(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, 2017, 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; amended Pub. L. 112–144, title II, § 204, July 9, 2012, 126 Stat. 1006.)

TERMINATION OF SECTION

For termination of section by section 207(a) of Pub. L. 112–144, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 201(b) of the Medical Device User Fee Amendments of 2012, referred to in subsec. (a)(1)(A), (B), is section 201(b) of Pub. L. 112–144, which is set out as a note under section 379i of this title.

AMENDMENTS

2012—Subsec. (a)(1). Pub. L. 112–144, § 204(b)(1), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: ''For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.''

Subsec. (a)(2). Pub. L. 112–144, § 204(b)(2), substituted ''2013 through 2017'' for ''2008 through 2012''.

Subsec. (b)(1). Pub. L. 112–144, § 204(a)(1), substituted ''2017'' for ''2012''.

Subsec. (b)(5). Pub. L. 112–144, § 204(a)(2), substituted ''2017'' for ''2012''.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2012, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Jan. 31, 2018, see section 207(a) of Pub. L. 112–144, set out as a note under section 379i of this title.

Section effective Oct. 1, 2007, except for certain premarket fees under this subpart, see section 216 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379i of this title.

SUBPART 4—FEES RELATING TO ANIMAL DRUGS

§ 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 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; Pub. L. 113–14, title I, §102, June 13, 2013, 127 Stat. 452.)

AMENDMENTS

2013—Pub. L. 113–14 amended section generally. Prior to amendment, section consisted of pars. (1) to (12) defining similar terms for this subpart.

2008—Par. (6). Pub. L. 110–316, §102(1), 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''.

Par. (8)(H). Pub. L. 110–316, §102(2), substituted ''but not after such application has been approved'' for ''but not such activities after an animal drug has been approved''.

Par. (10). Pub. L. 110–316, §102(3), substituted ''month being October 2002'' for ''year being 2003''.

Pars. (11), (12). Pub. L. 110–316, §102(4), (5), added par. (11) and redesignated former par. (11) as (12).

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 DATE OF 2013 AMENDMENT

Pub. L. 113–14, title I, §106, June 13, 2013, 127 Stat. 464, provided that: ''The amendments made by this title [amending this section and sections 379j–12 and 379j–13 of this title and repealing provisions set out as notes under this section] shall take effect on October 1, 2013, or the date of enactment of this Act [June 13, 2013], whichever is later, except that 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 October 1, 2013, regardless of the date of the enactment of this Act.''

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, which provided that the amendments made by sections 102 and 103 of Pub. L. 110–316 (amending this section and section 379j–12 of this title) would cease to be effective Oct. 1, 2013, and that the amendment made by section 104 of Pub. L. 110–316 (enacting section 379j–13 of this title) would cease to be effective Jan. 31, 2014, was repealed by Pub. L. 113–14, title I, §107(c)(1), June 13, 2013, 127 Stat. 464.

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, which provided that the amendments made by section 3 of Pub. L. 108–130 (enacting this subpart) would not be in effect after Oct. 1, 2008, and that section 4 of Pub. L. 108–130 (enacting provisions set out as a note below) would not be in effect after 120 days after Oct. 1, 2008, was repealed by Pub. L. 113–14, title I, §107(d), June 13, 2013, 127 Stat. 464.

[Pub. L. 113–14, title I, §107(d), June 13, 2013, 127 Stat. 464, provided that the repeal of section 5 of Pub. L. 108–130, formerly set out above, is effective Nov. 18, 2003.]

SAVINGS PROVISIONS

Pub. L. 113–14, title I, §105, June 13, 2013, 127 Stat. 463, provided that: ''Notwithstanding the amendments made by this title [amending this section and sections 379j–12 and 379j–13 of this title and repealing provisions set out as notes under this section], 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 [June 13, 2013], 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 October 1, 2008, but before October 1, 2013, 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 2014.''

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] ([former] 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. 113–14, title I, §101(b), June 13, 2013, 127 Stat. 451, provided that: ''Congress finds that the fees authorized by the amendments made in this title [amending this section and sections 379j–12 and 379j–13 of this title and repealing provisions set out as notes under this section] 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. 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, 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