(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.

(7)(A) The term ''biosimilar biological product establishment'' means a foreign or domestic place of business—

(i) that is at one general physical location consisting of one or more buildings, all of which are within 5 miles of each other; and

(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

(B) For purposes of subparagraph (A)(ii), the term ''manufactured'' does not include packaging.

(8) The term ''biosimilar initial advisory meeting''—

(A) means a meeting, if requested, that is limited to—

(i) a general discussion regarding whether licensure under section 262(k) of title 42 may be feasible for a particular product; and

(ii) if so, general advice on the expected content of the development program; and

(B) does not include any meeting that involves substantive review of summary data or full study reports.

(9) The term ''costs of resources allocated for the process for the review of biosimilar biological product applications'' means the expenses in connection with the process for the review of biosimilar biological product applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers employees and committees and to contracts with such contractors;

(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–52 of this title and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(10) The term ''final dosage form'' means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

(11) The term ''financial hold''—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 379j–52(a)(1) of this title; and

(B) does not mean that any of the bases for a ''clinical hold'' under section 355(i)(3) of this title have been determined by the Secretary to exist concerning the investigation.

(12) The term ''person'' includes an affiliate of such person.

(13) The term ''process for the review of biosimilar biological product applications'' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 262(k) of title 42.

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 355(*o*) of this title (relating to postapproval studies and clinical trials and labeling changes) and section 355(p) of this title (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 355(k)(5) of this title (relating to adverse-event reports and postmarket safety activities).

(14) The term ''supplement'' means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 262(k)(4) of title 42.

(June 25, 1938, ch. 675, §744G, as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1026.)

TERMINATION OF SECTION

*For termination of section by section 404(a) of Pub. L. 112–144, see Effective and Termination Dates note set out below.*

EFFECTIVE AND TERMINATION DATES

Pub. L. 112–144, title IV, § 404(a), July 9, 2012, 126 Stat. 1038, provided that: ''Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–51, 379j–52], as added by section 402 of this Act, shall cease to be effective October 1, 2017.''

Pub. L. 112–144, title IV, § 405, July 9, 2012, 126 Stat. 1039, provided that:

''(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by this title [enacting this section and sections 379j–52 and 379j–53 of this title and amending sections 379d–4 and 379g of this title] shall take effect on the later of—

''(1) October 1, 2012; or

''(2) the date of the enactment of this title [July 9, 2012].

''(b) EXCEPTION.—Fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as added by this title, shall be assessed for all biosimilar biological product applications received on or after October 1, 2012, regardless of the date of the enactment of this title.''

FINDING

Pub. L. 112–144, title IV, § 401(b), July 9, 2012, 126 Stat. 1026, provided that: ''The Congress finds that the fees authorized by the amendments made in this title [enacting this section and sections 379j–52 and 379j–53 of this title and amending sections 379d–4 and 379g of this title] will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 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 Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.''

### § 379j–52. Authority to assess and use biosimilar biological product fees

#### (a) Types of fees

Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

**(1) Biosimilar development program fees**

**(A) Initial biosimilar biological product development fee**

**(i) In general**

Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

**(ii) Meeting request**

The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

**(iii) Clinical protocol for IND**

A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 355(i) of this title, including any regulations promulgated under section 355(i) of this title, (referred to in this section as ''investigational new drug application'') describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

**(iv) Due date**

The initial biosimilar biological product development fee shall be due by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

**(v) Transition rule**

Each person that has submitted an investigational new drug application prior to July 9, 2012, shall pay the initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after July 9, 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

**(B) Annual biosimilar biological product development fee**

**(i) In general**

A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as ''annual biosimilar biological product development fee'').

**(ii) Due date**

The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

(I) the first business day on or after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

**(iii) Exception**

The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

(I) submitted a marketing application for the biological product that was accepted for filing; or