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, provided that:

''(a) PUBLIC ACCOUNTABILITY.—

''(1) CONSULTATION.—In developing recommendations to Congress for the goals and plans for meeting the goals for the process for the review of animal drug applications for the fiscal years after fiscal year 2008, and for the reauthorization of sections 739 and 740 of the Federal Food, Drug, and Cosmetic Act (as added by section 3) [21 U.S.C. 379j–11, 379j–12], 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, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry.

''(2) RECOMMENDATIONS.—The Secretary shall—

''(A) publish in the Federal Register recommendations under paragraph (1), after negotiations with the regulated industry;

''(B) present the recommendations to the Committees referred to in that paragraph;

''(C) hold a meeting at which the public may comment on the recommendations; and

''(D) provide for a period of 30 days for the public to provide written comments on the recommendations.

''(b) PERFORMANCE REPORTS.—Beginning with fiscal year 2004, not later than 60 days after the end of each fiscal year during which fees are collected 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.], 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 2(3) of this Act [set out as a note above] 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.

''(c) FISCAL REPORT.—Beginning with fiscal year 2004, 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 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.''

§ 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 (c) for an animal drug application, except an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title.

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

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

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

(B) Payment

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

(C) Exception for previously filed application or supplement

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

(D) Refund of fee if application refused for filing

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

(E) Refund of fee if application withdrawn

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

(A) In general

Each person—

(i) 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

(ii) 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 (c).

(B) Payment; fee due date

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 due each subsequent fiscal year that the product remains listed, upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) Limitation

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

(A) In general

Each person—

(i) who owns or operates, directly or through an affiliate, an animal drug establishment;

(ii) 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

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

shall be assessed an annual establishment fee as established in subsection (c) 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.

(B) Payment; fee due date

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 under this paragraph for a fiscal year shall be due upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) Limitation

(i) In general

An establishment shall be assessed only one fee per fiscal year under this section, subject to clause (ii).

(ii) Certain manufacturers

If 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

(A) In general

Each person—

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

(ii) 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 sponsor fee as established under subsection (c).

(B) Payment; fee due date

The fee under this paragraph for a fiscal year shall be due upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) Limitation

Each animal drug sponsor shall pay only one such fee each fiscal year.

(b) Fee revenue amounts

(1) In general

Subject to subsections (c), (d), (f), and (g)—

(A) for fiscal year 2014, the fees required under subsection (a) shall be established to generate a total revenue amount of $23,600,000; and

(B) for each of fiscal years 2015 through 2018, the fees required under subsection (a) shall be established to generate a total revenue amount of $21,600,000.

(2) Types of fees

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

(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to animal drug applications and supplements);

(B) 27 percent shall be derived from fees under subsection (a)(2) (relating to animal drug products);

(C) 26 percent shall be derived from fees under subsection (a)(3) (relating to animal drug establishments); and

(D) 27 percent shall be derived from fees under subsection (a)(4) (relating to animal drug sponsors).

(c) Annual fee setting; adjustments

(1) 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) and the adjustments provided under this subsection.

(2) Inflation adjustment

For fiscal year 2015 and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

(A) one;

(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under this paragraph.

(3) Workload adjustment

For fiscal year 2015 and subsequent fiscal years, after the revenue amounts established in subsection (b) are adjusted for inflation in accordance with paragraph (2), the revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications. With respect to such adjustment—

(A) such 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;

(B) the Secretary shall publish in the Federal Register the fees resulting from such adjustment and the supporting methodologies; and

(C) under no circumstances shall such adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under paragraph (2).

(4) Final year adjustment

For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, 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 2019. 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 2018.

(5) 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 one or more fees assessed under subsection (a) 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) 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) 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) 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) 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) relating to the date fees are to be paid.

(g) Crediting and availability of fees

(1) In general

Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for 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) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

(ii) shall be available 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).

(C) Provision for early payments

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

(3) Authorization of appropriations

For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

(4) Offset of overcollections; recovery of collection shortfalls

(A) Offset of overcollections

If the sum of the cumulative amount of fees collected under this section for fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 (including any increased fee collections attributable to subparagraph (B)), exceeds the cumulative amount appropriated pursuant to paragraph (3) for the fiscal years 2014 through 2017, 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 2018.

(B) Recovery of collection shortfalls

(i) Fiscal year 2016

For fiscal year 2016, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2014 falls below the amount of fees authorized for fiscal year 2014 under paragraph (3).

(ii) Fiscal year 2017

For fiscal year 2017, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2015 falls below the amount of fees authorized for fiscal year 2015 under paragraph (3).

(iii) Fiscal year 2018

For fiscal year 2018, the amount of fees otherwise authorized to be collected under this section (including any reduction in the authorized amount under subparagraph (A)), shall be increased by the cumulative amount, if any, by which the amount collected under this section and appropriated for fiscal years 2016 and 2017 (including estimated collections for fiscal year 2017) falls below the cumulative amount of fees authorized under paragraph (3) for fiscal years 2016 and 2017.

(h) Collection of unpaid fees

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

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

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

(j) Construction

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of 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; Pub. L. 113–14, title I, §103, June 13, 2013, 127 Stat. 454.)

TERMINATION OF SECTION

For termination of section by section 107(a) of Pub. L. 113–14, see Termination Date note below.

AMENDMENTS

2013—Pub. L. 113–14 amended section generally. Prior to amendment, section related to authority to assess and use animal drug fees.

2008—Subsec. (a)(1)(A)(i). Pub. L. 110–316, §103(a)(1), 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''.

Subsec. (a)(1)(A)(ii). Pub. L. 110–316, §103(a)(2), 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).''

Subsec. (b)(1). Pub. L. 110–316, §103(b)(1), 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.''

Subsec. (b)(2). Pub. L. 110–316, § 103(b)(2), 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.''

Subsec. (b)(3). Pub. L. 110–316, § 103(b)(3), 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.''

Subsec. (b)(4). Pub. L. 110–316, § 103(b)(4), 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.''

Subsec. (c)(1). Pub. L. 110–316, § 103(c)(1)–(3), 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.

Subsec. (c)(2). Pub. L. 110–316, § 103(c)(2), (4), redesignated par. (3) as (2) and substituted ''2013'' for ''2008'' in two places and ''2014'' for ''2009''. Former par. (2) redesignated (1).

Subsec. (c)(3) to (5). Pub. L. 110–316, § 103(c)(2), redesignated pars. (4) and (5) as (3) and (4), respectively. Former par. (3) redesignated (2).

Subsec. (g)(3)(A) to (E). Pub. L. 110–316, § 103(d), 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;''.

Subsec. (g)(4). Pub. L. 110–316, § 103(e), 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.''

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–14 effective Oct. 1, 2013, see section 106 of Pub. L. 113–14, set out as a note under section 379j–11 of this title.

EFFECTIVE DATE 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, see section 107 of Pub. L. 110–316, set out as an Effective and Termination Dates of 2008 Amendment note under section 379j–11 of this title.

TERMINATION DATE

Pub. L. 113–14, title I, § 107(a), June 13, 2013, 127 Stat. 464, provided that: ''Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall cease to be effective October 1, 2018.''

§ 379j–13. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Animal Drug User Fee Amendments of 2013 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 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(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 2018, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

(B) the Committee on Energy and Commerce of the House of Representatives;

(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—