(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 premarket 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 ap-

plication 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 withdrawn 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 fis-

cal 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 Federal 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 pro-

posal 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 application 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 pub-