

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

§ 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) 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 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; Pub. L. 112-144, title I, §102, title IV, §407, July 9, 2012, 126 Stat. 996, 1039.)

TERMINATION OF SECTION

For termination of section by section 105(a) of Pub. L. 112-144, see Termination Date note below.

AMENDMENTS

2012—Par. (1)(B). Pub. L. 112-144, §407, struck out "or (k)" after "subsection (a)".

Par. (7). Pub. L. 112-144, §102, substituted "expenses in connection with" for "expenses incurred in connection with".

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), in introductory provisions, substituted "For purposes of this subpart" for "For purposes of this part".

Par. (1). Pub. L. 110-85, §102(2)(D), substituted "subparagraph (B)" for "subparagraph (C)" in concluding provisions.

Par. (1)(A). Pub. L. 110-85, §102(2)(A), substituted "355(b) of this title, or" for "355(b)(1) of this title,".

Par. (1)(B), (C). Pub. L. 110-85, §102(2)(B), (C), 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".

Par. (3)(C). Pub. L. 110-85, §102(3), 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.

Par. (4). Pub. L. 110-85, §102(4), inserted "(such as capsules, tablets, or lyophilized products before reconstitution)" before period at end.

Par. (6)(F). Pub. L. 110-85, §102(5), 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."

Par. (8). Pub. L. 110-85, §102(6), substituted "October of the preceding fiscal year" for "April of the preceding fiscal year" and "October 1996" for "April 1997".

Pars. (9) to (11). Pub. L. 110-85, §102(7), (8), added pars. (9) and (10) and redesignated former par. (9) as (11).

2002—Par. (1). Pub. L. 107-188, §503(1), substituted "licensure, as described in subparagraph (C)" for "licensure, as described in subparagraph (D)" in concluding provisions.

Par. (3). Pub. L. 107-188, §503(2)(D), which directed the 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.

Par. (3)(C). Pub. L. 107-188, §503(2)(A)–(C), added subpar. (C).

Par. (6)(F). Pub. L. 107-188, §503(3), added subpar. (F).

Par. (8). Pub. L. 107-188, §503(4), 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.

1997—Par. (1). Pub. L. 105-115, §102(1), in closing provisions, 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.

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), in closing provisions, 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.

Par. (4). Pub. L. 105-115, §102(3), substituted “without substantial further manufacturing” for “without further manufacturing”.

Par. (5). Pub. L. 105-115, §102(4), 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.”

Par. (7)(A). Pub. L. 105-115, §102(5), 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.”

Par. (8)(A). Pub. L. 105-115, §102(6)(A), substituted “April of the preceding fiscal year” for “August of the preceding fiscal year” and “April 1997” for “August 1992”.

Par. (8)(B). Pub. L. 105-115, §102(6)(B), 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”.

Par. (9). Pub. L. 105-115, §102(7), added par. (9).

EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112-144, title I, §106, July 9, 2012, 126 Stat. 1002, provided that: “The amendments made by this title [amending this section and sections 379h and 379h-2 of this title and repealing provisions set out as notes under this section and section 379h-2 of this title] shall take effect on October 1, 2012, or the date of the enactment of this Act [July 9, 2012], 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, 2012, regardless of the date of the enactment of this Act.”

Amendment by section 407 of Pub. L. 112-144 effective Oct. 1, 2012, see section 405 of Pub. L. 112-144, set out as a note under section 379j-51 of this title.

EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Pub. L. 110-85, title I, §106(a), Sept. 27, 2007, 121 Stat. 842, which provided that the amendments made by sections 102, 103, and 104 of Pub. L. 110-85 (enacting section 379h-1 of this title and amending this section and section 379h of this title) would cease to be effective Oct. 1, 2012, was repealed by Pub. L. 112-144, title I, §105(c)(1), July 9, 2012, 126 Stat. 1001.

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, which provided that the amendments made by sections 503 and 504 of Pub. L. 107-188 (amending this section and section 379h of this title) would cease to be effective Oct. 1, 2007, and the amendment by section 505 of Pub. L. 107-188 (enacting provisions set out as a note below) would cease to be effective 120 days after Oct. 1, 2007, was repealed by Pub. L. 112-144, title I, §105(d)(1)(A), July 9, 2012, 126 Stat. 1001.

[Pub. L. 112-144, title I, §105(d)(1), July 9, 2012, 126 Stat. 1001, provided that the repeal of section 509 of Pub. L. 107-188, formerly set out above, is effective Sept. 30, 2007.]

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, which provided that the amendments by sections 102 and 103 of Pub. L. 105-115 (amending this section and section 379h of this title) would cease to be effective Oct. 1, 2002, and the amendment by section 104 (enacting provisions set out as a note below) would cease to be effective 120 days after Oct. 1, 2002, was repealed by Pub. L. 112-144, title I, §105(d)(2)(A), July 9, 2012, 126 Stat. 1001.

[Pub. L. 112-144, title I, §105(d)(2), July 9, 2012, 126 Stat. 1001, provided that: “Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2017.”]

TERMINATION DATE

Pub. L. 112-144, title I, §105(a), July 9, 2012, 126 Stat. 1001, provided that: “Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2017.”

Pub. L. 102-571, title I, §105, Oct. 29, 1992, 106 Stat. 4498, which provided that the amendment by section 103 of Pub. L. 102-571 (enacting this subpart) would not be in effect after Oct. 1, 1997, and the amendment by section 104 of Pub. L. 102-571 (enacting provisions set out as a note below) would not be in effect after 120 days after Oct. 1, 1997, was repealed by Pub. L. 112-144, title I, §105(d)(3), July 9, 2012, 126 Stat. 1002.

[Pub. L. 112-144, title I, §105(d)(3), July 9, 2012, 126 Stat. 1002, provided that the repeal of section 105 of Pub. L. 102-571, formerly set out above, is effective Sept. 30, 1997.]

SAVINGS PROVISION

Pub. L. 112-144, title I, §107, July 9, 2012, 126 Stat. 1002, provided that: “Notwithstanding the amendments made by this title [amending this section and section 379h and 379h-2 of this title and repealing provisions set out as notes under this section and section 379h-2 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 [July 9, 2012], 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, 2007, but before October 1, 2012, 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 2012.”

Pub. L. 112-144, title IV, §406, July 9, 2012, 126 Stat. 1039, provided that: “Notwithstanding the amendments made by this title [enacting sections 379j-51 to 379j-53 of this title and amending this section and section 379d-4 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 [July 9, 2012], shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2007, but before October 1, 2012, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.”

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 [Pub. L. 107-188] (former 21 U.S.C. 379g note), 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, formerly set out as an Effective and Termination Dates of 1997 Amendment note above], and notwithstanding the amendments made by 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], 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, formerly set out as a Termination Date note 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, provided that:

“(a) PUBLIC ACCOUNTABILITY.—

“(1) CONSULTATION.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of human drug applications for the fiscal years after fiscal year 2007, and for the reauthorization of sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379g, 379h], 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.

“(2) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under paragraph (1), 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.

“(b) PERFORMANCE REPORT.—Beginning with fiscal year 2003, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the President, 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 502(4) [section 502(4) of Pub. L. 107-188, set out below] during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

“(c) FISCAL REPORT.—Beginning with fiscal year 2003, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (b), the Secretary of Health and Human Services 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.”

CONGRESSIONAL FINDINGS CONCERNING FEES RELATING TO DRUGS

Pub. L. 112-144, title I, §101(b), July 9, 2012, 126 Stat. 996, provided that: “The Congress finds that the fees authorized by the amendments made in this title [amending this section and sections 379h and 379h-2 of this title and repealing sections set out as notes under this section and section 379h-2 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. 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, provided that:

“(a) PERFORMANCE REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each

fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources 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(4) [section 101(4) of Pub. L. 105-115, set out above] during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

“(b) FISCAL REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources 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.”

Pub. L. 102-571, title I, §104, Oct. 29, 1992, 106 Stat. 4498, provided that:

“(a) FIRST REPORT.—Within 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration’s progress in achieving the goals identified in section 102(3) of this Act [set out as a note above] during such fiscal year and that agency’s future plans for meeting such goals.

“(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit 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 for which the report is made.

“(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.”

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 2013, 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)(4) of this section for a human drug ap-

plication 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)(4) 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