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

(a) **Short Title.—**This Act may be cited as the ‘‘Generic Drug User Fee Amendments 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) **Findings.—**The Congress finds that the fees authorized by the amendments made in this Act 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 Representatives, as set forth in the Congressional Record. These fees are intended to help the Food and Drug Administration (FDA) ensure that participants in the United States generic drug system comply with United States quality standards, and to increase the likelihood that American consumers get 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:

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.

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.

Transparency – Enhance FDA’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 FDA’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 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et. seq) is amended by inserting after part 7 the following:

"PART 8 – FEES RELATING TO GENERIC DRUGS

"SEC. 744G. 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 established under subparagraph (B).

(B) **Method of Fee Amount Calculation; Notice --** The amount of each one time backlog fee shall be calculated by dividing $50 million by the total number of applicable abbreviated new drug applications pending on October 1, 2012 that have not received a tentative approval as of that date. By October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fee.

(C) **Fee Due Date --** The fee required by subparagraph (A) shall be paid no later than 30 calendar days from the publication of the notice specified in subparagraph (B).

(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 established under subsection (d). Once 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 referenced in additional generic drug submissions.

(B) **Method of Fee Amount Calculation; Notice** – The amount of the drug master file fee established in subparagraph (A) shall be calculated pursuant to subsection (d). For fiscal year 2013, by 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 each of fiscal years 2014 to 2017, the Secretary shall cause to be published in the Federal Register, 60 days before the start of each such fiscal year, the amount for the drug master file fee established by this paragraph for the coming fiscal year.

(C) **Availability for Reference** -- Starting 20 calendar days after the date that payment of fees for the Type II active pharmaceutical ingredient drug master file is first required as provided in subparagraph (D), 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. To be deemed available for reference:

(i) the person that owns a Type II active pharmaceutical ingredient drug master file must pay the fee required under subparagraph (A) as calculated under subsection (d); and

(ii) the drug master file must not have failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

The Secretary shall make available a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment and are available for reference.

(D) **Fee Due Date** –

(i) Starting 30 calendar days after publication of the notice provided for in subparagraph (B), or the date that is 30 calendar days after the date an appropriations Act provides for the collection and obligation of fees under this section, whichever is later, a drug master file fee shall be paid no later than upon submission of the first generic drug submission submitted on or after October 1, 2012, that references the associated Type II active pharmaceutical ingredient drug master file, subject to clause (ii).

(ii) If an appropriations Act providing for the collection and obligation of fees under this section is not enacted by October 1, 2012, the fee shall be due on the later of submission of---

(I) the first generic drug submission submitted after October 1, 2012, that references the associated Type II active pharmaceutical ingredient drug master file; or

(II) 30 calendar days after the date that such an appropriations Act is enacted.

(iii)(I) If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012 references a Type II active pharmaceutical ingredient drug master file for which a fee under subparagraph (A) is due that has not been paid, 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) as implemented in Food and Drug Administration regulations.

(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 submission as follows:

(i) A fee established under subsection (d) for an abbreviated new drug application.

(ii) A fee established under subsection (d) for a prior approval supplement to an abbreviated new drug application.

(B) **Method of Fee Amount Calculation; Notice** – The amount of the abbreviated new drug application filing fee and the prior approval supplement filing fee established in subparagraph (A) shall be calculated pursuant to subsection (d). 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) by October 31, 2012. For each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register, 60 days before the start of each such fiscal year, the amount of the fees established by this paragraph for the coming fiscal year.

(C) **Fee Due Date** – 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, except that, for fiscal year 2013, the fee shall be due on the later of---

(i) the date of submission of the abbreviated new drug application or prior approval supplement; or

(ii) 30 calendar days after publication of the notice referred to in subparagraph (B), 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.

(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 (C) 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 pursuant to section 505(j)(5)(A) as implemented in Food and Drug Administration regulations, 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 be subject to a new full fee under subparagraph (A) upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application.

(F) **Fee for Active Pharmaceutical Ingredient Information Not Included by Reference to Type II Active Pharmaceutical Ingredient Drug Master File.--**

(i) An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, as determined in clause (ii), in addition to the application fee required by 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.

(ii) The fee referred to in clause (i) shall be determined by—

(I) totaling the number of such active pharmaceutical ingredients;

(II) for each such ingredient that is manufactured at more than one such facility, totaling the number of such additional facilities;

(III) adding the totals determined in subclauses (I) and (II); and

(IV) multiplying the number determined pursuant to subclause (III) by the amount equal to the drug master file fee established in paragraph (2).

(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 shall be assessed an annual fee established under subsection (d) 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 established under subsection (d) 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 form subject to clause (i) and one or more active pharmaceutical ingredient subject to clause (ii) shall be subject to fees under both such clauses for that facility.

(B) **Method of Fee Calculation; Notice**—The fees established by subparagraph (A) shall be calculated as specified in subsection (d). 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). For each of fiscal years 2014 through 2017, the Secretary shall cause to be published in the Federal Register, with 60 days before the start of each such fiscal year, the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d) for the coming fiscal year.

(C) **Fee Due Date**—

(i) For fiscal year 2013, the fees required by subparagraph (A) shall be paid within 45 calendar days of the publication of the notice required in subparagraph (B) except that if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the notice required by subparagraph (B), the fee shall be due 30 calendar days after the date that such an appropriations Act is enacted.

(ii) For each of fiscal years 2014 through 2017, such fees 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.

(iii) 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 that is due has not been paid, 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, and if the facility 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) as implemented in Food and Drug Administration regulations.

(b) **Fee revenue amounts**

(1) **In general –** 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, $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) of such subsection. For each of the fiscal years 2014 through 2017, fees under paragraphs (2)-(4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to the sum of $299,000,000, as adjusted pursuant to subsection (c).

(2) **Types of fees --** Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) for fiscal year 2013, $50 million shall be derived from fees under subsection (a)(1) (relating to abbreviated new drug applications pending on October 1, 2012); and $249 million will be derived from fees divided as follows:

(i) 6% shall be derived from fees under subsection (a)(2) (relating to drug master files).

(ii) 24% 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.

(iii) 56 % shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug finished dosage form facilities). The amount of the fee for a facility located outside the United States, 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, 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, its territories and possessions, and those located outside of the United States, its territories and possessions.

(iv) 14% 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, 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, 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, its territories and possessions, and those located outside of the United States, its territories and possessions.

(B) for fiscal years 2014 through 2017, $299 million, as adjusted pursuant to subsection (c), shall be derived from fees divided as follows:

(i) 6 % shall be derived from fees under subsection (a)(2) (relating to drug master files).

(ii) 24 % 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.

(iii) 56 % 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, its territories and possessions shall be not less than $15,000 and not more than $30,000 (based on current available data) higher than the amount of the fee for a facility located in the United States, 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, its territories and possessions, and those located outside of the United States, its territories and possessions.

(iv) 14 % 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, its territories and possessions shall be not less than $15,000 and not more than $30,000 (based on current available data) higher than the amount of the fee for a facility located in the United States, 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, its territories and possessions, and those located outside of the United States, 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 Register, for a fiscal year to reflect the sum of one plus —

(A) 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

(B) 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 by this subsection will 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 process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

(d) **Annual fee setting**

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

(B) The Secretary shall establish, within 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(1), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

(2) For each of fiscal years 2014 through 2017, the Secretary shall, 60 days before the start of each such fiscal year, 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), based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

(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) By October 1, 2012, the Secretary shall cause to be published in the Federal Register a notice requiring each person that owns a facility as identified in subsection (a)(4)(A) or a site identified in subsection (f)(3) to identify each such facility or site. Each such person shall comply with that requirement within 60 calendar days of the publication of such notice. For each subsequent fiscal year, each such person shall submit, update, or reconfirm such information annually, on or before June 1 of each year starting with June 1, 2013.

(2) The notice required by paragraph (1) shall specify the type of information to be submitted and the means and format for submission of such information. At a minimum the submission 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, 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.

(3) Any person that owns or operates

(A) a site in which a bioanalytical study is conducted,

(B) a clinical research organization,

(C) a contract analytical testing site, or

(D) a contract repackager site

identified in a generic drug submission, shall provide to the Secretary information concerning the ownership, name, and address of the site. The Secretary may, by notice published in the Federal Register, specify the means and format for submission of such information and may specify additional or different information to be submitted. The Secretary's inspectional authority shall extend to all such sites.

(g) **Effect of failure to pay fees**

(1) Failure to pay the fee established by 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) as implemented in Food and Drug Administration regulations, until such outstanding fee is paid.

(2) (A) Failure to pay the fee established by subsection (a)(2) within 20 calendar days of the date due as specified in subparagraph (D) of such subsection will 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) as implemented in Food and Drug Administration regulations, 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 (D) of such subsection.

(3) Failure to pay the fee established by subsection (a)(3) within 20 calendar days of the due date as specified in subparagraph (C) of such subsection will 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) as implemented in Food and Drug Administration regulations until such outstanding fee is paid.

(4) Failure to pay the fee established by subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (C) of such subsection will result in:

(A) identification of the facility on a publicly available 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) as implemented in Food and Drug Administration regulations;

(B) 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) as implemented in Food and Drug Administration regulations 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 as specified in subsection (a)(4)(C); and

(C) all drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility being deemed misbranded under section 502(aa).

The penalties in 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.

(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 defined in subsection (m)(3) 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. 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); 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 million multiplied by the adjustment factor defined in subsection (m)(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 or otherwise affected under subsection (c) and 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.

(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, employers, 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 --** 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) . Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f). For purposes of this subsection, 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.

(m) **Definitions --** For purposes of this section,

(1) **Abbreviated new drug application** 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 [enacted Nov. 21, 1997]), or an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984 but does not include an application for a positron emission tomography drug.

(2) **Active pharmaceutical ingredient** means

(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended to be used as a component of a drug and intended 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 the final active pharmaceutical ingredient as defined in paragraph (A).

(3) **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) **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) **Facility** means business or other entity under one management either direct or indirect and at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form, but 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. For purposes of this definition, separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are closely related to the same business enterprise, under the supervision of the same local management, and are capable of being inspected by the Food and Drug Administration during a single inspection.

(6) **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, as defined in paragraph (2), with another component of a drug product for purposes of production of such a drug product.

(7) **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) **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 approval letters which approve abbreviated new drug applications or supplements to such applications or 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 set forth in detail the specific deficiencies in such submissions and, where appropriate, the actions necessary to resolve those deficiencies or, if appropriate, 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) [21 USC § 355(o)] (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) [21 USC § 355(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) [21 USC § 355(k)(5)] (relating to adverse event reports and postmarket safety activities).

(G) Regulatory science activities related to generic drugs.

(9) **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.

(10) **Resources allocated for the 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, and costs related to such officers, 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.

(11) **Submission** occurs on the date a generic drug submission or Type II pharmaceutical master file 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.

(12) **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.

(n) **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.

(o) **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 8 of subchapter C of chapter VII, as added by section 102, is amended by inserting after section 744G the following:

"SEC. 744H. 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 Act shall take effect on October 1, 2012, or the date of the enactment of this Act, 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 Act.

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 new subsection):

"(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 744G(a)(4) or for which identifying information required by section 744G(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 new section:

"SEC. 745A [(21 U.S.C. 379l) – Electronic Submission of Applications:

"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. 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. 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, the Secretary may, without regard to those 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 744G (m)(8).

"(c) **OBJECTIVES SPECIFIED.---**The objectives specified in this subsection are the performance goals with respect to section 744G (regarding assessment and use of human generic drug fees), as set forth in letters from the Secretary 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 published in the Congressional Record.

"(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.".