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—

(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, 2018, the Secretary shall transmit to Congress the revised recommendations under paragraph (4)[1] a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) Minutes of negotiation meetings

(A) Public availability

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

(B) Content

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

(June 25, 1938, ch. 675, §740A, as added Pub. L. 110–316, title I, §104, Aug. 14, 2008, 122 Stat. 3511; amended Pub. L. 113–14, title I, §104, June 13, 2013, 127 Stat. 462.)

TERMINATION OF SECTION

For termination of section by section 107(b) of Pub. L. 113–14, see Effective and Termination Dates note below.

[1] So in original. Probably should be followed by a comma.

REFERENCES IN TEXT

Section 101(b) of the Animal Drug User Fee Amendments of 2013, referred to in subsec. (a), is section 101(b) of Pub. L. 113–14, which is set out as a note under section 379j–11 of this title.

AMENDMENTS

2013—Pub. L. 113–14 amended section generally. Prior to amendment, section related to reauthorization of this subpart and reporting requirements.

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 AND TERMINATION DATES

Pub. L. 113–14, title I, §107(b), June 13, 2013, 127 Stat. 464, provided that: ''Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) shall cease to be effective January 31, 2019.''

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, 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.

SUBPART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

TERMINATION OF SUBPART

For termination of subpart by section 206(a), (b) of Pub. L. 113–14, 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 (c) for such an application.

(B) Payment

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

(C) Exceptions

(i) 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).

(ii) Certain abbreviated applications involving combination animal drugs

An abbreviated application which is subject to the criteria in section 360b(d)(4) of