I

112TH CONGRESS
2D SESSION

H. R. 3988

To amend the Federal Food, Drug, and Cosmetic Act to establish user-fee programs for generic drugs and biosimilars.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2012

Mr. MURPHY of Pennsylvania (for himself, Mr. PALLONE, Mr. PITTS, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish user-fee programs for generic drugs and biosimilars.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

This Act may be cited as the ''Generic Drug and Biosimilar User Fee Act of 2012''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—FEES RELATING TO GENERIC DRUGS

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

(a) SHORT TITLE.—This title may be cited as the ''Generic Drug User Fee Amendments of 2012''.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this title 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) FINDINGS.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated, 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 Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Rep-

resentatives, as set forth in the Congressional Record. These fees are intended to help the Food and Drug Administration ensure that participants in the United States generic drug system comply with United States quality standards, and to increase the likelihood that American consumers have timely access to low-cost, high-quality generic drugs. A comprehensive human generic drug user fee program, to be supplemental to traditional appropriated funding, should be focused on three key aims:

(1) SAFETY.—Ensure that industry participants, foreign or domestic, who participate in the United States generic drug system are held to consistent high-quality standards and are inspected biennially, using a risk-based approach, with foreign and domestic parity.

(2) ACCESS.—Expedite the availability of low-cost, high-quality generic drugs by bringing greater predictability to the review times for abbreviated new drug applications, amendments, and supplements, increasing predictability and timeliness in the review process.

(3) TRANSPARENCY.—Enhance the Food and Drug Administration's ability to protect Americans in the complex global supply environment by requiring the identification of facilities involved in the

manufacture of generic drugs and associated active pharmaceutical ingredients, and improving the Food and Drug Administration's communications and feedback with industry in order to expedite product access.

SEC. 102. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 7—FEES RELATING TO GENERIC DRUGS

"SEC. 744A. DEFINITIONS.

''For purposes of this part:

''(1) The term 'abbreviated new drug application'—

''(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

''(B) does not include an application for a positron emission tomography drug.

''(2) The term 'active pharmaceutical ingredient' means—

''(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

''(i) to be used as a component of a drug; and

''(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

''(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

''(3) The term 'adjustment factor' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

''(4) 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.

''(5)(A) The term 'facility'—

''(i) means a business or other entity—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

''(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

''(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(6) The term 'finished dosage form' means—

''(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

''(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

''(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a

drug product described in subparagraph (A) or (B).

''(7) The term 'generic drug submission' means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

''(8) The term 'human generic drug activities' means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

''(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

''(B) The issuance of—

''(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

''(ii) complete response letters 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 issuance of letters related to Type II active pharmaceutical drug master files which—

"(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

"(ii) document that no deficiencies need to be addressed.

"(D) Inspections related to generic drugs.

"(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

"(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

"(i) Collecting, developing, and reviewing safety information on approved drugs, 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) insofar as those activities relate to abbreviated new drug applications.

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

''(G) Regulatory science activities related to generic drugs.

''(9) The term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

''(10) The term 'prior approval supplement' means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential

to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

''(11) The term 'resources allocated for human generic drug activities' means the expenses 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 and employees 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 subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

''(12) The term 'Type II active pharmaceutical ingredient drug master file' means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

"SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG 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) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

''(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

''(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog

fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

''(C) NOTICE.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

''(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

''(2) DRUG MASTER FILE FEE.—

''(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

''(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a

subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

''(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

''(D) AVAILABILITY FOR REFERENCE.—

''(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

''(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

''(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

''(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

''(iii) LIST.—The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

''(E) FEE DUE DATE.—

"(i) IN GENERAL.—Subject to clauses (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

"(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

"(I) 30 calendar days after publication of the notice provided for in clause (i) or (ii) of subparagraph (C), as applicable; or

"(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section

"(3) ABBREVIATED NEW DRUG APPLICATION AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

"(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application or a prior approval supplement to an abbreviated new drug application shall be subject to a fee for each such sub-

mission in the amount established under subsection (d).

''(B) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(C) FEE DUE DATE.—

''(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

''(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

''(I) the date on which the fee is due under clause (i);

''(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

''(III) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

''(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received with-

in the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.

''(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval supplement that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

''(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, in the amount determined under subsection (d)(3), in addition to the fee required under subparagraph (A), if—

''(i) such submission contains information concerning the manufacture of an

active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

"(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

"(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

"(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

"(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

"(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission, shall be assessed an annual fee for each such facility.

"(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject to fees under both such clauses for that facility.

''(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall cause to be published in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(D) FEE DUE DATE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

''(I) not later than 45 days after the publication of the notice under subparagraph (B); or

''(II) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall 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 under this section for such year.

''(5) DATE OF SUBMISSION.—For purposes of this part, a generic drug submission or Type II pharmaceutical master file is deemed to be 'submitted' to the Food and Drug Administration when it arrives in the appropriate electronic portal of the Food and Drug Administration or, if in paper form,

at the appropriate designated document room of the Food and Drug Administration.

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—

''(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of $299,000,000. Of that amount—

''(i) $50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

''(ii) $249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).

''(B) FISCAL YEARS 2014 THROUGH 2017.—For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $299,000,000, as adjusted pursuant to subsection (c).

''(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue

amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from the fees under paragraphs (2) through (4) of subsection (a) as follows:

"(A) 6 percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

"(B) 24 percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

"(C) 56 percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located

in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

"(D) 14 percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

"(c) ADJUSTMENTS.—

"(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Reg-

ister, for a fiscal year, by an amount equal to the sum of—

"(A) one;

"(B) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

"(C) the average annual change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to

the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

''(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2018. Such fees may only be used in fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

''(d) ANNUAL FEE SETTING.—

''(1) FISCAL YEAR 2013.—For fiscal year 2013—

''(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the ab-

breviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

''(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

''(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

''(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the

fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

"(A) the sum of—

"(i) the total number of such active pharmaceutical ingredients in such submission; and

"(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

"(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

"(e) LIMIT.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

"(f) IDENTIFICATION OF FACILITIES.—

"(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall cause to be published in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph

(4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.

''(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (4) shall submit to the Secretary the information required under this subsection each year. Such information shall—

''(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

''(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of such year.

''(3) CONTENTS OF NOTICE.—At a minimum, the submission required by paragraph (2) shall include for each such facility—

''(A) identification of a facility identified or intended to be identified in an approved or pending generic drug submission;

"(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

"(C) whether or not the facility is located within the United States and its territories and possessions;

"(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; and

"(E) whether the facility manufactures drugs that are not generic drugs.

"(4) CERTAIN SITES AND ORGANIZATIONS.—

"(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

"(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

"(i) a site in which a bioanalytical study is conducted;

"(ii) a clinical research organization;

"(iii) a contract analytical testing site; or

"(iv) a contract repackager site.

"(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

"(D) INSPECTION AUTHORITY.—The Secretary's inspectional authority under section 704(a)(1) shall extend to all such sites and organizations.

"(g) EFFECT OF FAILURE TO PAY FEES.—

"(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on an arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(2) DRUG MASTER FILE FEE.—

''(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

''(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

''(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

"(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

"(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

"(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received

within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

''(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the

facility to pay the facility fee under subsection (a)(4)(C).

''(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

''(C) NONRECEIVAL FOR NONPAYMENT.—

''(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

''(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of

the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

''(h) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for Type II active pharmaceutical ingredient drug master files, abbreviated

new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(i) 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 human generic drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) subject to subparagraphs (C) and (D), 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; and

''(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (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 activities), 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 $97,000,000 multiplied by the adjustment factor defined in subsection (p)(3) applicable to the fiscal year involved.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

"(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 the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

''(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar 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, United States Code.

''(k) 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, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

''(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such

drugs are required to be identified pursuant to subsection (f).

''(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person 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 505(j)(5)(A) 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 505(j)(5)(B)(iv)(II)(cc). 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 505(j)(5)(A) as of the date such applicable fee is received.''.

SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as added by section 102 of this Act, is 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 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 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) 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 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 generic drug industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, 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 part; 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 part 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 public 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.''.

SEC. 104. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by section 102 cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendments made by section 103 cease to be effective January 31, 2018.

SEC. 105. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this title, whichever is later, except that fees under section 102 shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after October 1, 2012, regardless of the date of enactment of this title.

SEC. 106. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744A(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.''.

SEC. 107. ELECTRONIC SUBMISSION OF APPLICATIONS.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 745 the following:

''SEC. 745A. ELECTRONIC SUBMISSION OF APPLICATIONS:.

''(a) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under section 505(j) shall be submitted in such electronic format as specified by the Secretary in such guidance.

''(b) GUIDANCE CONTENTS.—In such guidance, the Secretary may provide a timetable for establishment by the Secretary of further standards for such electronic submission, and set forth criteria for waivers of and exemptions from the requirements of this section.

''(c) EXCEPTION.—This section shall not apply to submissions described in section 561.''.

SEC. 108. STREAMLINED HIRING AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

''SEC. 714. STREAMLINED HIRING AUTHORITY.

''(a) IN GENERAL.—In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

''(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are activities under this Act related to human generic drug activities (as defined in section 744A).

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are the performance goals with re-

spect to section 744A (regarding assessment and use of human generic drug fees), as set forth in the letters described in section 101(c) of the Generic Drug User Fee Amendments of 2012.

''(d) INTERNAL CONTROLS.—The Secretary shall institute appropriate internal controls for appointments under this section.

''(e) SUNSET.—The authority to appoint employees under this section shall terminate on the date that is three years after the date of enactment of this section.''.

TITLE II—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Biosimilar User Fee Act of 2012''.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this title 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 title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safe-

ty 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, 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. 202. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by inserting after part 7, as added by title I of this Act, the following:

"PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

"SEC. 744G. DEFINITIONS.

''For purposes of this part:

''(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 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; or

''(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.

''(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 part for expediting the process for the review of sub-

missions 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 five 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 351(k) of the Public Health Service Act 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 744H and accounting for resources allocated for the review of submissions in connection with bio-

similar 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 744H(a)(1); and

''(B) does not mean that any of the bases for a 'clinical hold' under section 505(i)(3) 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 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).

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

"SEC. 744H. 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 defined 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 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.

''(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 the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

''(I) Not later than 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 de-

scribes 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

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

''(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

''(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

''(ii) if an investigational new drug application concerning the product has been submitted, by withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

''(D) REACTIVATION FEE.—

''(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as 're-activation fee') by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product develop-

ment meeting for the product (after the date on which such participation was discontinued).

''(II) Upon the date of submission (after the date on which such participation was discontinued) 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.

''(ii) APPLICATION OF ANNUAL FEE.—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 an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as re-

quired 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 shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

"(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

"(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

"(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical in-

vestigation from continuing the investigation if—

"(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

"(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

"(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee 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 such fees owed by such person have been paid.

''(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO REFUNDS.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

''(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 fee due or payable under subparagraph (A) or (B), or any reactivation fee 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 the following fees:

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

"(I) the amount of the fee established under subsection (b)(1)(D) 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 (b)(1)(D) 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 (b)(1)(D) for a biosimilar biological product application.

"(B) REDUCTION IN FEES.—Notwithstanding section 204 of the Biosimilars User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of 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.

"(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

"(D) 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).

"(E) 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.

"(F) 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 fil-

ing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (c).

''(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (E)(ii), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

''(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for 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 such fiscal year.

"(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

"(i) the first business day on or after October 1 of such fiscal year; or

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

"(D) APPLICATION TO ESTABLISHMENT.—

"(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 clause (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).

''(E) EXCEPTION FOR NEW PRODUCTS.—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 shall 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) IN GENERAL.—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 (b)(1)(F).

''(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall 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.

''(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

''(b) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to paragraph (2), 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 fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under

subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(5) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

"(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(5) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

"(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section 736(c)(5) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

"(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(5) for a

human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) 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.

''(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) 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.

''(2) LIMIT.—The total amount of fees charged for a fiscal year under this section 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.

''(c) 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 is not 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 is not 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 this subsection, the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug prod-

uct that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

''(d) 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.

''(e) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Subject to paragraph (2), 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. 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.—Subject to subparagraphs (C) and (D), 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.

''(B) USE OF FEES AND 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.

''(f) 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, United States Code.

''(g) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), 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.

''(h) 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. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 8 of subchapter C of chapter VII, as amended by section 202 of this Act, is further amended by inserting after section 744H the following:

''SEC. 744I. 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 201(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 such 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.—Not later than 120 days after the end of fiscal year 2013 and each subsequent 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.—

''(1) IN GENERAL.—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.

''(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

''(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

''(e) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), 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. 204. SUNSET DATES.

(a) AUTHORIZATION.—The amendment made by section 202 shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendment made by section 203 shall cease to be effective January 31, 2018.

SEC. 205. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by this title shall take effect on the later of—

(1) October 1, 2012; or

(2) the date of the enactment of this title.

(b) EXCEPTION.—Fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, 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.

SEC. 206. 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 title, 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 title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2007, but before October 1, 2012, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 207. TECHNICAL AMENDMENT; CONFORMING AMENDMENT.

Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amended by striking ''or (k)''.

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