TERMINATION OF SECTION

For termination of section by section 206(a) of Pub. L. 113–14, see Termination Date note below.

PRIOR PROVISIONS

A prior section 741 of act June 25, 1938, was renumbered section 745 and is classified to section 379k of this title.

AMENDMENTS

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

EFFECTIVE DATE OF 2013 AMENDMENT

Pub. L. 113–14, title II, §205, June 13, 2013, 127 Stat. 474, provided that: ''The amendments made by this title [amending this section and section 379j–22 of this title and repealing provisions set out as notes under this section and section 379j–22 of this title] 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 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–21 et seq.], as amended by this title, shall be assessed for all abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2013, regardless of the date of enactment of this Act.''

TERMINATION DATE

Pub. L. 113–14, title II, §206(a), June 13, 2013, 127 Stat. 474, provided that: ''Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall cease to be effective October 1, 2018.''

Pub. L. 110–316, title II, §204(a), Aug. 14, 2008, 122 Stat. 3524, which provided that the amendments made by section 202 of Pub. L. 110–316 (enacting this section and amending sections 379k, 379*l*, and 379*o* of this title) would cease to be effective Oct. 1, 2013, was repealed by Pub. L. 113–14, title II, §206(c)(1), June 13, 2013, 127 Stat. 474.

SAVINGS PROVISIONS

Pub. L. 113–14, title II, §204, June 13, 2013, 127 Stat. 474, provided that: ''Notwithstanding the amendments made by this title [amending this section and section 379j–22 of this title and repealing provisions set out as notes under this section and section 379j–22 of this title], part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–21 et seq.], as in effect on the day before the date of enactment of this title [June 13, 2013], shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (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.''

FINDINGS

Pub. L. 113–14, title II, §201(b), June 13, 2013, 127 Stat. 464, provided that: ''The fees authorized by this title [see Short Title of 2013 Amendment note set out under section 301 of this title] will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified 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 II, §201(b), Aug. 14, 2008, 122 Stat. 3515, provided that: ''Congress finds as follows:

''(1) Prompt approval of abbreviated applications for safe and effective generic new animal drugs will reduce animal healthcare costs and promote the well-being 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 the review of abbreviated applications for the approval of generic new animal drugs.

''(3) The fees authorized by this title [see Short Title of 2008 Amendment note set out under section 301 of this title] will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified 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.''

§ 379j–22. Reauthorization; reporting requirements

(a) Performance reports

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 201(b) of the Animal Generic Drug User Fee Amendments of 2013 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

(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 Committee[1] 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.

[1] So in original. Probably should be preceded by ''the''.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs 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 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, 2018, 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 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, § 742, as added Pub. L. 110–316, title II, § 203, Aug. 14, 2008, 122 Stat. 3522; amended Pub. L. 113–14, title II, § 203, June 13, 2013, 127 Stat. 472.)

TERMINATION OF SECTION

For termination of section by section 206(b) of Pub. L. 113–14, see Termination Date note below.

REFERENCES IN TEXT

Section 201(b) of the Animal Generic Drug User Fee Amendments of 2013, referred to in subsec. (a), is section 201(b) of Pub. L. 113–14, which is set out as a note under section 379j–21 of this title.

PRIOR PROVISIONS

A prior section 742 of act June 25, 1938, was renumbered section 746 and is classified to section 379*l* 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 205 of Pub. L. 113–14, set out as a note under section 379j–21 of this title.

TERMINATION DATE

Pub. L. 113–14, title II, § 206(b), June 13, 2013, 127 Stat. 474, provided that: ''Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) shall cease to be effective January 31, 2019.''

Pub. L. 110–316, title II, § 204(b), Aug. 14, 2008, 122 Stat. 3524, which provided that the amendment made by section 203 of Pub. L. 110–316 (enacting this section) would cease to be effective Jan. 31, 2014, was repealed by Pub. L. 113–14, title II, § 206(c)(1), June 13, 2013, 127 Stat. 474.

SUBPART 6—FEES RELATED TO FOOD

§ 379j–31. Authority to collect and use fees

(a) In general

(1) Purpose and authority

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—