son shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(n) Substantially complete applications

An abbreviated new drug application that is not considered to be received within the meaning of section 355(j)(5)(A) of this title because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been ''substantially complete'' on the date of its submission within the meaning of section 355(j)(5)(B)(iv)(II)(cc) of this title. An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 355(j)(5)(A) of this title as of the date such applicable fee is received.

(June 25, 1938, ch. 675, §744B, as added Pub. L. 112–144, title III, §302, July 9, 2012, 126 Stat. 1011; amended Pub. L. 112–193, §2(b)(2), (3), Oct. 5, 2012, 126 Stat. 1443.)

TERMINATION OF SECTION

For termination of section by section 304(a) of Pub. L. 112–144, see Effective and Termination Dates note below.

AMENDMENTS

2012—Subsec. (a). Pub. L. 112–193, §2(b)(2), inserted ''for such year'' after ''obligation of fees'' wherever appearing.

Subsec. (i)(2)(C). Pub. L. 112–193, §2(b)(3), inserted comma after ''September 30, 2013'' and struck out comma after ''for fiscal year 2013''.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2017, see section 304(a) of Pub. L. 112–144, set out as a note under section 379j–41 of this title.

Section effective Oct. 1, 2012, with fees under this section and section 379j–41 of this title to be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after Oct. 1, 2012, see section 305 of Pub. L. 112–144, set out as a note under section 379j–41 of this title.

FEES AUTHORIZED FOR FISCAL YEAR 2013

Pub. L. 112–193, §2(c), Oct. 5, 2012, 126 Stat. 1443, provided that:

''(1) Notwithstanding section 744B(a)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)(2)(E)(ii)), the fee authorized under section 744B(a)(2) of such Act for fiscal year 2013 shall be due 30 calendar days after publication of the notice provided for in section 744B(a)(2)(C)(i) of such Act.

''(2) Notwithstanding section 744B(a)(3)(C)(ii) of such Act, the fee authorized under section 744B(a)(3) of such Act for fiscal year 2013 shall be due on the later of—

''(A) the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies; or

''(B) 30 calendar days after publication of the notice referred to in section 744B(a)(3)(B)(i) of such Act.

''(3) Notwithstanding section 744B(a)(4)(D)(i) of such Act, the fee authorized under section 744B(a)(4) of such Act for fiscal year 2013 shall be due not later than 45 days after the publication of the notice under section 744B(a)(4)(C)(i) of such Act.''

§ 379j–43. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for 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 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) Fiscal report

Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for 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 for such fiscal year.

(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 human generic drug activities for the first 5 fiscal years after fiscal year 2017, 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) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the generic drug industry.

(2) Prior public input

Prior to beginning negotiations with the generic drug 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 month during negotiations with the generic drug 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 generic drug 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 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 generic drug 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, § 744C, as added Pub. L. 112–144, title III, § 303, July 9, 2012, 126 Stat. 1022.)

TERMINATION OF SECTION

For termination of section by section 304(b) of Pub. L. 112–144, see Effective and Termination Dates note set out below.

REFERENCES IN TEXT

Section 301(b) of the Generic Drug User Fee Amendments of 2012, referred to in subsec. (a), is section 301(b) of Pub. L. 112–144, which is set out as a note under section 379j–41 of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 112–144, title III, § 304(b), July 9, 2012, 126 Stat. 1024, provided that: ''Section 744C of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–43], as added by section 303 of this Act, shall cease to be effective January 31, 2018.''

Section effective Oct. 1, 2012, see section 305 of Pub. L. 112–144, set out as a note under section 379j–41 of this title.

SUBPART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

§ 379j–51. Definitions

For purposes of this subpart:

(1) The term ''adjustment factor'' applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

(2) The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) The term ''biosimilar biological product'' means a product for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term ''biosimilar biological product application'' means an application for licensure of a biological product under section 262(k) of title 42.

(B) Such term does not include—

(i) a supplement to such an application;

(ii) an application filed under section 262(k) of title 42 that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

(iii) an application filed under section 262(k) of title 42 with respect to—

(I) whole blood or a blood component for transfusion;

(II) an allergenic extract product;

(III) an in vitro diagnostic biological product; or

(IV) a biological product for further manufacturing use only; or

(iv) an application for licensure under section 262(k) of title 42 that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

(5) The term ''biosimilar biological product development meeting'' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

(6) The term ''biosimilar biological product development program'' means the program under this subpart for expediting the process for the review of submissions in connection with biosimilar biological product development.