Draft Legislation for Biosimilars User Fees

SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.--This title may be cited as the "Biosimilars User Fee Act of 2012".

(b) REFERENCES IN ACT.--Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.--The Congress finds that the fees authorized by the amendments made in this Act will be dedicated toward 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 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, 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.

SEC. 102. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Chapter VII is amended by adding at the end of subchapter C the following:

"PART 7--FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

"SEC. 744A. DEFINITIONS.

"For purposes of this part:

"(1) (A) Subject to subparagraph (B), the term "biosimilar biological product application" means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

"(B) Such term does not include---

"(i) a supplement to such an application;

"(ii) an application filed under section 351(k) of the Public Health Service Act 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 351(k) of the Public Health Service Act 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.

"(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

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

"(3) 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 351(k)(4) of the Public Health Service Act.

"(4) 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).

"(5) The term "biosimilar biological product 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 five miles of each other and at which one or more biosimilar biological products are manufactured in final dosage form. For purposes of this paragraph, the term "manufactured" does not include packaging.

"(6) 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 351(k) of the Public Health Service Act.

"(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 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).

"(7) 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 744B and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development,

biosimilar biological product applications, and supplements.

"(8) The term "adjustment factor" applicable to a fiscal year 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.

"(9) The term "person" includes an affiliate thereof.

"(10) 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.

"(11) The term "biosimilar initial advisory meeting" means a meeting, if requested, that is limited to a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. Such term does not include any meeting that involves substantive review of summary data or full study reports.

"(12) 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.

"(13) The term "financial hold" 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 section 744B(a)(1)(A), (B), or (D). "Financial hold" does not mean that any of the bases for "clinical hold" identified in section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

"SEC. 744B. 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) Each person that submits to the Secretary--

"(I) a request for a biosimilar biological product development meeting for a product; or

"(II) a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i) (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,

shall pay for the product named in the meeting request or the investigational new drug application the initial fee established under subsection (c)(1)(A) for biosimilar biological product development (referred to in this section as "initial biosimilar biological product development fee").

"(ii) The initial biosimilar biological product development fee shall be due:

"(I) within 5 days after the Secretary grants a request for a biosimilar biological product development meeting; or

"(II) upon 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;

whichever is earlier.

"(iii) Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee:

"(I) within 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012 if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application; or

"(II) within 5 days after the Secretary grants a request for a biosimilar biological product development meeting;

whichever is earlier.

"(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—(i) A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the next fiscal year, an annual fee established under subsection (c)(1)(B) for biosimilar biological product development (referred to in this section as "annual biosimilar biological product development fee"). 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

"(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

"(ii) The date specified in this clause with respect to each fiscal year is the later of—

"(I) the first business day 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.

"(C) DISCONTINUATION OF FEE OBLIGATION.-- A person may discontinue participation in the biosimilar biological product development program for a product as of October 1 of the next fiscal year by notifying the Secretary on or before August 1. If no investigational new drug application concerning the product has been submitted, a person may effectuate such discontinuation only after submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product. If an investigational new drug application concerning the product has been submitted, a person may effectuate such discontinuation only after withdrawing the investigational new drug application as specified in Part 312 of Title 21 of the Code of Federal Regulations (or any successor regulation).

"(D) REACTIVATION FEE.--A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) must pay a fee (referred to in this section as "reactivation fee"):

"(i) within 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product; or

"(ii) upon 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 for that product;

whichever is earlier. The reactivation fee shall be equal to twice the amount of the initial biosimilar biological product development fee for that fiscal year. A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

"(E) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.--

"(i) No biosimilar biological product development meetings.--If a person has failed to pay initial or annual biosimilar biological product development fees as required under subparagraph (A) or (B), or reactivation fees as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

"(ii) No receipt of investigational new drug applications.--Except in extraordinary circumstances, the Secretary will not consider an investigational new drug application to have been received under section 505(i)(2) if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay initial or annual biosimilar biological product development

fees for the product as required under subparagraph (A) or (B), or reactivation fees as required under subparagraph (D).

"(iii) Financial hold.--Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary will prohibit the sponsor of a clinical investigation from continuing the investigation (referred to in this paragraph as "financial hold") if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay initial or annual biosimilar biological product development fees for the product as required under subparagraph (A) or (B), or reactivation fees as required under subparagraph (D).

"(iv) No acceptance of biosimilar biological product applications or supplements.--If a person has failed to pay initial or annual biosimilar biological product development fees as required under subparagraph (A) or (B), or reactivation fees as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

"(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.--

"(i) No refunds.--Initial or annual biosimilar biological product development fees paid under subparagraph (A) or (B), or reactivation fees paid under subparagraph (D), shall not be refunded.

"(ii) No waivers, exemptions, or reductions.--The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fees due or payable under subparagraph (A) or (B), or reactivation fees due or payable under subparagraph (D).

"(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION AND SUPPLEMENT FEE.--

"(A) IN GENERAL.--Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to a fee as follows:

"(i) A fee for a biosimilar biological product application that is equal to--

"(I) the amount of the fee established under subsection (c)(1)(C) for a biosimilar biological product application; minus

"(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

"(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to--

"(I) half of the amount of the fee established under subsection (c)(1)(C) for a biosimilar biological product application; minus

"(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

"(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (c)(1)(C) for a biosimilar biological product application.

"(iv) Notwithstanding section 104 of the Biosimilars User Fee Act of 2012, any person who pays a biosimilar development program fee before October 1, 2017, but submits a biosimilar biological product application after such date, shall be entitled to the reduction in any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

"(B) PAYMENT DUE DATE.--The fee required by subparagraph (A) shall be due upon submission of the application or supplement.

"(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.--If a biosimilar biological product application or supplement 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), the submission of a biosimilar biological product application or a supplement 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 APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.--The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

"(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.--A biosimilar biological product application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (d).

"(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.--

"(A) IN GENERAL.—

"(i) Except as provided in subparagraph (B), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (c)(1)(D) for each biosimilar biological product establishment listed in its approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in the application.

"(ii) The annual establishment fee shall be assessed in each fiscal year in which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during the fiscal year.

"(iii) The establishment fee for each fiscal year shall be due on the later of—

"(I) the first business day 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.

"(iv)(I) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to subclause (II).

"(II) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

"(B) EXCEPTION.--If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

"(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

"(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun;

the applicant will not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

"(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—(A) Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (c)(1)(E). Such fee shall be due each fiscal year on the date specified in subparagraph (B). Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

"(B) The date specified in this subparagraph with respect to each fiscal year is the later of—

"(i) the first business day 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.

"(b) FEE AMOUNTS--Except as provided in subsection (d), the fees under subsection (a) shall be based on the following fee amounts:

"(1) The initial biosimilar biological product development fee for a fiscal year shall be equal to 10% of the amount established under section 736(c)(5) for a human drug application for that fiscal year.

"(2) The annual biosimilar biological product development fee for a fiscal year shall be equal to 10% of the amount established under section 736(c)(5) for a human drug application for that fiscal year.

"(3) The biosimilar biological product application fee for a fiscal year shall be equal to the amount established under section 736(c)(5) for a human drug application for that fiscal year.

"(4) The biosimilar biological product establishment fee for a fiscal year shall be equal to the amount established under section 736(c)(5) for a prescription drug establishment for that fiscal year.

"(5) The biosimilar biological product fee for a fiscal year shall be equal to the amount established under section 736(c)(5) for a prescription drug product for that fiscal year.

"(c) ANNUAL FEE SETTING.--

"(1) The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the--

"(A) initial biosimilar biological product development fee;

"(B) annual biosimilar biological product development fee;

"(C) biosimilar biological product application fee;

"(D) biosimilar biological product establishment fee; and

"(E) biosimilar biological product fee.

"(2) Limit**.--**The total amount of fees charged for a fiscal year may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

"(d) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

"(1) Waiver of application fee.--The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

"(A) application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

"(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

"(2) CONSIDERATIONS.--In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

"(3) "SMALL BUSINESS" DEFINED.--In paragraph (1), the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application as defined in section 735 or a biosimilar biological product application as defined in section 744A and introduced or delivered for introduction into interstate commerce.

"(e) EFFECT OF FAILURE TO PAY FEES.--A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

"(f) CREDITING AND AVAILABILITY OF FEES.

(1) IN GENERAL. Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, subject to subparagraphs (C) and (D).

"(B) LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

"(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this

section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

"(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

"(3) AUTHORIZATION OF APPROPRIATIONS. For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

"(g) COLLECTION OF UNPAID FEES.--In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

"(h) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.--To qualify for consideration for a waiver under subsection (d), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

"(i) CONSTRUCTION.--This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.".

SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as amended by section 102, is further amended by inserting after section 744B the following:

"SEC. 744C. 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 part, 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 101(c) of the Biosimilars User Fee Act of 2012 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 biosimilar biological product applications and supplements in the cohort.

"(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 part, 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) STUDY.-- The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications. The Secretary shall publish interim results of the study by June 1, 2015. The Secretary shall publish the final results of the study by the end of fiscal year 2016. The reports will be published for public comment.

"(e) 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 biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part 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 regulated industry.

"(2) 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.

"(3) TRANSMITTAL OF RECOMMENDATIONS.--Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), 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.".

SEC. 104. SUNSET DATES.

(a) AUTHORIZATION.--The amendment made by section 102 shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.--The amendment made by section 103 shall cease to be effective January 31, 2018.

SEC. 105. EFFECTIVE DATE.

The amendments made by this Act shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act 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 Act.

SEC. 106. SAVINGS CLAUSE.

Notwithstanding section 106 of the Prescription Drug User Fee Amendments of 2007 (21 U.S.C. 379g note), and notwithstanding the amendments made by this Act, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2007, but before October 1, 2012, 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 2013.

SEC. 107. TECHNICAL AMENDMENT; CONFORMING AMENDMENT.

(a) Paragraph (1) of section 735 (21 USC § 379g) is amended in subparagraph (B) by striking “or (k).”