. 14, 2008, 122 Stat. 3515, provided that: “Congress finds as follows:

“(1) Prompt approval of abbreviated applications for safe and effective generic new animal drugs will reduce animal healthcare costs and promote the well-being of animal health and the public health.

“(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of abbreviated applications for the approval of generic new animal drugs.

“(3) The fees authorized by this title [see Short Title of 2008 Amendment note set out under section 301 of this title] will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.”

### § 379j-22. Reauthorization; reporting requirements

#### (a) Performance reports

Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(3)<sup>1</sup> of the Animal Generic Drug User Fee Act of 2008 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

#### (b) Fiscal report

Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives 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 during such fiscal year for which the report is made.

#### (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 Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year 2013, 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) veterinary professionals;
- (E) representatives of patient and consumer advocacy groups; and
- (F) the regulated industry.

##### (2) Prior public input

Prior to beginning negotiations with the regulated 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
- (D) publish the comments on the Food and Drug Administration's Internet Web site.

##### (3) Periodic consultation

Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

##### (4) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

- (A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;
- (B) publish such recommendations in the Federal Register;
- (C) provide for a period of 30 days for the public to provide written comments on such recommendations;

<sup>1</sup> See References in Text note below.

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

**(5) Transmittal of recommendations**

Not later than January 15, 2013, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

**(6) Minutes of negotiation meetings**

**(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

**(B) Content**

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §742, as added Pub. L. 110-316, title II, §203, Aug. 14, 2008, 122 Stat. 3522.)

TERMINATION OF SECTION

*For termination of section by section 204(b) of Pub. L. 110-316, see Termination Date note below.*

REFERENCES IN TEXT

Section 201(3) of the Animal Generic Drug User Fee Act of 2008, referred to in subsec. (a), probably means section 201(b)(3) of Pub. L. 110-316, which is set out as a note under section 379j-21 of this title.

PRIOR PROVISIONS

A prior section 742 of act June 25, 1938, was renumbered section 746 and is classified to section 379l of this title.

TERMINATION DATE

Pub. L. 110-316, title II, §204(b), Aug. 14, 2008, 122 Stat. 3524, provided that: "The amendment made by section 203 [enacting this section] shall cease to be effective January 31, 2014."

SUBPART 6—FEES RELATED TO FOOD

**§ 379j-31. Authority to collect and use fees**

**(a) In general**

**(1) Purpose and authority**

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

(A) the responsible party for each domestic facility (as defined in section 350d(b) of this title) and the United States agent for each foreign facility subject to a reinspection in

such fiscal year, to cover reinspection-related costs for such year;

(B) the responsible party for a domestic facility (as defined in section 350d(b) of this title) and an importer who does not comply with a recall order under section 350l of this title or under section 350a(f) of this title in such fiscal year, to cover food recall activities associated with such order performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for such year;

(C) each importer participating in the voluntary qualified importer program under section 384b of this title in such year, to cover the administrative costs of such program for such year; and

(D) each importer subject to a reinspection in such fiscal year, to cover reinspection-related costs for such year.

**(2) Definitions**

For purposes of this section—

(A) the term "reinspection" means—

(i) with respect to domestic facilities (as defined in section 350d(b) of this title), 1 or more inspections conducted under section 374 of this title subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary's satisfaction; and

(ii) with respect to importers, 1 or more examinations conducted under section 381 of this title subsequent to an examination conducted under such provision which identified noncompliance materially related to a food safety requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary's satisfaction;

(B) the term "reinspection-related costs" means all expenses, including administrative expenses, incurred in connection with—

(i) arranging, conducting, and evaluating the results of reinspections; and

(ii) assessing and collecting reinspection fees under this section; and

(C) the term "responsible party" has the meaning given such term in section 350f(a)(1) of this title.

**(b) Establishment of fees**

**(1) In general**

Subject to subsections (c) and (d), the Secretary shall establish the fees to be collected under this section for each fiscal year specified in subsection (a)(1), based on the methodology described under paragraph (2), and shall publish such fees in a Federal Register notice not later than 60 days before the start of each such year.

**(2) Fee methodology**

**(A) Fees**

Fees amounts established for collection—

(i) under subparagraph (A) of subsection (a)(1) for a fiscal year shall be based on the

Secretary's estimate of 100 percent of the costs of the reinspection-related activities (including by type or level of reinspection activity, as the Secretary determines applicable) described in such subparagraph (A) for such year;

(ii) under subparagraph (B) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (B) for such year;

(iii) under subparagraph (C) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (C) for such year; and

(iv) under subparagraph (D) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (D) for such year.

**(B) Other considerations**

**(i) Voluntary qualified importer program**

In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers who have submitted to the Secretary a notice under section 384b(c) of this title informing the Secretary of the intent of such importer to participate in the program under section 384b of this title in such fiscal year.

**(II)<sup>1</sup> Recoupment**

In establishing the fee amounts under subparagraph (A)(iii) for the first 5 fiscal years after January 4, 2011, the Secretary shall include in such fee a reasonable surcharge that provides a recoupment of the costs expended by the Secretary to establish and implement the first year of the program under section 384b of this title.

**(ii) Crediting of fees**

In establishing the fee amounts under subparagraph (A) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out such activities, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

**(iii) Published guidelines**

Not later than 180 days after January 4, 2011, the Secretary shall publish in the Federal Register a proposed set of guidelines in consideration of the burden of fee amounts on small business. Such consideration may include reduced fee amounts for small businesses. The Secretary shall provide for a period of public comment on such guidelines. The Secretary shall adjust the fee schedule for small businesses subject to such fees only through notice and comment rulemaking.

**(3) Use of fees**

The Secretary shall make all of the fees collected pursuant to clause<sup>2</sup> (i), (ii), (iii), and (iv) of paragraph (2)(A) available solely to pay for the costs referred to in such clause (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.

**(c) Limitations**

**(1) In general**

Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 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

<sup>1</sup> So in original. No subcl. (I) has been enacted.

<sup>2</sup> So in original. Probably should be "clauses".

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.

PART D—INFORMATION AND EDUCATION

**§ 379k. Information system**

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(June 25, 1938, ch. 675, §745, formerly §741, as added Pub. L. 105-115, title IV, §407(a), Nov. 21, 1997, 111 Stat. 2370; renumbered §745, Pub. L. 110-316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

AMENDMENT OF SECTION

*For termination of amendment renumbering this section by section 204(a) of Pub. L. 110-316, see Termination Date of 2008 Amendment note below.*

TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110-316, set out as a Termination Date note under section 379j-21 of this title.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT ON STATUS OF SYSTEM

Section 407(b) of Pub. L. 105-115 provided that not later than 1 year after Nov. 21, 1997, Secretary of Health and Human Services was to submit report to Congress on status of system to be established under this section, including projected costs of system and concerns about confidentiality.

**§ 379l. Education**

**(a) In general**

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

- (1) scientific training;
- (2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;
- (3) training to achieve product specialization in such inspections; and
- (4) training in administrative process and procedure and integrity issues.

**(b) Intramural fellowships and other training programs**

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or