AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

I

112TH CONGRESS
2D SESSION

H. R. 5651

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2012

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

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Reform Act of 2012''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References in Act.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.
Sec. 102. Definitions.
Sec. 103. Authority to assess and use drug fees.
Sec. 104. Reauthorization; reporting requirements.
Sec. 105. Sunset dates.
Sec. 106. Effective date.
Sec. 107. Savings clause.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

Sec. 201. Short title; findings.
Sec. 202. Definitions.
Sec. 203. Authority to assess and use device fees.
Sec. 204. Reauthorization; reporting requirements.
Sec. 205. Savings clause.
Sec. 206. Effective date.
Sec. 207. Sunset clause.
Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

TITLE III—FEES RELATING TO GENERIC DRUGS

Sec. 301. Short title.
Sec. 302. Authority to assess and use human generic drug fees.
Sec. 303. Reauthorization; reporting requirements.
Sec. 304. Sunset dates.
Sec. 305. Effective date.
Sec. 306. Amendment with respect to misbranding.
Sec. 307. Streamlined hiring authority to support activities related to human generic drugs.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Sec. 401. Short title; finding.
Sec. 402. Fees relating to biosimilar biological products.
Sec. 403. Reauthorization; reporting requirements.
Sec. 404. Sunset dates.
Sec. 405. Effective date.
Sec. 406. Savings clause.
Sec. 407. Conforming amendment.

TITLE V—REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT

Sec. 501. Permanent extension of Best Pharmaceuticals for Children Act and Pediatric Research Equity Act.
Sec. 502. Food and Drug Administration Report.
Sec. 503. Internal Committee for Review of Pediatric Plans, Assessments, Deferrals, Deferral Extensions, and Waivers.
Sec. 504. Staff of Office of Pediatric Therapeutics.

Sec. 505. Continuation of operation of Pediatric Advisory Committee.
Sec. 506. Pediatric Subcommittee of the Oncologic Drugs Advisory Committee.

TITLE VI—FOOD AND DRUG ADMINISTRATION ADMINISTRATIVE REFORMS

Sec. 601. Public participation in issuance of FDA guidance documents.
Sec. 602. Conflicts of interest.
Sec. 603. Electronic submission of applications.
Sec. 604. Notification of FDA intent to regulate laboratory-developed tests.

TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

Sec. 701. Investigational device exemptions.
Sec. 702. Clarification of least burdensome standard.
Sec. 703. Agency documentation and review of significant decisions.
Sec. 704. Transparency in clearance process.
Sec. 705. Device Modifications Requiring Premarket Notification Prior to Marketing.

Subtitle B—Patients Come First

Sec. 711. Establishment of schedule and promulgation of regulation.
Sec. 712. Program to improve the device recall system.

Subtitle C—Novel Device Regulatory Relief

Sec. 721. Modification of de novo application process.

Subtitle D—Keeping America Competitive Through Harmonization

Sec. 731. Harmonization of device premarket review, inspection, and labeling symbols; report.
Sec. 732. Participation in international fora.

Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

Sec. 741. Reauthorization of Third Party Review.
Sec. 742. Reauthorization of third party inspection.

Subtitle F—Humanitarian Device Reform

Sec. 751. Expanded access to humanitarian use devices.

Subtitle G—Records and Reports on Devices

Sec. 761. Unique device identification system regulations.
Sec. 762. Effective device sentinel program.

Subtitle H—Miscellaneous

Sec. 771. Custom devices.
Sec. 772. Pediatric device reauthorization.
Sec. 773. Report on regulation of health information technology.

TITLE VIII—DRUG REGULATORY IMPROVEMENTS

Subtitle A—Drug Supply Chain

Sec. 801. Registration of producers of drugs.
Sec. 802. Inspection of drugs.
Sec. 803. Drug supply quality and safety.
Sec. 804. Prohibition against delaying, denying, limiting, or refusing inspection.
Sec. 805. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.
Sec. 806. Administrative detention.
Sec. 807. Enhanced criminal penalty for counterfeit drugs.
Sec. 808. Unique facility identification number.
Sec. 809. Documentation for admissibility of imports.
Sec. 810. Registration of commercial importers.
Sec. 811. Notification.
Sec. 812. Exchange of information.
Sec. 813. Extraterritorial jurisdiction.
Sec. 814. Protection against intentional adulteration.
Sec. 815. Records for inspection.

Subtitle B—Medical Gas Safety

Sec. 821. Regulation of medical gases.
Sec. 822. Changes to regulations.
Sec. 823. Rules of construction.

Subtitle C—Generating Antibiotic Incentives Now

Sec. 831. Extension of exclusivity period for drugs.
Sec. 832. Study on incentives for qualified infectious disease biological products.
Sec. 833. Clinical trials.
Sec. 834. Reassessment of qualified infectious disease product incentives in 5 years.
Sec. 835. Guidance on pathogen-focused antibacterial drug development.

Subtitle D—Accelerated Approval

Sec. 841. Expedited approval of drugs for serious or life-threatening diseases or conditions.
Sec. 842. Guidance; amended regulations.
Sec. 843. Independent review.

Subtitle E—Critical Path Reauthorization

Sec. 851. Reauthorization of the critical path public-private partnerships.

Subtitle F—Miscellaneous

Sec. 861. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
Sec. 862. Extension of period for first applicant to obtain tentative approval without forfeiting 180-day exclusivity period.
Sec. 863. Final agency action relating to petitions and civil actions.
Sec. 864. Deadline for determination on certain petitions.
Sec. 865. Rare pediatric disease priority review voucher incentive program.
Sec. 866. Combating prescription drug abuse.
Sec. 867. Assessment and modification of REMS.
Sec. 868. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.

Sec. 869. Breakthrough therapies.
Sec. 870. Grants and Contracts for the Development of Orphan Drugs.

TITLE IX—DRUG SHORTAGES

Sec. 901. Discontinuance and interruptions of manufacturing of certain drugs.
Sec. 902. Drug shortage list.
Sec. 903. Quotas applicable to drugs in shortage.
Sec. 904. Expedited review of major manufacturing changes for potential and verified shortages of drugs that are life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition.
Sec. 905. Study on drug shortages.
Sec. 906. Annual report on drug shortages.
Sec. 907. Attorney General report on drug shortages.
Sec. 908. Hospital repackaging of drugs in shortage.

SEC. 3. 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.).

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

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

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and

Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735(7) (21 U.S.C. 379g) is amended by striking ''expenses incurred in connection with'' and inserting ''expenses in connection with''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

Section 736 (21 U.S.C. 379h) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(B) in paragraph (1)(A)—

(i) in clause (i), by striking ''(c)(5)'' inserting ''(c)(4)''; and

(ii) in clause (ii), by striking ''(c)(5)'' inserting ''(c)(4)'';

(C) in the matter following clause (ii) in paragraph (2)(A)—

(i) by striking ''(c)(5)'' inserting ''(c)(4)''; and

(ii) by striking ''payable on or before October 1 of each year'' and inserting ''due on the later of the first business day on or after October 1 of such fiscal year or 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) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(4)''; and

(II) by striking ''payable on or before October 1 of each year.'' and inserting ''due on the later of the first business day on or after October 1 of each such fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for each such fiscal year under this section.''; and

(ii) by amending subparagraph (B) to read as follows:

"(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

"(i) identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL;

"(ii) the same product as another product that—

"(I) was approved under an application filed under section 505(b) or 505(j); and

"(II) is not in the list of discontinued products compiled under section 505(j)(7)(A);

"(iii) the same product as another product that was approved under an abbreviated application filed 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

"(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implemen-

tation of the Drug Price Competition and Patent Term Restoration Act of 1984.'';

(2) in subsection (b)—

(A) in paragraph (1)—

(i) in the language preceding subparagraph (A), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(ii) in subparagraph (A), by striking ''$392,783,000; and'' and inserting ''$693,099,000;''; and

(iii) by striking subparagraph (B) and inserting the following:

''(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

''(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).''; and

(B) by striking paragraphs (3) and (4) and inserting the following:

''(3) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload

adjustments for fiscal year 2013 shall be determined as follows:

''(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

''(i) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

''(ii) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

''(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

''(i) $652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

''(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the methodology described in subsection (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year

2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

''(C) LIMITATION.—Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).'';

(3) by striking subsection (c) and inserting the following:

''(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 by the amount equal to the sum of—

''(A) one;

''(B) the average annual percent 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 pre-

ceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years, and

''(C) the average annual percent 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 the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

''(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, after the fee revenues established in subsection (b) are adjusted

for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

''(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

"(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

"(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the

methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

''(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), 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 the process for the review of human drug applications for the first 3 months of 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.

''(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, es-

tablish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

''(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.''; and

(4) in subsection (g)—

(A) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(B) in paragraph (2)—

(i) in subparagraph (A)(i), by striking ''shall be retained'' and inserting ''shall be collected and available'';

(ii) in subparagraph (A)(ii), by striking ''shall only be collected and available'' and inserting ''shall be available''; and

(iii) by adding at the end the following new subparagraph:

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section

for a fiscal year, 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.'';

(C) in paragraph (3), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(D) in paragraph (4)—

(i) by striking ''fiscal years 2008 through 2010'' and inserting ''fiscal years 2013 through 2015'';

(ii) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(iii) by striking ''fiscal years 2008 though 2011'' and inserting ''fiscal years 2013 through 2016''; and

(iv) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B (21 U.S.C. 379h–2) is amended—

(1) by amending subsection (a) to read as follows:

''(a) PERFORMANCE REPORT.—

''(1) IN GENERAL.—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—

''(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

''(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

''(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

"(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

"(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

"(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

"(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

"(vi) the number of applications filed for review as fast track products per fiscal year for each review division; and

"(vii) the number of applications filed for orphan-designated products per fiscal year for each review division.

"(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.".

(2) in subsection (b), by striking ''2008'' and inserting ''2013''; and

(3) in subsection (d), by striking ''2012'' each place it appears and inserting ''2017''.

SEC. 105. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 (21 U.S.C. 379g; 379h) are repealed October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 736B (21 U.S.C. 379h–2) is repealed January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—Section 106 of the Prescription Drug User Fee Amendments of 2007 (Title I of Public Law 110–85) is repealed.

(d) TECHNICAL CLARIFICATIONS.—

(1) Effective September 30, 2007, section 508 of the Prescription Drug User Fee Amendments Act of 2002 (Title V of Public Law 107–188) is repealed.

(2) Effective September 30, 2002, section 107 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) is repealed.

(3) Effective September 30, 1997, section 105 of the Prescription Drug User Fee Act of 1992 (Public Law 102–571) is repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 107. SAVINGS CLAUSE.

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 on or after October 1, 2007, but before October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2012.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device User Fee Amendments of 2012''.

(b) FINDINGS.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 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. DEFINITIONS.

Section 737 (21 U.S.C. 379i) is amended—

(1) in paragraph (9), by striking ''incurred'' after ''expenses'';

(2) in paragraph (10), by striking ''October 2001'' and inserting ''October 2011''; and

(3) in paragraph (13), by striking ''is required to register'' and all that follows through the end of paragraph (13) and inserting the following: ''is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.''.

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(2) in paragraph (2)(A)—

(A) in the matter preceding clause (i)—

(i) by striking ''subsections (d) and (e)'' and inserting ''subsections (d), (e), and (f)'';

(ii) by striking ''October 1, 2002'' and inserting ''October 1, 2012''; and

(iii) by striking ''subsection (c)(1)'' and inserting ''subsection (c)''; and

(B) in clause (viii), by striking ''1.84'' and inserting ''2''; and

(3) in paragraph (3)—

(A) in subparagraph (A), by inserting ''and subsection (f)'' after ''subparagraph (B)''; and

(B) in subparagraph (C), by striking ''initial registration'' and all that follows through ''section 510.'' and inserting ''later of—

''(i) the initial or annual registration (as applicable) of the establishment under section 510; or

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

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—

"(1) IN GENERAL.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

"(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

"Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application	$248,000	$252,960	$258,019	$263,180	$268,443
Establishment Registration	$2,575	$3,200	$3,750	$3,872	$3,872

"(3) TOTAL REVENUE AMOUNTS.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

"(A) $97,722,301 for fiscal year 2013.

"(B) $112,580,497 for fiscal year 2014.

"(C) $125,767,107 for fiscal year 2015.

"(D) $129,339,949 for fiscal year 2016.

''(E) $130,184,348 for fiscal year 2017.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) (21 U.S.C. 379j(c)) is amended—

(1) in the subsection heading, by inserting ''; ADJUSTMENTS'' after ''SETTING'';

(2) by striking paragraphs (1) and (2);

(3) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(4) by inserting before paragraph (4), as so redesignated, the following:

''(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

''(2) INFLATION ADJUSTMENTS.—

''(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2014 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

''(B) APPLICABLE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The applicable inflation adjustment for a fiscal year is—

''(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

''(I) the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.

''(C) BASE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—

''(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

''(I) the average annual percent change in the cost, per full-time equiv-

alent 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 0.60; and

''(II) the average annual percent 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 0.40.

''(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

''(I) is less than 1, such adjustment shall be considered to be equal to 1; or

''(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

"(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

"(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years 2014 through 2017, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be further adjusted, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).".

(d) FEE WAIVER OR REDUCTION.—Section 738 (21 U.S.C. 379j) is amended by—

(1) redesignating subsections (f) through (k) as subsections (g) through (l), respectively; and

(2) by inserting after subsection (e) the following new subsection (f):

"(f) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

''(2) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

''(3) DURATION.—The authority provided by this subsection terminates October 1, 2017.''.

(e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C. 379j(h)(1)(A)), as redesignated by subsection (d)(1), is amended by striking ''$205,720,000'' and inserting ''$280,587,000''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 738(i) (21 U.S.C. 379j(i)), as redesignated by subsection (d)(1), is amended—

(1) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''shall be retained'' and inserting ''subject to subparagraph (C), shall be collected and available''; and

(ii) in clause (ii)—

(I) by striking ''collected and'' after ''shall only be''; and

(II) by striking ''fiscal year 2002'' and inserting ''fiscal year 2009''; and

(B) by adding at the end, the following:

''(C) PROVISION FOR EARLY YEAR PAYMENTS.—Payment of fees authorized under this section for a fiscal year, 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) in paragraph (3), by amending to read as follows:

''(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c) and, for

fiscal year 2017 only, as further adjusted under paragraph (4).''; and

(4) in paragraph (4)—

(A) by striking ''fiscal years 2008, 2009, and 2010'' and inserting ''fiscal years 2013, 2014, and 2015'';

(B) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(C) by striking ''June 30, 2011'' and inserting ''June 30, 2016'';

(D) by striking ''the amount of fees specified in aggregate in'' and inserting ''the cumulative amount appropriated pursuant to'';

(E) by striking ''aggregate amount in'' before ''excess shall be credited''; and

(F) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

(g) CONFORMING AMENDMENT.—Section 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by striking ''738(g)'' and inserting ''738(h)''.

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REAUTHORIZATION.—Section 738A(b) (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking ''2012'' and inserting ''2017''; and

(2) in paragraph (5), by striking ''2012'' and inserting ''2017''.

(b) PERFORMANCE REPORTS.—Section 738A(a) (21 U.S.C. 379j–1(a)) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) PERFORMANCE REPORT.—

''(A) IN GENERAL.—Beginning with fiscal year 2013, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described

in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

''(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.''; and

(2) in paragraph (2), by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

SEC. 205. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this

title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (as defined in such part as of such day) that on or after October 1, 2007, but before October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 206. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 207. SUNSET CLAUSE.

(a) IN GENERAL.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2017. Section 738A (21 U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and reporting requirements) are repealed January 31, 2018.

(b) PREVIOUS SUNSET PROVISION.—Section 217 of the Medical Device User Fee Amendments of 2007 (Title II of Public Law 110–85) is repealed.

(c) TECHNICAL CLARIFICATION.—Effective September 30, 2007, section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) is repealed.

SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

Subchapter A of chapter VII (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 re-

lated to the process for the review of device applications (as defined in section 737(8)).

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are with respect to the activities under subsection (b)(1), the goals referred to in section 738A(a)(1).

''(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 III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE.

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

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and

the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. 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 publicly available on the 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 clause (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—

''(A) if it is submitted via a Food and Drug Administration electronic gateway, on the

day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; and

''(B) if it is submitted in physical media form, on the day it arrives 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 paragraph (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 Register, for a fiscal year, by an amount equal to the sum of—

''(A) one;

''(B) the average annual percent 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 percent 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 no-

tice 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 abbreviated 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 re-

quired 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 the previous 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 inspection 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 section 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 section 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 section 744A(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. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as added by section 302 of this Act, is amended by inserting after section 744B the following:

''SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—

''(1) IN GENERAL.—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 re-

port concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(2) REGULATORY SCIENCE ACCOUNTABILITY METRICS.—The report required by paragraph (1) shall describe the amounts spent, data generated, and activities undertaken, including any FDA Advisory Committee consideration, by the Secretary for each of the local acting bioequivalence topics (Topics 1–3) in the Regulatory Science Plan described in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012.

''(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 Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 304. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744A and 744B, as added by section 302 of this Act, are repealed October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 744C, as added by section 303 of this Act, is repealed January 31, 2018.

SEC. 305. 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 302 shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files re-

ceived on or after October 1, 2012, regardless of the date of enactment of this title.

SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 (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. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

Section 714, as added by section 208 of this Act, is amended—

(1) by amending subsection (b) to read as follows:

''(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are—

''(1) activities under this Act related to the process for the review of device applications (as defined in section 737(8)); and

''(2) activities under this Act related to human generic drug activities (as defined in section 744A).''; and

(2) by amending subsection (c) to read as follows:

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are—

''(1) with respect to the activities under subsection (b)(1), the goals referred to in section 738A(a)(1); and

''(2) with respect to the activities under subsection (b)(2), the goals referred to in section 744C(a).''.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

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

(b) 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 safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Fed-

eral 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. 402. 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 III 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 submissions in connection with biosimilar biological product development.

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

''(i) that is at one general physical location consisting of one or more buildings, all of which are within 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 biosimilar biological product development, biosimilar biological product applications, and supplements.

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

"(11) The term 'financial hold'—

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

similar 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 describes an investigation that is intended to support a biosimilar biological product application.

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

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

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

''(ii) DUE DATE.—The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

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

''(II) the first business day after the enactment of an appropriations

Act providing for the collection and obligation of fees for such year under this section.

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

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

''(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 'reactivation fee') 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 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 required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

"(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary 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 investigation 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 404 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 filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (c).

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

''(A) IN GENERAL.—Except as provided in subparagraph (E), 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)(4) 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)(4) 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)(4) 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)(4) 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)(4) 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)(4) 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 product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 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. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 8 of subchapter C of chapter VII, as added by section 402 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 401(b)

of the Biosimilar 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 as-

sociated 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 para-

graph, and any changes made to the recommendations in response to such views and comments.''.

SEC. 404. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744G and 744H, as added by section 402 of this Act, are repealed October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 744I, as added by section 403 of this Act, is repealed January 31, 2018.

SEC. 405. 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 8 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. 406. SAVINGS CLAUSE.

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. 407. CONFORMING AMENDMENT.

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

TITLE V—REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT

SEC. 501. PERMANENT EXTENSION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT.

(a) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) is amended—

(1) in subsection (c)(1)—

(A) in the matter preceding subparagraph (A), by inserting ''or section 351(m) of this Act,'' after ''Cosmetic Act,'';

(B) in subparagraph (A)(i), by inserting ''or section 351(k) of this Act'' after ''Cosmetic Act''; and

(C) by amending subparagraph (B) to read as follows:

''(B)(i) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act, has ended for at least one form of the drug; and'';

(2) in subsection (c)(2)—

(A) in the heading of paragraph (2), by striking ''FOR DRUGS LACKING EXCLUSIVITY'';

(B) by striking ''under section 505 of the Federal Food, Drug, and Cosmetic Act''; and

(C) by striking ''505A of such Act'' and inserting ''505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act''; and

(3) in subsection (e)(1), by striking ''to carry out this section'' and all that follows through the end of paragraph (1) and inserting ''$25,000,000 for each of fiscal years 2013 through 2017.''.

(b) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A (21 U.S.C. 355a) is amended—

(1) in subsection (d)(1)(A), by adding at the end the following: ''If a request under this subparagraph does not request studies in neonates, such request shall include a statement describing the rationale for not requesting studies in neonates.'';

(2) by amending subsection (h) to read as follows:

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are the subject of a written request and for which reports are submitted and accepted in accordance with subsection

(d)(3). Written requests under this section may consist of a study or studies required under section 505B.'';

(3) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(4) in subsection (l)—

(A) in paragraph (1)—

(i) in the paragraph heading, by striking ''YEAR ONE'' and inserting ''FIRST 18-MONTH PERIOD''; and

(ii) by striking ''one-year'' and inserting ''18-month'';

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''YEARS'' and inserting ''PERIODS''; and

(ii) by striking ''one-year period'' and inserting ''18-month period'';

(C) by redesignating paragraph (3) as paragraph (4); and

(D) by inserting after paragraph (2) the following:

''(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory

Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.'';

(5) in subsection (n)—

(A) in the subsection heading, by striking ''COMPLETED'' and inserting ''SUBMITTED''; and

(B) in paragraph (1)—

(i) in the text preceding subparagraph (A), by striking ''have not been completed'' and inserting ''have not been submitted by the date specified in the written request issued and agreed upon''; and

(ii) by revising subparagraphs (A) and (B) to read as follows:

''(A) For a drug for which there remains any listed patent or exclusivity protection eligible for extension under subsection (b)(1) or (c)(1) of this section, or any exclusivity protection eligible for extension under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act, the Secretary shall make a determination regarding whether an assessment shall be required to be submitted under section 505B(b).

"(B) For a drug that has no remaining listed patents or exclusivity protection eligible for extension under subsection (b)(1) or (c)(1) of this section, or any exclusivity protection eligible for extension under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.";

(6) in subsection (o)(2), by amending subparagraph (B) to read as follows:

"(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use."; and

(7) by striking subsection (q) (relating to a sunset).

(c) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the matter before subparagraph (A), by inserting "for a drug" after "(or supplement to an application)";

(B) in paragraph (3)—

(i) by redesignating subparagraph (B) as subparagraph (D); and

(ii) by inserting after subparagraph (A) the following:

''(B) DEFERRAL EXTENSION.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral under subparagraph (A) if—

''(i) the Secretary finds that the criteria specified in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

''(ii) the applicant submits the materials required under subparagraph (A)(ii).

''(C) CONSIDERATION DURING DEFERRAL PERIOD.—If the Secretary has under this paragraph deferred the date by which an assessment must be submitted, then until the date specified in the deferral under subparagraph (A) (including any extension of such date under subparagraph (B))—

''(i) the assessment shall not be considered late or delayed;

''(ii) the Secretary shall not classify the assessment as late or delayed in any report, database, or public posting.''; and

(iii) in subparagraph (D), as redesignated, by amending clause (ii) to read as follows:

''(ii) PUBLIC AVAILABILITY.—Not later than 60 days after the submission to the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration—

''(I) such information;

''(II) the name of the applicant for the product subject to the assessment;

''(III) the date on which the product was approved; and

''(IV) the date of each deferral or deferral extension under this paragraph for the product.''; and

(C) in paragraph (4)(C)—

(i) in the first sentence, by inserting ''partial'' before ''waiver is granted''; and

(ii) in the second sentence, by striking ''either a full or partial waiver'' and inserting ''a partial waiver'';

(2) in subsection (b)(1), by striking ''After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary'' and inserting ''The Secretary'';

(3) by amending subsection (d) to read as follows:

''(d) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit a required assessment described in subsection (a)(2), fails to meet the applicable requirements in subsection (a)(3), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

''(1)(A) the Secretary shall issue a letter to such person informing such person of such failure;

''(B) not later than 30 calendar days after the issuance of a letter under subparagraph (A), the person who receives such letter shall submit to the Secretary a written response to such letter; and

''(C) not later than 45 calendar days after the issuance of a letter under subparagraph (A), the Secretary shall make such letter, and any response to such letter under subparagraph (B), available to the public on the Web site of the Food and Drug Administration, with appropriate redactions made to protect trade secrets and confidential commercial information, except that, if the Secretary determines that the letter under subparagraph (A) was issued in error, the requirements of this subparagraph shall not apply with respect to such letter; and

''(2)(A) the drug or biological product that is the subject of the required assessment, applicable requirements in subsection (a)(3), or required request for approval of a pediatric formulation may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

''(B) the failure to submit the required assessment, meet the applicable requirements in subsection

(a)(3), or submit the required request for approval of a pediatric formulation shall not be the basis for a proceeding—

"(i) to withdraw approval for a drug under section 505(e); or

"(ii) to revoke the license for a biological product under section 351 of the Public Health Service Act.";

(4) by amending subsection (e) to read as follows:

"(e) INITIAL PEDIATRIC PLAN.—

"(1) IN GENERAL.—

"(A) SUBMISSION.—An applicant who is required to submit an assessment under subsection (a)(1) shall submit an initial pediatric plan.

"(B) TIMING.—An applicant shall submit the initial pediatric plan under paragraph (1)—

"(i) before the date on which the applicant submits the assessments under subsection (a)(2); and

"(ii) not later than—

"(I) 60 calendar days after the date of end-of-Phase 2 meeting (as such term is used in section 312.47 of

title 21, Code of Federal Regulations, or successor regulations); or

"(II) such other time as may be agreed upon between the Secretary and the applicant.

Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric plan earlier than the date otherwise applicable under this subparagraph.

"(C) CONTENTS.—The initial pediatric plan shall include—

"(i) an outline of the pediatric studies that the applicant plans to conduct;

"(ii) any request for a deferral, partial waiver, or waiver under this section, along with supporting information; and

"(iii) other information the Secretary determines necessary, including any information specified in regulations under paragraph (5).

"(2) MEETING.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 calendar days after receiving an initial pediatric plan under

paragraph (1), the Secretary shall meet with the applicant to discuss the plan.

''(B) WRITTEN RESPONSE.—If the Secretary determines that a written response to the initial pediatric plan is sufficient to communicate comments on the initial pediatric plan, and that no meeting is necessary the Secretary shall, not later than 90 days after receiving an initial pediatric plan under paragraph (1)—

''(i) notify the applicant of such determination; and

''(ii) provide to the applicant the Secretary's written comments on the plan.

''(3) AGREED PEDIATRIC PLAN.—

''(A) SUBMISSION.—The applicant shall submit to the Secretary a document reflecting the agreement between the Secretary and the applicant on the initial pediatric plan (referred to in this subsection as an 'agreed pediatric plan').

''(B) CONFIRMATION.—Not later than 30 days after receiving the agreed pediatric plan under subparagraph (A), the Secretary shall provide written confirmation to the applicant

that such plan reflects the agreement of the Secretary.

''(C) DEFERRAL AND WAIVER.—If the agreed pediatric plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under subparagraph (B) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

''(D) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed pediatric plan may be amended at any time. The requirements of paragraph (2) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric plan under paragraph (1). The requirements of subparagraphs (A) through (C) of this paragraph shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed pediatric plan.

''(4) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section

505C on the review of the initial pediatric plan, agreed pediatric plan, and any amendments to such plans.

''(5) MANDATORY RULEMAKING.—Not later than one year after the date of enactment of the Food and Drug Administration Reform Act of 2012, the Secretary shall promulgate proposed regulations and guidance to implement the provisions of this subsection.

''(6) EFFECTIVE DATE.—The provisions of this subsection shall take effect 180 calendar days after the date of enactment of the Food and Drug Administration Reform Act of 2012, irrespective of whether the Secretary has promulgated final regulations to carry out this subsection by such date.'';

(5) in subsection (f)—

(A) in the subsection heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,'';

(B) in paragraph (4)—

(i) in the paragraph heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,''; and

(ii) in the second sentence, by inserting ", deferral extensions," after "deferrals"; and

(C) in paragraph (6)(D)—

(i) by inserting "and deferral extensions" before "requested and granted"; and

(ii) by inserting "and deferral extensions" after "the reasons for such deferrals";

(6) in subsection (g)—

(A) in paragraph (1)(A), by striking "after the date of the submission of the application or supplement" and inserting "after the date of the submission of an application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review"; and

(B) in paragraph (2), by striking "the label of such product" and inserting "the labeling of such product";

(7) in subsection (h)(1)—

(A) by inserting ''an application (or supplement to an application) that contains'' after ''date of submission of''; and

(B) by inserting ''if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review,'' after ''under this section,'';

(8) in subsection (i)—

(A) in paragraph (1)—

(i) in the paragraph heading, by striking ''YEAR ONE'' and inserting ''FIRST 18-MONTH PERIOD''; and

(ii) by striking ''one-year'' and inserting ''18-month'';

(B) in paragraph (2)—

(i) in the paragraph heading, by striking ''YEARS'' and inserting ''PERIODS''; and

(ii) by striking ''one-year period'' and inserting ''18-month period'';

(C) by redesignating paragraph (3) as paragraph (4); and

(D) by inserting after paragraph (2) the following:

''(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.'';

(9) by striking subsection (m) (relating to integration with other pediatric studies); and

(10) by redesignating subsection (n) as subsection (m).

(d) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS IN PHSA.—Section 351(m)(1) of the Public Health Service Act (42 U.S.C. 262(m)(1)) is amended by striking ''(f), (i), (j), (k), (l), (p), and (q)'' and inserting ''(f), (h), (i), (j), (k), (l), (n), and (p)''.

(e) APPLICATION; TRANSITION RULE.—

(1) APPLICATION.—Notwithstanding any provision of section 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provision applies beginning on the

date of the enactment of the Best Pharmaceuticals for Children Act of 2007 or the date of the enactment of the Pediatric Research Equity Act of 2007, any amendment made by this Act to such a provision applies beginning on the date of the enactment of this Act.

(2) TRANSITIONAL RULE FOR ADVERSE EVENT REPORTING.—With respect to a drug for which a labeling change described under section 505A(l)(1) or 505B(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved or made, respectively, during the one-year period that ends on the day before the date of enactment of this Act, the Secretary shall apply section 505A(l) and section 505B(i), as applicable, to such drug, as such sections were in effect on such day.

(f) CONFORMING AMENDMENT.—Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act''.

(g) PUBLIC MEETING ON PEDIATRIC CANCERS.—Not later than December 31, 2013, the Secretary of Health and Human Services shall hold a public meeting

on the impact of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) on the development of new therapies for children with cancer.

SEC. 502. FOOD AND DRUG ADMINISTRATION REPORT.

(a) IN GENERAL.—Not later than four years after the date of enactment of this Act and every five years thereafter, the Secretary of Health and Human Services shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the Web site of the Food and Drug Administration, a report on the implementation of section 505A and 505B.

(b) CONTENTS.—The report described in paragraph (1) shall include—

(1) an assessment of the effectiveness of sections 505A and 505B in improving information about pediatric uses for approved drugs and biologics, including the number and type of labeling changes made since the date of enactment of this Act;

(2) the number of waivers and partial waivers granted under section 505B since the date of enact-

ment of this Act, and the reasons such waivers and partial waivers were granted;

(3) the number of deferrals and deferral extensions granted under section 505B since the date of enactment of this Act, and the reasons such deferrals and deferral extensions were granted;

(4) the number of letters issued under section 505B(d);

(5) an assessment of the timeliness and effectiveness of pediatric study planning since the date of enactment of this Act, including the number of pediatric plans not submitted in accordance with the requirements of section 505B(e) and any resulting rulemaking;

(6) the number of written requests issued, accepted, and declined under section 505A since the date of enactment of this Act, and a listing of any important gaps in pediatric information as a result of such declined requests;

(7) a description and current status of referrals made under section 505A(n);

(8) an assessment of the effectiveness of studying drugs for rare diseases under 505A;

(9) an assessment of the effectiveness of studying drugs for children with cancer under 505A and

505B, and any recommendations for modifications to the programs under such sections that would lead to new and better therapies for children with cancer;

(10) an assessment of the effectiveness of studying drugs in the neonate population under 505A and 505B;

(11) an assessment of the effectiveness of studying biological products in pediatric populations under 505A and 505B;

(12) an assessment of the Secretary's efforts to address the suggestions and options described in the report required under 505A(p);

(13) any suggestions for modification to the programs that would improve pediatric drug research and increase pediatric labeling of drugs and biologics that the Secretary determines to be appropriate.

(c) STAKEHOLDER COMMENT.—At least 180 days prior to the submission of the report required in paragraph (1), the Secretary shall consult with representatives of patient groups, including pediatric patient groups, consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the study and report including sugges-

tions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biologics.

SEC. 503. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.

Section 505C (21 U.S.C. 355d) is amended—

(1) in the section heading, by inserting ''**DEFERRAL EXTENSIONS,**'' after ''**DEFERRALS,**''; and

(2) by inserting ''neonatology'' after ''pediatric ethics''.

SEC. 504. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.

Section 6(c) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(c)) is amended—

(1) in paragraph (1), by striking ''and'' at the end;

(2) by redesignating paragraph (2) as paragraph (4);

(3) by inserting after paragraph (1) the following:

''(2) one or more additional individuals with expertise in neonatology;

''(3) one or more additional individuals with expertise in pediatric epidemiology; and''.

SEC. 505. CONTINUATION OF OPERATION OF PEDIATRIC ADVISORY COMMITTEE.

Section 14(d) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''to carry out the advisory committee's responsibilities under sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c, and 360j(m))''.

SEC. 506. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

Section 15(a) of the Best Pharmaceuticals for Children Act (Public Law 107–109), as amended by section 502(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), is amended—

(1) in paragraph (1)(D), by striking ''section 505B(f)'' and inserting ''section 505C''; and

(2) in paragraph (3), by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''to carry out the Subcommittee's responsibilities under this section''.

TITLE VI—FOOD AND DRUG ADMINISTRATION ADMINISTRATIVE REFORMS

SEC. 601. PUBLIC PARTICIPATION IN ISSUANCE OF FDA GUIDANCE DOCUMENTS.

Section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended by striking subparagraph (C) and inserting the following:

''(C) For any guidance document that sets forth initial interpretations of a statute or regulation, sets forth changes in interpretation or policy that are of more than a minor nature, includes complex scientific issues, or covers highly controversial issues—

''(i) the Secretary—

''(I) at least 30 days before issuance of a draft of such guidance document, shall publish notice in the Federal Register of the Secretary's intent to prepare such guidance document; and

''(II) during preparation and before issuance of such guidance document, may meet with interested stakeholders, including industry, medical,

and scientific experts and others, and solicit public comment;

''(ii) if the Secretary for good cause finds that, with respect to such guidance document, compliance with clause (i) is impracticable, unnecessary, or contrary to the public interest—

''(I) the Secretary shall publish such finding and a brief statement of the reasons for such finding in the Federal Register;

''(II) clause (i) shall not apply with respect to such guidance document; and

''(III) during a 90-day period beginning not later than the date of issuance of the draft of such guidance document, the Secretary may meet with interested stakeholders, including industry, medical, and scientific experts and others, and shall solicit public comment;

''(iii) beginning on the date of enactment of the Food and Drug Administration Reform Act of 2012, upon issuance of

a draft guidance document under clause (i) or (ii), the Secretary shall—

"(I) designate the document as draft or final; and

"(II) not later than 18 months after the close of the comment period for such guidance, issue a final version of such guidance document in accordance with clauses (i) and (ii);

"(iv) the Secretary may extend the deadline for issuing final guidance under clause (iii)(II) by not more than 180 days upon submission by the Secretary of a notification of such extension in the Federal Register;

"(v) if the Secretary issues a draft guidance document and fails to finalize the draft by the deadline determined under clause (iii)(II), as extended under clause (iv), the Secretary shall, beginning on the date of such deadline, treat the draft as null and void; and

"(vi) not less than every 5 years after the issuance of a final guidance document

in accordance with clause (iii), the Secretary shall—

"(I) conduct a retrospective analysis of such guidance document to ensure it is not outmoded, ineffective, insufficient, or excessively burdensome; and

"(II) based on such analysis, modify, streamline, expand, or repeal the guidance document in accordance with what has been learned.

"(D) With respect to devices, a notice to industry guidance letter, a notice to industry advisory letter, and any similar notice that sets forth initial interpretations of a statute or regulation or sets forth changes in interpretation or policy shall be treated as a guidance document for purposes of subparagraph (C).

"(E) The following shall not be treated as a guidance document for purposes of subparagraph (C):

"(i) Any document that does not set forth an initial interpretation or a reinterpretation of a statute or regulation.

''(ii) Any document that sets forth or changes a policy relating to internal procedures of the Food and Drug Administration.

''(iii) Agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or communications directed to individual persons or firms.''.

SEC. 602. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Section 712 (21 U.S.C. 379d–1) is amended—

(1) by striking subsections (b) and (c) and inserting the following subsections:

''(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

''(1) IN GENERAL.—The Secretary shall—

''(A) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

''(B) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities;

''(C) at least every 180 days, request referrals for potential members of advisory committees from a variety of stakeholders, including—

''(i) product developers, patient groups, and disease advocacy organizations; and

''(ii) relevant—

''(I) professional societies;

''(II) medical societies;

''(III) academic organizations; and

''(IV) governmental organizations; and

''(D) in carrying out subparagraphs (A) and (B), take into account the levels of activity (including the numbers of annual meetings) and the numbers of vacancies of the advisory committees.

''(2) RECRUITMENT ACTIVITIES.—The recruitment activities under paragraph (1) may include—

"(A) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

"(B) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

"(C) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person whom the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

"(3) EXPERTISE.—In carrying out this subsection, the Secretary shall seek to ensure that the Secretary has access to the most current expert advice.

"(c) DISCLOSURE OF DETERMINATIONS AND CERTIFICATIONS.—Notwithstanding section 107(a)(2) of the Ethics in Government Act of 1978, the following shall apply:

"(1) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but (except as provided in paragraph (2)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, or a written certification as referred to in section 208(b)(3) of such title, applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Website of the Food and Drug Administration—

"(A) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination or certification applies; and

"(B) the reasons of the Secretary for such determination or certification, including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.

"(2) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to

the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, or a written certification as referred to in section 208(b)(3) of such title applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 552a of title 5, United States Code) on the Internet Website of the Food and Drug Administration, the information described in subparagraphs (A), (B), and (C) of paragraph (1) as soon as practicable after the Secretary makes such determination or certification, but in no case later than the date of such meeting.'';

(2) in subsection (d), by striking ''subsection (c)(3)'' and inserting ''subsection (c)'';

(3) by amending subsection (e) to read as follows:

''(e) ANNUAL REPORT.—

''(1) IN GENERAL.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the

Committee on Energy and Commerce of the House of Representatives, a report that describes—

"(A) with respect to the fiscal year that ended on September 30 of the previous year, the number of persons nominated for participation at meetings for each advisory committee, the number of persons so nominated, and willing to serve, the number of vacancies on each advisory committee, and the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

"(B) with respect to such year, the number of persons contacted for services as members for each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18, United States Code;

''(C) with respect to such year, the number of members attending meetings for each advisory committee; and

''(D) with respect to such year, the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom such disclosures did not apply who served on such committee.

''(2) PUBLIC AVAILABILITY.—Not later than 30 days after submitting any report under paragraph (1) to the committees specified in such paragraph, the Secretary shall make each such report available to the public.''; and

(4) in subsection (f), by striking ''shall review guidance'' and all that follows through the end of the subsection and inserting the following: ''shall—

''(1) review guidance of the Food and Drug Administration with respect to advisory committees regarding disclosure of conflicts of interest and the application of section 208 of title 18, United States Code; and

''(2) update such guidance as necessary to ensure that the Food and Drug Administration receives appropriate access to needed scientific exper-

tise, with due consideration of the requirements of such section 208.''.

(b) APPLICABILITY.—The amendments made by subsection (a) apply beginning on October 1, 2012.

SEC. 603. ELECTRONIC SUBMISSION OF APPLICATIONS.

Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is amended by inserting after section 745 the following:

''SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

''(a) DRUGS AND BIOLOGICS.—

''(1) 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 subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

"(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

"(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561.

"(b) DEVICES.—

"(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such pre-submissions or submissions, shall include an electronic copy of such pre-submissions or submissions.

"(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

"(A) provide standards for the electronic copy required under such paragraph; and

"(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.".

SEC. 604. NOTIFICATION OF FDA INTENT TO REGULATE LABORATORY-DEVELOPED TESTS.

The Food and Drug Administration may not issue any draft or final guidance on the regulation of laboratory-developed tests under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) without, at least 60 days prior to such issuance—

(1) notifying the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the Administration's intent to take such action; and

(2) including in such notification the anticipated details of such action.

TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

SEC. 701. INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended—

(1) in paragraph (2)(B)(ii), by inserting ''safety or effectiveness'' before ''data obtained''; and

(2) in paragraph (4), by adding at the end the following:

''(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

''(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

''(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

''(iii) an additional or different investigation may be necessary to support clearance or approval of the device.''.

SEC. 702. CLARIFICATION OF LEAST BURDENSOME STANDARD.

(a) PREMARKET APPROVAL.—Section 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) by redesignating clause (iii) as clause (v); and

(2) by inserting after clause (ii) the following:

''(iii) For purposes of clause (ii), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

''(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.''.

(b) PREMARKET NOTIFICATION UNDER SECTION 510(k).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is amended—

(1) by striking ''(D) Whenever'' and inserting ''(D)(i) Whenever''; and

(2) by adding at the end the following:

''(ii) For purposes of clause (i), the term 'necessary' means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

''(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.''.

SEC. 703. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.

Chapter V is amended by inserting after section 517 (21 U.S.C. 360g) the following:

"SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.

"(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

"(1) IN GENERAL.—The Secretary shall completely document the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

"(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such complete documentation to the person who is seeking to submit, or who has submitted, such report or application.

"(b) REVIEW OF SIGNIFICANT DECISIONS.—

"(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher

above the individual who made the significant decision.

''(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

''(3) TIMEFRAME.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

''(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.''.

SEC. 704. TRANSPARENCY IN CLEARANCE PROCESS.

(a) PUBLICATION OF DETAILED DECISION SUMMARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended by adding at the end the following:

''(5) Subject to subsection (c) and section 301(j), the Secretary shall regularly publish detailed decision summaries for each clearance of a device under section 510(k) requiring clinical data.''.

(b) APPLICATION.—The requirement of section 520(h)(5) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to clearance of a device occurring after the date of the enactment of this Act.

SEC. 705. DEVICE MODIFICATIONS REQUIRING PREMARKET NOTIFICATION PRIOR TO MARKETING.

Section 510(n) (21 U.S.C. 360(n)) is amended by—

(1) striking ''(n) The Secretary'' and inserting ''(n)(1) The Secretary''; and

(2) by adding at the end the following:

''(2)(A) Not later than 18 months after the enactment of this paragraph, the Secretary shall 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 regarding when a premarket notification under subsection (k) should be submitted for a

modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: 'could significantly affect the safety or effectiveness of the device', 'a significant change or modification in design, material, chemical composition, energy source, or manufacturing process,', and 'major change or modification in the intended use of the device'. The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement. and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

''(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled 'Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device', dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review

or any compliance or enforcement decisions or actions. The Secretary shall not issue—

"(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

"(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

"(C) The Food and Drug Administration guidance entitled 'Deciding When to Submit a 510(k) for a Change to an Existing Device', dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner

that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.''.

Subtitle B—Patients Come First

SEC. 711. ESTABLISHMENT OF SCHEDULE AND PROMULGATION OF REGULATION.

(a) ESTABLISHMENT OF SCHEDULE.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish the schedule referred to in section 515(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

(b) REGULATION.—Not later than one year after the date that the schedule is established under such section 515(i)(3) (as required by subsection (a)) the Secretary shall issue a final regulation under section 515(b) of such Act for each device that the Secretary requires to remain in class III through a determination under section 515(i)(2) of such Act.

SEC. 712. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

Chapter V is amended by inserting after section 518 (21 U.S.C. 360h) the following:

''SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.

''(a) IN GENERAL.—The Secretary shall—

''(1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

''(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

''(3) develop detailed criteria for assessing whether a person performing a device recall has performed an effective correction or action plan for the recall; and

''(4) document the basis for each termination by the Food and Drug Administration of a device recall.

''(b) ASSESSMENT CONTENT.—The program established under subsection (a)(1) shall, at a minimum, identify—

''(1) trends in the number and types of device recalls;

''(2) devices that are most frequently the subject of a recall; and

''(3) underlying causes of device recalls.

''(c) DEFINITION.—In this section, the term 'recall' means—

''(1) the removal from the market of a device pursuant to an order of the Secretary under subsection (b) or (e) of section 518; or

''(2) the correction or removal from the market of a device at the initiative of the manufacturer or importer of the device that is required to be reported to the Secretary under section 519(g).''.

Subtitle C—Novel Device Regulatory Relief

SEC. 721. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) IN GENERAL.—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended—

(1) by inserting ''(i)'' after ''(2)(A)'';

(2) in subparagraph (A)(i), as so designated by paragraph (1), by striking ''under the criteria set forth'' and all that follows through the end of subparagraph (A) and inserting a period;

(3) by adding at the end of subparagraph (A) the following:

''(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection

(i)), a person may submit a request under this clause for the Secretary to classify the device.

''(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

''(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification of a device pursuant to a request under clause (ii) if the Secretary—

''(I) identifies a legally marketed device that would permit a substantial equivalence determination under paragraph (1) for the device; or

''(II) determines that the device submitted is not of low-moderate risk or special controls to mitigate the risks cannot be developed for the device.

''(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed in-

formation and reasons for the recommended classification.''; and

(4) in subparagraph (B), by striking ''Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary'' and inserting ''The Secretary''.

(b) CONFORMING AMENDMENTS.—Section 513(f) of such Act (21 U.S.C. 360c(f)) is amended in paragraph (1)—

(1) in subparagraph (A), by striking '', or'' at the end and inserting a semicolon;

(2) in subparagraph (B), by striking the period and inserting ''; or''; and

(3) by inserting after subparagraph (B) the following:

''(C) the device is classified pursuant to a request submitted under paragraph (2).''.

Subtitle D—Keeping America Competitive Through Harmonization

SEC. 731. HARMONIZATION OF DEVICE PREMARKET REVIEW, INSPECTION, AND LABELING SYMBOLS; REPORT.

(a) IN GENERAL.—Paragraph (4) of section 803(c) (21 U.S.C. 383(c)) is amended to read as follows:

''(4) With respect to devices, the Secretary may, when appropriate, enter into arrangements with nations regarding methods and approaches to harmonizing regulatory requirements for activities, including inspections and common international labeling symbols''.

(b) REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the Food and Drug Administration's harmonization activities, itemizing methods and approaches that have been harmonized pursuant to section 803(c)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a).

SEC. 732. PARTICIPATION IN INTERNATIONAL FORA.

Paragraph (3) of section 803(c) (21 U.S.C. 383(c)) is amended—

(1) by striking ''(3)'' and inserting ''(3)(A)''; and

(2) by adding at the end the following:

''(B) In carrying out subparagraph (A), the Secretary may participate in appropriate fora, including the International Medical Device Regulators Forum, and may—

''(i) provide guidance to such fora on strategies, policies, directions, membership, and other activities of a forum as appropriate;

''(ii) to the extent appropriate, solicit, review, and consider comments from industry, academia, health care professionals, and patient groups regarding the activities of such fora; and

''(iii) to the extent appropriate, inform the public of the Secretary's activities within such fora, and share with the public any documentation relating to a forum's strategies, policies, and other activities of such fora.''.

Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

SEC. 741. REAUTHORIZATION OF THIRD PARTY REVIEW.

(a) PERIODIC REACCREDITATION.—Section 523(b)(2) (21 U.S.C. 360m(b)(2)) is amended by adding at the end of the following:

''(E) PERIODIC REACCREDITATION.—

''(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

''(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

''(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which such persons are reaccredited.''.

(b) DURATION OF AUTHORITY.—Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

SEC. 742. REAUTHORIZATION OF THIRD PARTY INSPECTION.

Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

Subtitle F—Humanitarian Device Reform

SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DEVICES.

(a) IN GENERAL.—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''subparagraph (D)'' and inserting ''subparagraph (C)'';

(ii) by striking clause (i) and inserting the following:

''(i) The device with respect to which the exemption is granted—

''(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

''(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the devel-

opment of the device for such patients is impossible, highly impracticable, or unsafe.'';

(iii) by striking clause (ii) and inserting the following:

''(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the number of such devices needed to treat, diagnose, or cure a population of 4,000 individuals in the United States (referred to in this paragraph as the 'annual distribution number').''; and

(iv) in clause (iv), by striking ''2012'' and inserting ''2017'';

(B) by striking subparagraph (C);

(C) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively; and

(D) in subparagraph (C), as so redesignated, by striking ''and modified under subparagraph (C), if applicable,'';

(2) in paragraph (7), by striking ''regarding a device'' and inserting ''regarding a device described in paragraph (6)(A)(i)(I)''; and

(3) in paragraph (8), by striking ''of all devices described in paragraph (6)'' and inserting ''of all devices described in paragraph (6)(A)(i)(I)''.

(b) APPLICABILITY TO EXISTING DEVICES.—A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the date of enactment of this Act may seek a determination under subclause (I) or (II) of paragraph (6)(A)(i) of such section 520(m) (as amended by subsection (a)). If the Secretary determines that such subclause (I) or (II) applies with respect to a device, then clauses (ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), and (D) of paragraph (6) of such section 520(m) shall apply to such device.

(c) REPORT.—Not later than January 1, 2017, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a) in stimulating innovation with respect to medical devices, including any favorable or adverse impact on pediatric device development;

(2) the impact of such amendments on pediatric device approvals for devices that received a humanitarian use designation under section 520(m) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) prior to the date of enactment of this Act;

(3) the status of public and private insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m) and costs to patients of such devices;

(4) the impact that paragraph (4) of such section 520(m) has had on access to and insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m); and

(5) the effect of the amendments made by subsection (a) on patients described in such section 520(m).

Subtitle G—Records and Reports on Devices

SEC. 761. UNIQUE DEVICE IDENTIFICATION SYSTEM REGULATIONS.

Not later than 120 days after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate the regulations required by section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

SEC. 762. EFFECTIVE DEVICE SENTINEL PROGRAM.

(a) INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Section 519

(21 U.S.C. 360i) is amended by adding at the end the following:

''(h) INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(1) IN GENERAL.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

''(2) DATA.—In expanding the system as described in paragraph (1), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, which may include claims data, patient survey data, and standardized analytic files that allow for the pooling and analysis of data from disparate data environments.

''(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system as described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program, through a public hearing, advisory

committee meeting, maintenance of a public docket, or other similar public measures.

''(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification, mitigation, and analysis for devices.''.

(b) AMENDMENTS TO POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Section 505(k)(3)(C)(i) (21 U.S.C. 355(k)(3)(C)(i)) is amended—

(1) by striking subclause (II);

(2) by redesignating subclauses (III) through (VI) as subclauses (II) through (V), respectively; and

(3) in item (bb) of subclause (II), as so redesignated, by striking ''pharmaceutical purchase data and health insurance claims data'' and inserting ''medical device utilization data, health insurance claims data, and procedure and device registries''.

Subtitle H—Miscellaneous

SEC. 771. CUSTOM DEVICES.

Section 520(b) (21 U.S.C. 360j) is amended to read as follows:

''(b) CUSTOM DEVICES.—

''(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

''(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

''(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

''(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

''(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

''(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such phy-

sician or dentist (or other specially qualified person so designated); or

''(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

''(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

''(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

''(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

''(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical; and

''(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that

such replication otherwise complies with this section.

''(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

''(4) NOTIFICATION TO THE SECRETARY.—The manufacturer of such device created or modified as described in paragraph (1) shall notify the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.''.

SEC. 772. PEDIATRIC DEVICE REAUTHORIZATION.

(a) FINAL RULE RELATING TO TRACKING OF PEDIATRIC USES OF DEVICES.—The Secretary of Health and Human Services shall issue—

(1) a proposed rule implementing section 515A(a)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360e–1(a)(2)) not later than December 31, 2012; and

(2) a final rule implementing such section not later than December 31, 2013.

(b) DEMONSTRATION GRANTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.—Section 305(e) of the Pediatric Medical Device Safety and Improvement Act of 2007 (Title III of Public Law 110–85) is amended by

striking ''2008 through 2012'' and inserting ''2013 through 2017''.

SEC. 773. REPORT ON REGULATION OF HEALTH INFORMATION TECHNOLOGY.

(a) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, the National Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall submit to the Committee on Energy and Commerce of the House of Representatives and the appropriate committees of the Senate a report that contains—

(1) a strategy for coordinating the regulation of health information technology in order to avoid regulatory duplication; and

(2) recommendations on an appropriate regulatory framework for health information technology, including a risk-based framework.

(b) DEFINITION.—In this section, the terms ''health information technology'' has the meaning given such term in section 3000(5) of the Public Health Service Act and includes technologies such as electronic health records, personal health records, mobile medical applications, com-

puterized health care provider order entry systems, and clinical decision support.

TITLE VIII—DRUG REGULATORY IMPROVEMENTS

Subtitle A—Drug Supply Chain

SEC. 801. REGISTRATION OF PRODUCERS OF DRUGS.

(a) TIMING.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)(1), by striking ''On or before'' and inserting ''During the period beginning on October 1 and ending on''; and

(2) in subsection (i)(1)(B)(i), by striking ''on or before'' and inserting ''during the period beginning on October 1 and ending on''.

(b) ESTABLISHMENTS NOT DULY REGISTERED; MISBRANDING.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking ''in any State''.

SEC. 802. INSPECTION OF DRUGS.

Subsection (h) of section 510 (21 U.S.C. 360) is amended—

(1) by striking ''(h)'' and inserting ''(h)(1)'';

(2) by inserting ''with respect to the manufacture, preparation, propagation, compounding, or processing of a device'' after ''registered with the Secretary pursuant to this section'';

(3) by striking ''of a drug or drugs or''; and

(4) by adding at the end the following:

''(2) INSPECTIONS WITH RESPECT TO DRUG ESTABLISHMENTS.—With respect to the manufacture, preparation, propagation, compounding, or processing of a drug:

''(A) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

''(B) RISK-BASED SCHEDULE.—In the case of an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as a 'drug establishment'), the inspections required under subparagraph (A) shall be conducted by officers or employees duly designated by the Secretary, on a risk-based schedule established by the Secretary.

''(C) RISK FACTORS.—In establishing the risk-based schedule under subparagraph (B), the Secretary shall allocate resources to inspect establishments according to the known safety risks of such establishments, based on the following factors:

''(i) The compliance history of the establishment.

"(ii) The inspection frequency and history of the establishment, including whether it has been inspected pursuant to section 704 within the last four years.

"(iii) The record, history, and nature of recalls linked to the establishment.

"(iv) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

"(v) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

"(D) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under subparagraph (B), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b)(1).

"(E) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit to Congress a report that contains the following:

"(i) The number of domestic and foreign establishments registered pursuant to this section in the previous calendar year.

"(ii) The number of such registered domestic and foreign establishments that the Secretary inspected in the previous calendar year.

"(iii) The number of such registered establishments that list one or more drugs approved pursuant to an application filed under section 505(j).

"(iv) The number of such registered establishments that list one or more drugs approved pursuant to an application filed under section 505(b).

"(v) The number of registered establishments that list both drug products approved pursuant to an application filed under section 505(j) and drug products approved pursuant to an application filed under section 505(b).

"(vi) A description of how the Secretary implemented the risk-based schedule under subparagraph (B) utilizing the factors under subparagraph (C).

"(F) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report re-

quired under subparagraph (E) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 803. DRUG SUPPLY QUALITY AND SAFETY.

Paragraph (a) of section 501 (21 U.S.C. 351) is amended by adding at the end the following: ''For purposes of subparagraph (2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.''.

SEC. 804. PROHIBITION AGAINST DELAYING, DENYING, LIMITING, OR REFUSING INSPECTION.

(a) IN GENERAL.—Section 501 (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is a drug and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.''.

(b) GUIDANCE.—Not later than 1 year after the date of enactment of this section, the Secretary of Health and Human Services shall issue guidance that defines the cir-

cumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

SEC. 805. DESTRUCTION OF ADULTERATED, MISBRANDED, OR COUNTERFEIT DRUGS OFFERED FOR IMPORT.

(a) IN GENERAL.—The sixth sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting before the period at the end the following: ‘‘, except that the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, may cause the destruction, without the opportunity for export, of any drug refused admission that has reasonable probability of causing serious adverse health consequences or death, as determined by the Secretary of Health and Human Services, or that is valued at an amount that is $2,000 or less (or such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code)’’.

(b) NOTICE.—Section 801(a) (21 U.S.C. 381(a)), as amended by subsection (a), is further amended by inserting after the sixth sentence the following: ‘‘The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity for a hearing on the

destruction of a drug under the previous sentence. For a drug with a value less than and or equal to $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code) the regulations under the previous sentence shall provide for prompt notice and an opportunity for a hearing for the owner or consignee before or after the destruction has occurred. For a drug with a value greater than $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code) that has reasonable probability of causing serious adverse health consequences or death as determined by the Secretary of Health and Human Services, the regulations under the seventh sentence of this subsection shall provide for notice and an opportunity for a hearing to the owner or consignee before the destruction occurs.''.

(c) RESTITUTION.—In the regulations described in the seventh sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)), the Secretary of Health and Human Services shall establish an administrative process whereby an owner or consignee of a drug destroyed without an opportunity for

a hearing on destruction may obtain restitution for the value of the drug destroyed under the sixth sentence of such section upon demonstration that such drug was wrongfully destroyed.

(d) CONFORMING AMENDMENT.—The first sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting ", except as otherwise described in the sixth and seventh sentences of this subsection," after "giving notice thereof".

SEC. 806. ADMINISTRATIVE DETENTION.

(a) IN GENERAL.—Section 304(g) (21 U.S.C. 335a(g)) is amended—

(1) in paragraph (1), by inserting ", drug," after "device", each place it appears;

(2) in paragraph (2)(A), by inserting ", drug," after "(B), a device"; and

(3) in paragraph (2)(B), by inserting "or drug" after "device" each place it appears.

(b) REGULATION.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement administrative detention authority with respect to drugs, as authorized by the amendments made by subsection (a). Before promulgating such regulations, the

Secretary shall consult with stakeholders, including manufacturers of drugs.

(c) EFFECTIVE DATE.—The amendments made by subsection (a) shall not take effect until the Secretary has issued a final regulation under subsection (b).

SEC. 807. ENHANCED CRIMINAL PENALTY FOR COUNTERFEIT DRUGS.

(a) IN GENERAL.—Section 303(a) (21 U.S.C. 333(a)) is amended by adding at the end the following:

''(3) Notwithstanding paragraph (2), any person who engages in any conduct described in section 301(i)(2) knowing or having reason to know that the conduct concerns the rendering of a drug as a counterfeit drug, or who engages in conduct described in section 301(i)(3) knowing or having reason to know that the conduct will cause a drug to be a counterfeit drug or knowing or having reason to know that a drug held, sold, or dispensed is a counterfeit drug, shall be fined in accordance with title 18, United States Code, or imprisoned not more than 20 years, or both, except that if the use of the counterfeit drug by a consumer is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life.''.

(b) CONFORMING AMENDMENT.—Section 201(g)(2) (21 U.S.C. 321(g)(2)) is amended by adding at the end

the following sentence: ''The term 'counterfeit drug' shall not include a drug or placebo intended for use in a clinical trial that is intentionally labeled or marked to maintain proper blinding of the study.''.

SEC. 808. UNIQUE FACILITY IDENTIFICATION NUMBER.

(a) DOMESTIC ESTABLISHMENTS.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)(1), by striking ''and all such establishments'' and inserting ''all such establishments, and the unique facility identifier of each such establishment''; and

(2) in subsection (c), by striking ''and such establishment'' and inserting ''such establishment, and the unique facility identifier of such establishment''.

(b) FOREIGN ESTABLISHMENTS.—Subparagraph (A) of section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by inserting ''the unique facility identifier of the establishment,'' after ''the name and place of business of the establishment,''.

(c) GUIDANCE.—Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

''(q) GUIDANCE ON SUBMISSION OF UNIQUE FACILITY IDENTIFIERS.—

''(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this subsection, the Secretary shall, by guidance, specify—

''(A) the unique facility identifier system to be used to meet the requirements of—

''(i) subsections (b)(1), (c), and (i)(1)(A) of this section; and

''(ii) section 801(s) (relating to registration of commercial importers); and

''(B) the form, manner, and timing of submissions of unique facility identifiers under the provisions specified in subparagraph (A).

''(2) CONSIDERATION.—In developing the guidance under paragraph (1), the Secretary shall take into account the utilization of existing unique identification schemes and compatibility with customs automated systems.''.

(d) IMPORTATION.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting ''or (5) for an article that is a drug, the appropriate unique facility identifiers under subsection (s) (relating to commercial importers) and section 510(i) (relating to foreign establishments), as specified by the Secretary, are not provided,'' before ''then such article shall be refused admission''.

SEC. 809. DOCUMENTATION FOR ADMISSIBILITY OF IMPORTS.

Section 801 (21 U.S.C. 381) is amended by adding at the end the following:

''(r) DOCUMENTATION.—

''(1) SUBMISSION.—The Secretary may require, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection as determined appropriate by the Secretary, the submission of documentation or other information for a drug that is imported or offered for import into the United States.

''(2) REFUSAL OF ADMISSION.—A drug imported or offered for import into the United States shall be refused admission unless all documentation and information the Secretary requires under this Act, the Public Health Service Act, or both, as appropriate, for such article is submitted.

''(3) REGULATIONS.—

''(A) DOCUMENTS AND INFORMATION.—The Secretary shall issue a regulation to specify the documentation or other information that is described in paragraph (1). Such information may include—

''(i) information demonstrating the regulatory status of the drug, such as the

new drug application, abbreviated new drug application, or investigational new drug or Drug Master File number;

''(ii) facility information, such as proof of registration and the unique facility identifier; and

''(iii) indication of compliance with current good manufacturing practice, such as satisfactory testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations.

''(B) EXEMPTION.—The Secretary may, by regulation, exempt drugs imported for research purposes only and other types of drug imports from some or all of the requirements of this subsection.

''(4) EFFECTIVE DATE.—The final rule under paragraph (3)(A) shall take effect not less than 180 days after the Secretary promulgates such final rule.''.

SEC. 810. REGISTRATION OF COMMERCIAL IMPORTERS.

(a) PROHIBITIONS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(aaa) The failure to register in accordance with section 801(s).".

(b) REGISTRATION.—Section 801 (21 U.S.C. 381), as amended by section 810, is further amended by adding at the end the following:

"(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

"(1) REGISTRATION.—The Secretary shall require a commercial importer of drugs—

"(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

"(B) consistent with the guidance under section 510(q), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

"(2) REGULATIONS.—

"(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the re-

quirements of this Act and the Public Health Service Act.

''(B) EXPEDITED CLEARANCE FOR CERTAIN IMPORTERS.—In promulgating good importer practice regulations under subparagraph (A), the Secretary may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies.

''(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

''(4) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.''.

(c) MISBRANDING.—Section 502(o) (21 U.S.C. 352) is amended by inserting ''if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s),'' after ''not duly registered under section 510,''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate the regulations required to carry out section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(2) EFFECTIVE DATE.—In establishing the effective date of the regulations under paragraph (1), the Secretary of Health and Human Services shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.

SEC. 811. NOTIFICATION.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 811, is further amended by adding at the end the following:

''(bbb) The failure to notify the Secretary in violation of section 568.''.

(b) NOTIFICATION.—Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568 NOTIFICATION.

''(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—

''(1) that the use of such drug in the United States may result in serious injury or death;

''(2) of a significant loss or known theft of such drug intended for use in the United States; or

''(3) that—

''(A) such drug has been or is being counterfeited; and

''(B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce; or

''(ii) such drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

''(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in such manner and by such means as the Secretary may specify by regulation or guidance.

''(c) SAVINGS CLAUSE.—Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this Act or the Public Health Service Act.

''(d) DEFINITION.—In this section, the term 'regulated person' means—

''(1) a person who is required to register under section 510 or 801(s);

''(2) a wholesale distributor of a drug product; or

''(3) any other person that distributes drugs except a person that distributes drugs exclusively for retail sale.''.

SEC. 812. EXCHANGE OF INFORMATION.

Section 708 (21 U.S.C. 379) is amended—

(1) by striking ''The Secretary may provide'' and inserting the following:

''(a) CONTRACTORS.—The Secretary may provide''; and

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION.—Except pursuant to an order of a court of the United States, the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law, any information relating to drugs obtained from a Federal, State, or local government agency, or from a foreign government agency, if the agency has requested that the information be kept confidential. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

''(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

''(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner of Food and Drugs.

''(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

''(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1), and that has executed a written agreement under paragraph (2), information referenced in section 301(j) in the following circumstances:

''(A) Information concerning the inspection of a facility may be provided if—

''(i) the Secretary reasonably believes, or the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

''(ii) the written agreement executed under paragraph (2) limits the recipient's

use of the information to the recipient's civil regulatory purposes.

''(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death.

''(d) NO LIMITATION ON AUTHORITY.—This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.''.

SEC. 813. EXTRATERRITORIAL JURISDICTION.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.''.

SEC. 814. PROTECTION AGAINST INTENTIONAL ADULTERATION.

Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally engages in an activity that results in a drug becoming adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and having a reasonable probability of causing serious adverse health consequences or death shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.''.

SEC. 815. RECORDS FOR INSPECTION.

Section 704(a) (21 U.S.C. 374(a)) is amended by adding at the end the following:

''(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's

request shall include a sufficient description of the records requested.

''(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

''(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.''.

Subtitle B—Medical Gas Safety

SEC. 821. REGULATION OF MEDICAL GASES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter G—Medical Gases

''SEC. 575. DEFINITIONS.

''In this subchapter:

''(1) The term 'designated medical gas' means any of the following:

''(A) Oxygen that meets the standards set forth in an official compendium.

''(B) Nitrogen that meets the standards set forth in an official compendium.

''(C) Nitrous oxide that meets the standards set forth in an official compendium.

"(D) Carbon dioxide that meets the standards set forth in an official compendium.

"(E) Helium that meets the standards set forth in an official compendium.

"(F) Carbon monoxide that meets the standards set forth in an official compendium.

"(G) Medical air that meets the standards set forth in an official compendium.

"(H) Any other medical gas deemed appropriate by the Secretary, after taking into account any investigational new drug application or investigational new animal drug application for the same medical gas submitted in accordance with regulations applicable to such applications in title 21 of the Code of Federal Regulations, unless any period of exclusivity under section 505(c)(3)(E)(ii) or section 505(j)(5)(F)(ii), or the extension of any such period under section 505A, applicable to such medical gas has not expired.

"(2) The term 'medical gas' means a drug that—

"(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

"(B) is administered as a gas.

"SEC. 576. REGULATION OF MEDICAL GASES.

"(a) CERTIFICATION OF DESIGNATED MEDICAL GASES.—

"(1) SUBMISSION.—Beginning 180 days after the date of enactment of this section, any person may file with the Secretary a request for certification of a medical gas as a designated medical gas. Any such request shall contain the following information:

"(A) A description of the medical gas.

"(B) The name and address of the sponsor.

"(C) The name and address of the facility or facilities where the medical gas is or will be manufactured.

"(D) Any other information deemed appropriate by the Secretary to determine whether the medical gas is a designated medical gas.

"(2) GRANT OF CERTIFICATION.—The certification requested under paragraph (1) is deemed to be granted unless, within 60 days of the filing of such request, the Secretary finds that—

"(A) the medical gas subject to the certification is not a designated medical gas;

"(B) the request does not contain the information required under paragraph (1) or oth-

erwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or

"(C) denying the request is necessary to protect the public health.

"(3) EFFECT OF CERTIFICATION.—

"(A) IN GENERAL.—

"(i) APPROVED USES.—A designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512, subject to all applicable post-approval requirements, for the following indications for use:

"(I) In the case of oxygen, the treatment or prevention of hypoxemia or hypoxia.

"(II) In the case of nitrogen, use in hypoxic challenge testing.

"(III) In the case of nitrous oxide, analgesia.

''(IV) In the case of carbon dioxide, use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

''(V) In the case of helium, the treatment of upper airway obstruction or increased airway resistance.

''(VI) In the case of medical air, to reduce the risk of hyperoxia.

''(VII) In the case of carbon monoxide, use in lung diffusion testing.

''(VIII) Any other indication for use for a designated medical gas or combination of designated medical gases deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 505(c)(3)(E), clause (iii) or (iv) of section 505(j)(5)(F), or section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas or combination of gases has not expired.

"(ii) LABELING.—The requirements of sections 503(b)(4) and 502(f) are deemed to have been met for a designated medical gas if the labeling on final use container for such medical gas bears—

"(I) the information required by section 503(b)(4);

"(II) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and

"(III) appropriate directions and warnings concerning storage and handling.

"(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

"(i) NO EXCLUSIVITY FOR A CERTIFIED MEDICAL GAS.—No designated medical gas deemed under subparagraph (A)(i) to have in effect an approved application is eligible for any period of exclusivity under section 505(c), 505(j), or 527, or the extension of any such period under section 505A, on the basis of such deemed approval.

"(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under section 505(c), 505(j), or section 527, or the extension of any such period under section 505A, with respect to an application for a drug product shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in subsection (a)(3)(A)(i)(VIII) and section 575(1)(H).

"(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

"(A) WITHDRAWAL, SUSPENSION OF APPROVAL.—Nothing in this subchapter limits the Secretary's authority to withdraw or suspend approval of a drug product, including a designated medical gas deemed under this section to have in effect an approved application under section 505 or section 512 of this Act.

"(B) REVOCATION OF CERTIFICATION.—The Secretary may revoke the grant of a certification under paragraph (2) if the Secretary determines that the request for certification contains any material omission or falsification.

"(b) PRESCRIPTION REQUIREMENT.—

"(1) IN GENERAL.—A designated medical gas shall be subject to the requirements of section 503(b)(1) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such medical gas from the requirements of section 503(b)(1), the gas is approved for use without a prescription pursuant to an application under section 505 or 512, or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

"(2) OXYGEN.—

"(A) NO PRESCRIPTION REQUIRED FOR CERTAIN USES.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

"(i) For use in the event of depressurization or other environmental oxygen deficiency.

"(ii) For oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

"(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements of section 503(b)(4) shall be deemed to have been met if its labeling bears a warning

that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

"SEC. 577. INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.

"A designated medical gas, alone or in combination with another designated gas or gases (as medically appropriate) deemed under section 576 to have in effect an approved application shall not be assessed fees under section 736(a) on the basis of such deemed approval.".

SEC. 822. CHANGES TO REGULATIONS.

(a) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public, shall—

(1) determine whether any changes to the Federal drug regulations are necessary for medical gases; and

(2) submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding any such changes.

(b) REGULATIONS.—If the Secretary determines under subsection (a) that changes to the Federal drug reg-

ulations are necessary for medical gases, the Secretary shall issue final regulations revising the Federal drug regulations with respect to medical gases not later than 48 months after the date of the enactment of this Act.

(c) DEFINITIONS.—In this section:

(1) The term ''Federal drug regulations'' means regulations in title 21 of the Code of Federal Regulations pertaining to drugs.

(2) The term ''medical gas'' has the meaning given to such term in section 575 of the Federal Food, Drug, and Cosmetic Act, as added by section 821 of this Act.

(3) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

SEC. 823. RULES OF CONSTRUCTION.

Nothing in this subtitle and the amendments made by this subtitle applies with respect to—

(1) a drug that is approved prior to May 1, 2012, pursuant to an application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b);

(2) any gas listed in subparagraphs (A) through (G) of section 575(1) of the Federal Food, Drug, and Cosmetic Act, as added by section 821 of this

Act, or any combination of any such gases, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(A)(i) of such Act; and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under Section 505 or 512; or

(3) any designated medical gas added pursuant to subparagraph (H) of section 575(1) of such Act for an indication that—

(A) is not included in, or is different from, those originally added pursuant to subparagraph (H) of section 575(1) and section 576(a)(3)(A)(i)(VIII); and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

Subtitle C—Generating Antibiotic Incentives Now

SEC. 831. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505D (21 U.S.C. 355e) the following:

"SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been determined to be a qualified infectious disease product under subsection (d), then the four- and five-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the three-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the seven year period described in section 527, as applicable, shall be extended by five years.

''(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

''(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

''(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

''(2) a subsequent application filed by the same sponsor or manufacturer of a qualified infectious disease product described in paragraph (1) (or a li-

censor, predecessor in interest, or other related entity) for—

"(A) a change (not including a modification to the active moiety of the qualified infectious disease product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(B) a modification to the active moiety of the qualified infectious disease product that does not result in a change in safety or effectiveness; or

"(3) a product that does not meet the definition of a qualified infectious disease product under subsection (f) based upon its approved uses.

"(d) DETERMINATION.—The manufacturer or sponsor of a drug may request that the Secretary designate a drug as a qualified infectious disease product at any time in the drug development process prior to the submission of an application under section 505(b) for the drug, but not later than 45 days before the submission of such application. The Secretary shall, not later than 30 days after the submission of such request, determine whether the drug is a qualified infectious disease product.

''(e) REGULATIONS.—The Secretary shall promulgate regulations for carrying out this section. The Secretary shall promulgate the initial regulations for carrying out this section not later than 12 months after the date of the enactment of this section.

''(f) DEFINITIONS.—In this section:

''(1) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use that treats or prevents an infection caused by a qualifying pathogen.

''(2) QUALIFYING PATHOGEN.—The term 'qualifying pathogen' means—

''(A) resistant gram-positive pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Staphylococcus aureus (VRSA), and vancomycin-resistant enterococcus (VRE);

''(B) multidrug resistant gram-negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

''(C) multi-drug resistant tuberculosis; or

''(D) any other infectious pathogen identified for purposes of this section by the Secretary.''.

(b) APPLICATION.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act.

SEC. 832. STUDY ON INCENTIVES FOR QUALIFIED INFECTIOUS DISEASE BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—The Comptroller General of the United States shall—

(1) conduct a study on the need for incentives to encourage research on and development and marketing of qualified infectious disease biological products; and

(2) not later than 1 year after the date of the enactment of this Act, submit a report to the Congress on the results of such study, including any recommendations of the Comptroller General on appropriate incentives for addressing such need.

(b) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The term ''qualified infectious disease biological product'' means a biological product for

human use that treats or prevents an infection caused by a qualifying pathogen.

(3) The term ''qualifying pathogen'' has the meaning given to such term in section 505E of the Federal Food, Drug, and Cosmetic Act, as added by section 831 of this Act.

SEC. 833. CLINICAL TRIALS.

(a) REVIEW AND REVISION OF GUIDELINES.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, and not later than 4 years thereafter, the Secretary shall—

(A) review the guidance of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revise such guidance to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of an antibiotic and antifungal drug under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

(2) ISSUES FOR REVIEW.—At a minimum, the review under paragraph (1) shall address the appro-

priate animal models of infection, in vitro techniques, valid microbiological surrogate markers, the use of noninferiority versus superiority trials, and appropriate delta values for noninferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary of Health and Human Services makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise affect the guidance of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be used to treat or prevent a qualifying pathogen may request that the Secretary provide written recommendations for nonclinical and clinical investigations which may be conducted with the drug before it may be approved for such use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the

Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) of such drug for the use described in paragraph (1).

(c) DEFINITIONS.—In this section:

(1) The term ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) The term ''qualified infectious disease product'' has the meaning given to such term in section 505E of the Federal Food, Drug, and Cosmetic Act, as added by section 831 of this Act.

(3) The term ''qualifying pathogen'' has the meaning given to such term in section 505E of the Federal Food, Drug, and Cosmetic Act, as added by section 831 of this Act.

(4) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

SEC. 834. REASSESSMENT OF QUALIFIED INFECTIOUS DISEASE PRODUCT INCENTIVES IN 5 YEARS.

Not later than five years after the date of enactment of this Act, the Secretary of Health and Human Services

shall, in consultation with the Food and Drug Administration, Centers for Disease Control and Prevention and other appropriate agencies, 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 that contains the following:

(1)(A) The number of initial designations of drugs as qualified infectious disease products under section 505E of the Federal Food, Drug, and Cosmetic Act;

(B) the number of qualified infectious disease products approved under this program; and

(C) whether such products address the need for antibacterial and antifungal drugs to treat serious and life-threatening infections.

(2) Recommendations—

(A) based on the information in paragraph (1) and any other relevant data, on any changes that should be made to the list of pathogens that are defined as qualifying pathogens under section 505E(f)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 831; and

(B) on whether any additional program (such as the development of public-private col-

laborations to advance antibacterial drug innovation) or changes to the incentives under this subtitle may be needed to promote the development of antibacterial drugs.

(3) An examination of—

(A) the adoption of programs to measure the use of antibacterial drugs in health care settings; and

(B) the implementation and effectiveness of antimicrobial stewardship protocols across all health care settings.

(4) Any recommendations for ways to encourage further development and establishment of stewardship programs.

SEC. 835. GUIDANCE ON PATHOGEN-FOCUSED ANTIBACTERIAL DRUG DEVELOPMENT.

(a) DRAFT GUIDANCE.—Not later than June 30, 2013, in order to facilitate the development of antibacterial drugs for serious or life-threatening bacterial infections, particularly in areas of unmet need, the Secretary of Health and Human Services shall publish draft guidance that—

(1) specifies how preclinical and clinical data can be utilized to inform an efficient and streamlined pathogen-focused antibacterial drug develop-

ment program that meets the approval standards of the Food and Drug Administration; and

(2) provides advice on approaches for the development of antibacterial drugs that target a more limited spectrum of pathogens.

(b) FINAL GUIDANCE.—Not later than December 31, 2014, after notice and opportunity for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall publish final guidance consistent with this section.

Subtitle D—Accelerated Approval

SEC. 841. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—The Congress finds as follows:

(A) The Food and Drug Administration (referred to in this subsection as the ''FDA'') serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate.

This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of the Congress that the FDA should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this sec-

tion, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(b) EXPEDITED APPROVAL.—Section 506 (21 U.S.C. 356) is amended to read as follows:

"SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

''(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request

for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

''(b) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) of this Act or section 351(a) of the Public Health Service Act upon making a determination that the product has an effect on—

"(A) a surrogate endpoint that is reasonably likely to predict clinical benefit; or

"(B) a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit,

taking into account the severity or rarity of the disease or condition and the availability of alternative treatments. The evidence to support that an endpoint is reasonably likely to predict clinical benefit may include epidemiological, pathophysiologic, pharmacologic, therapeutic or other evidence developed using, for example, biomarkers, or other scientific methods or tools.

"(2) LIMITATION.—Approval of a product under this subsection may, as determined by the Secretary, be subject to the following requirements—

"(A) that the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect of the product on irreversible morbidity or mortality or other clinical benefit; and

"(B) that the sponsor submit copies of all promotional materials related to the product, at least 30 days prior to dissemination of the materials—

"(i) during the preapproval review period; and

"(ii) following approval, for a period that the Secretary determines to be appropriate.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved pursuant to this subsection using expedited procedures (as prescribed by the Secretary in regulations, which shall include an opportunity for an informal hearing) if—

"(A) the sponsor fails to conduct any required post-approval study of the product with due diligence;

"(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

''(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

''(A) provides a schedule for submission of information necessary to make the application complete; and

''(B) pays any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals

identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

''(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.''.

SEC. 842. GUIDANCE; AMENDED REGULATIONS.

(a) INITIAL GUIDANCE.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (in this subtitle referred to

as the ''Secretary'') shall issue draft guidance to implement the amendment made by section 841.

(b) FINAL GUIDANCE.—Not later than one year after the issuance of draft guidance under subsection (a), after an opportunity for public comment, the Secretary shall—

(1) issue final guidance to implement the amendment made by section 841; and

(2) amend the regulations governing accelerated approval in parts 314 and 601 of title 21, Code of Federal Regulations, as necessary to conform such regulations with the amendments made by section 841.

(c) CONSIDERATIONS.—In developing the guidance under subsections (a) and (b)(1) and the amendments under subsection (b)(2), the Secretary shall consider—

(1) issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act (as amended by section 841) for drugs designated for a rare disease or condition under section 526 of the Federal, Food, Drug, and Cosmetic Act; and

(2) how to incorporate novel approaches to the review of surrogate endpoints based on pathophysiologic and pharmacologic evidence in such guidance, especially in instances where the low preva-

lence of a disease renders the existence or collection of other types of data unlikely or impractical.

(d) NO DELAY IN REVIEW OR APPROVAL.—The issuance (or non-issuance) of guidance or conforming regulations implementing the amendments made by section 841 shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by section 841.

SEC. 843. INDEPENDENT REVIEW.

(a) IN GENERAL.—The Secretary may, in conjunction with other planned reviews of the new drug review process, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs, to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by section 841, and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions.

(b) CONSULTATION.—Any evaluation under subsection (a) shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

Subtitle E—Critical Path Reauthorization

SEC. 851. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subsection (f) of section 566 (21 U.S.C. 360bbb–5) is amended to read as follows:

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $6,000,000 for each of fiscal years 2013 through 2017.''.

Subtitle F—Miscellaneous

SEC. 861. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ''2012'' and inserting ''2017''.

SEC. 862. EXTENSION OF PERIOD FOR FIRST APPLICANT TO OBTAIN TENTATIVE APPROVAL WITHOUT FORFEITING 180-DAY EXCLUSIVITY PERIOD.

(a) EXTENSION OF PERIOD.—

(1) IN GENERAL.—Subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)) is amended to read as follows:

''(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first appli-

cant fails to obtain tentative approval of the application within 45 months after the date on which—

"(aa) the application is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV), or

"(bb) the application is amended to first contain such a certification,

unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is so filed or amended.".

(2) APPLICABILITY.—

(A) IN GENERAL.—Subject to subsection (b), the amendment made by paragraph (1) applies—

(i) only with respect to an application that is filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) on or after the day that is 30 months prior to the date of the enactment of this Act; and

(ii) only if no certification under paragraph (2)(A)(vii)(IV) of such section 505(j) was made before such day with respect to the listed drug (as such term is used in such section 505(j)).

(B) CERTAIN APPLICATIONS.—If an application was filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) prior to the day specified in subparagraph (A)(i) and, on such day, contained a certification described in paragraph (2)(A)(vii)(IV), the application shall be subject to paragraph (5)(D)(i)(IV) of such section 505(j) as in effect on the day before the date of the enactment of this Act.

(b) INCREMENTAL REDUCTION OF EXTENDED PERIOD.—

(1) PERIOD DURATION.—

(A) Effective on October 1, 2013, subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)), as amended by subsection (a)(1) of this section, is amended by striking ''45 months'' and inserting ''42 months''.

(B) Effective on October 1, 2014, subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)), as amended by subparagraph (A) of this paragraph, is amended by striking ''42 months'' and inserting ''39 months''.

(C) Effective on October 1, 2015, subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)), as amended by subparagraph (B) of this paragraph, is amended by striking ''39 months'' and inserting ''36 months''.

(D) Effective on October 1, 2016, subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)), as amended by subparagraph (C) of this paragraph, is amended by striking ''36 months'' and inserting ''33 months''.

(E) Effective on October 1, 2017, subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)), as amended by subparagraph (D) of this paragraph, is amended by striking ''33 months'' and inserting ''30 months''.

(2) APPLICABILITY.—

(A) The amendments made by subparagraphs (A), (B), (C), and (D) of paragraph (1) apply only with respect to an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that—

(i) is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV) during the period of one fiscal year beginning on the effective date of the respective amendment; or

(ii) is amended to initially contain such a certification during such period.

(B) The amendment made by paragraph (1)(E) applies only with respect to an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that—

(i) is filed and initially contains a certification described in paragraph (2)(A)(vii)(IV) on or after October 1, 2017; or

(ii) is amended to initially contain such a certification on or after October 1, 2017.

(c) CONFORMING AMENDMENT.—Subparagraph (G) of section 505(q)(1) (21 U.S.C. 355(q)(1)) is amended—

(1) in the subparagraph heading, by striking ''30-MONTH PERIOD'' and inserting ''PERIOD''; and

(2) by striking ''the 30-month period'' and inserting ''the period''.

SEC. 863. FINAL AGENCY ACTION RELATING TO PETITIONS AND CIVIL ACTIONS.

Section 505(q) (21 U.S.C. 355(q)) is amended—

(1) in paragraph (1)(F), by striking ''180 days'' and inserting ''150 days''; and

(2) in paragraph (2)(A)—

(A) in the subparagraph heading, by striking ''180'' and inserting ''150''; and

(B) in clause (i), by striking ''180-day'' and inserting ''150-day''.

SEC. 864. DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.

(a) IN GENERAL.—Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

''(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal

Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.''.

(b) APPLICATION.—The amendment made by subsection (a) shall apply to any petition that is submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), on or after the date of enactment of this Act.

SEC. 865. RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM.

Subchapter B of Chapter V (21 U.S.C. 360aa et seq.) is amended by adding at the end the following:

''SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

"(2) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a rare pediatric disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the rare pediatric disease product application.

"(3) RARE PEDIATRIC DISEASE.—The term 'rare pediatric disease' means a disease that meets each of the following criteria:

"(A) The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

"(B) The disease is a rare disease or condition, within the meaning of section 526.

"(4) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term 'rare pediatric disease product application' means a human drug application, as defined in section 735(1), that—

"(A) is for a drug or biological product—

"(i) that is for the prevention or treatment of a rare pediatric disease;

"(ii) that contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of this Act or section 351(a) or 351(k) of the Public Health Service Act;

"(B) is submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act;

"(C) the Secretary deems eligible for priority review;

"(D) that relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;

"(E) that does not seek approval for an adult indication in the original rare pediatric disease product application; and

"(F) is approved after the date of the enactment of the Prescription Drug User Fee Amendments of 2012.

"(b) PRIORITY REVIEW VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a rare pe-

diatric disease product application upon approval by the Secretary of such rare pediatric disease product application.

''(2) TRANSFERABILITY.—

''(A) IN GENERAL.—The sponsor of a rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

''(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.

''(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012.

''(4) NOTIFICATION.—

"(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

"(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary, based on the difference between—

''(A) the average cost incurred by the Food and Drug Administration in the review of a human drug application subject to priority review in the previous fiscal year; and

''(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2012, the amount of the priority review user fee for that fiscal year.

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(4)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

''(d) DESIGNATION PROCESS.—

''(1) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate—

''(A) the new drug as a drug for a rare pediatric disease; and

''(B) the application for the new drug as a rare pediatric disease product application.

''(2) REQUEST FOR DESIGNATION.—The request for a designation under paragraph (1), shall be made at the same time a request for designation of orphan disease status under section 526 or fast-track designation under section 506 is made. Requesting designation under this subsection is not a prerequisite to receiving a priority review voucher under this section.

''(3) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted

under paragraph (1), the Secretary shall determine whether—

"(A) the disease or condition that is the subject of such request is a rare pediatric disease; and

"(B) the application for the new drug is a rare pediatric disease product application.

"(e) MARKETING OF RARE PEDIATRIC DISEASE PRODUCTS.—

"(1) IN GENERAL.—The Secretary shall deem a rare pediatric disease product application incomplete if such application does not contain a description of the plan of the sponsor of such application to market the product in the United States.

"(2) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the rare pediatric disease product for which such voucher was awarded is not marketed in the United States within the 365 day period beginning on the date of the approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act.

"(3) POSTAPPROVAL PRODUCTION REPORT.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not

later than 5 years after the approval of the applicable rare pediatric disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

"(A) The estimated population in the United States suffering from the rare pediatric disease.

"(B) The estimated demand in the United States for such rare pediatric disease product.

"(C) The actual amount of such rare pediatric disease product distributed in the United States.

"(f) NOTICE AND REPORT.—

"(1) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Web site of the Food and Drug Administration not later than 30 days after the occurrence of each of the following:

"(A) The Secretary issues a priority review voucher under this section.

"(B) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Pub-

lic Health Service Act for which the sponsor of the application used a priority review voucher under this section.

''(2) REPORT.—If, after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, a sponsor of an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug uses a priority review voucher under this section for such application, the Secretary shall 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 document—

''(A) notifying such Committees of the use of such voucher; and

''(B) identifying the drug for which such priority review voucher is used.

''(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act.

''(h) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any

other provisions of this Act or the Public Health Service Act that encourage the development of drugs for tropical diseases and rare pediatric diseases.

''(i) GAO STUDY AND REPORT.—

''(1) STUDY.—

''(A) IN GENERAL.—Beginning on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, the Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under this section in the development of on human drug products that treat or prevent such diseases.

''(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

''(i) The indications for which each rare disease product for which a priority review voucher was awarded was approved under section 505 or section 351 of the Public Health Service Act.

''(ii) Whether, and to what extent, an unmet need related to the treatment or

prevention of a rare pediatric disease was met through the approval of such a rare disease product.

''(iii) The value of the priority review voucher if transferred.

''(iv) Identification of each drug for which a priority review voucher was used.

''(v) The length of the period of time between the date on which a priority review voucher was awarded and the date on which it was used.

''(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), the Comptroller General shall 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 containing the results of the study under paragraph (1).''.

SEC. 866. COMBATING PRESCRIPTION DRUG ABUSE.

(a) IN GENERAL.—To combat the significant rise in prescription drug abuse and the consequences of such abuse, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') and in coordina-

tion with other Federal agencies, as appropriate, shall review current Federal initiatives and identify gaps and opportunities with respect to ensuring the safe use of prescription drugs with the potential for abuse.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue a report to Congress on the findings of the review under subsection (a). Such report shall include recommendations on—

(1) how best to leverage and build upon existing Federal and federally funded data sources, such as prescription drug monitoring program data and the sentinel initiative of the Food and Drug Administration under section 505(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool;

(2) how best to develop and disseminate widely best practices models and suggested standard requirements to States for achieving greater interoperability and effectiveness of prescription drug monitoring programs, especially with respect to producing standardized data on adverse events, patient safety, and patient outcomes; and

(3) how best to develop provider and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON TAMPER-DETERRENT PRODUCTS.—Not later than 6 months after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall promulgate guidance on the development of tamper-deterrent drug products.

SEC. 867. ASSESSMENT AND MODIFICATION OF REMS.

(a) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—Section 505–1(g) (21 U.S.C. 355–1(g)) is amended—

(1) in paragraph (1), by striking ", and propose a modification to,";

(2) in paragraph (2)—

(A) in the matter before subparagraph (A)—

(i) by striking ", subject to paragraph (5),"; and

(ii) by striking ", and may propose a modification to,";

(B) in subparagraph (C), by striking "new safety or effectiveness information indicates that" and all that follows and inserting the following: "an assessment is needed to evaluate

whether the approved strategy should be modified to—

"(i) ensure the benefits of the drug outweigh the risks of the drug; or

"(ii) minimize the burden on the health care delivery system of complying with the strategy."; and

(C) by striking subparagraph (D);

(3) in paragraph (3), by striking "for a drug shall include—" and all that follows and inserting the following "for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified."; and

(4) by amending paragraph (4) to read as follows:

"(4) MODIFICATION.—

"(A) ON INITIATIVE OF RESPONSIBLE PERSON.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the

addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, modification, or removal of any goal or element of the strategy.

''(B) ON INITIATIVE OF SECRETARY.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

''(i) ensure the benefits of the drug outweigh the risks of the drug; or

''(ii) minimize the burden on the health care delivery system of complying with the strategy.''.

(b) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS AND MODIFICATIONS OF APPROVED STRATEGIES.—Section 505–1(h) (21 U.S.C. 355–1(h)) is amended—

(1) in the subsection heading by inserting ''AND MODIFICATIONS'' after ''REVIEW OF ASSESSMENTS'';

(2) in paragraph (1)—

(A) by inserting ''and proposed modification to'' after ''under subsection (a) and each assessment of''; and

(B) by inserting '', and, if necessary, promptly initiate discussions with the responsible person about such proposed strategy, assessment, or modification'' after ''subsection (g)'';

(3) by striking paragraph (2);

(4) by redesignating paragraphs (3) through (9) as paragraphs (2) through (8), respectively;

(5) in paragraph (2), as redesignated by paragraph (4)—

(A) by amending subparagraph (A) to read as follows:

''(A) IN GENERAL.—

''(i) TIMEFRAME.—Unless the dispute resolution process described under paragraph (3) or (4) applies, and, except as provided in clause (ii) or clause (iii) below, the Secretary, in consultation with the of-

fices described in subsection (c)(2), shall review and act on the proposed risk evaluation and mitigation strategy for a drug or any proposed modification to any required strategy within 180 days of receipt of the proposed strategy or modification.

''(ii) MINOR MODIFICATIONS.—The Secretary shall review and act on a proposed minor modification, as defined by the Secretary in guidance, within 60 days of receipt of such modification.

''(iii) REMS MODIFICATION DUE TO SAFETY LABEL CHANGES.—Not later than 60 days after the Secretary receives a proposed modification to an approved risk evaluation and mitigation strategy to conform the strategy to approved safety label changes, including safety labeling changes initiated by the sponsor in accordance with FDA regulatory requirements, or to a safety label change that the Secretary has directed the holder of the application to make pursuant to section 505(o)(4), the Secretary shall review and act on such pro-

posed modification to the approved strategy.

''(iv) GUIDANCE.—The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.''; and

(B) by amending subparagraph (C) to read as follows:

''(C) PUBLIC AVAILABILITY.—Upon acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary shall make publicly available an action letter describing the actions taken by the Secretary under such subparagraph (A).''.

(6) in paragraph (4), as redesignated by paragraph (4)—

(A) in subparagraph (A)(i)—

(i) by striking ''Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the'' and inserting ''The''; and

(ii) by inserting ", after the sponsor is required to make a submission under subsection (a)(2) or (g)," before "request in writing"; and

(B) in subparagraph (I)—

(i) by striking clauses (i) and (ii); and

(ii) by striking "if the Secretary—" and inserting "if the Secretary has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under subparagraphs (B), (F), and (G), respectively.";

(7) in paragraph (5), as redesignated by paragraph (4)—

(A) in subparagraph (A), by striking "any of subparagraph (B) through (D)" and inserting "subparagraph (B) or (C)"; and

(B) in subparagraph (C), by striking "paragraph (4) or (5)" and inserting "paragraph (3) or (4)"; and

(8) in paragraph (8), as redesignated by paragraph (4), by striking "paragraphs (7) and (8)" and inserting "paragraphs (6) and (7).".

(c) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance that, for purposes of section 505–1(h)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h)(2)(A)), describes the types of modifications to approved risk evaluation and mitigation strategies that shall be considered to be minor modifications of such strategies.

SEC. 868. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 568. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

''(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

''(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and

Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

''(2) CONSULTATION WITH EXTERNAL EXPERTS.—

''(A) IN GENERAL.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and

the necessary expertise can be provided by the external experts.

''(B) EXTERNAL EXPERTS.—For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

''(b) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

''(1) rare diseases;

''(2) the severity of rare diseases;

''(3) the unmet medical need associated with rare diseases;

''(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

''(5) an assessment of the benefits and risks of therapies to treat rare diseases;

''(6) the general design of clinical trials for rare disease populations and subpopulations; and

''(7) the demographics and the clinical description of patient populations.

''(c) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employ-

ees, as defined under section 202 of title 18, United States Code.

"(d) PROTECTION OF CONFIDENTIAL INFORMATION AND TRADE SECRETS.—

"(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

"(2) CONSENT REQUIRED FOR DISCLOSURE.—The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18, United States Code) or the disclosure is otherwise authorized by law.

"(e) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary

to consult with individuals and organizations as authorized prior to the date of enactment of this section.

''(f) NO RIGHT OR OBLIGATION.—

''(1) NO RIGHT TO CONSULTATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

''(2) NO ALTERING OF GOALS.—Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

''(3) NO CHANGE TO NUMBER OF REVIEW CYCLES.—Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.

''(g) NO DELAY IN PRODUCT REVIEW.—Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 505(i), a new drug application under section 505(b), or a biologics license application under section 351 of the Public Health Service Act, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or ap-

propriate Division Director), as appropriate, shall determine that—

''(1) such consultation will—

''(A) facilitate the Secretary's ability to complete the Secretary's review;

''(B) address outstanding deficiencies in the application; and

''(C) increase the likelihood of an approval decision in the current review cycle; or

''(2) the sponsor authorized such consultation.''.

SEC. 869. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 841, is further amended—

(1) by redesignating subsection (d) as subsection (f);

(2) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(3) by inserting before subsection (b), as so redesignated, the following:

''(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other

drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—

''(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take

such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

''(i) holding meetings with the sponsor and the review team throughout the development of the drug;

''(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable;

''(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison be-

tween the review team and the sponsor; and

''(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.'';

(4) in subsection (f)(1), as so redesignated, by striking ''applicable to accelerated approval'' and inserting ''applicable to breakthrough therapies, accelerated approval, and''; and

(5) by adding at the end the following:

''(g) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, with respect to this section for the previous fiscal year—

''(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

''(2) the number of products designated as a breakthrough therapy; and

''(3) for each product designated as a breakthrough therapy, a summary of the actions taken under subsection (a)(3).''.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(B) AMENDED REGULATIONS.—

(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall

amend such regulations not later than 2 years after the date of enactment of this Act.

(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by section only as described in clause (ii).

(2) REQUIREMENTS.—Guidance issued under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under

section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) CONFORMING AMENDMENTS.—Section 506B(e) (21 U.S.C. 356b) is amended by striking ''section 506(b)(2)(A)'' each place such term appears and inserting ''section 506(c)(2)(A)''.

SEC. 870. GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.

(a) QUALIFIED TESTING DEFINITION.—Section 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A)(ii)) is amended by striking ''after the date such drug is designated under section 526 of such Act and''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) AUTHORIZATION OF APPROPRIATIONS.—For grants and contracts under subsection (a), there is authorized to be appropriated $30,000,000 for each of fiscal years 2013 through 2017.''.

TITLE IX—DRUG SHORTAGES

SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

(a) IN GENERAL.—Section 506C (21 U.S.C. 356c) is amended to read as follows:

''SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF MANUFACTURING OF CERTAIN DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug subject to section 503(b)(1)—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining; or

"(C) intended for use in the prevention or treatment of a debilitating disease or condition; and

"(2) that is not a radio pharmaceutical drug product, a product derived from human plasma protein and their recombinant analogs, or any other product as designated by the Secretary,

shall notify the Secretary of a discontinuance of the manufacture of the drug, or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the manufacturer's supply of the drug, and the reason for such discontinuance or interruption, in accordance with subsection (b).

"(b) TIMING.—A notice required by subsection (a) shall be submitted to the Secretary—

"(1) at least 6 months prior to the date of the discontinuance or interruption; or

"(2) if compliance with paragraph (1) is not possible, as soon as practicable.

"(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation or interruption of the manufacture of the drugs described in subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, as described in section 506D.

''(d) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(e) COORDINATION WITH ATTORNEY GENERAL.—Not later than 30 days after the receipt of a notification described in subsection (a), the Secretary shall—

''(1) determine whether the notification pertains to a controlled substance subject to a production quota under section 306 of the Controlled Substances Act; and

''(2) if necessary, as determined by the Secretary—

''(A) notify the Attorney General that the Secretary has received such a notification;

''(B) request that the Attorney General increase the aggregate and individual production quotas under section 306 of the Controlled Substances Act applicable to such controlled substance and any ingredient therein to a level the Secretary deems necessary to address a shortage of a controlled substance based on the best available market data; and

"(C) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (C) available to the public on the Web site of the Food and Drug Administration.

"(f) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

"(1) the Secretary shall issue a letter to such person informing such person of such failure;

"(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

"(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the pub-

lic on the Web site of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.''.

(b) REGULATIONS.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, after issuing a notice of proposed rule and holding a public hearing, shall promulgate final regulations that implement the amendment made by subsection (a).

(2) CONTENTS.—Such regulations shall, for purposes of section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c)—

(A) define the terms ''life-supporting'', ''life-sustaining'', and ''intended for use in the prevention or treatment of a debilitating disease or condition''; and

(B) define the term ''interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the manufactur-

er's supply of the drug'' to mean a change in production that is highly likely to lead to more than a negligible reduction in the supply of the drug and affects the ability of the manufacturer to meet demand for such drug, but not to include a change in production due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

SEC. 902. DRUG SHORTAGE LIST.

Title V (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following new section:

"SEC. 506D. DRUG SHORTAGE LIST.

''(a) ESTABLISHMENT.—The Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States.

''(b) CONTENTS.—For each drug on such list, the Secretary shall include the following information:

''(1) The name of the drug in shortage.

''(2) The name of each manufacturer of such drug.

''(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

''(A) Requirements related to complying with good manufacturing practices.

''(B) Regulatory delay.

''(C) Shortage of an active ingredient.

''(D) Shortage of an inactive ingredient component.

''(E) Discontinuation of the manufacture of the drug.

''(F) Delay in shipping of the drug.

''(G) Demand increase for the drug.

''(4) The estimated duration of the shortage as determined by the Secretary.

''(c) PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

''(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

''(3) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available under paragraph (1) if the Secretary determines that disclosure of such information would adversely affect the public

health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients).''.

SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

''(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

''(A) complete review of such request; and

''(B)(i) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or

''(ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination. The Secretary shall make the written response provided under subparagraph (B)(ii) available to the public on the Web site of the Food and Drug Administration.

''(2) A request is described in this paragraph if—

''(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 506D of the Federal Food, Drug, and Cosmetic Act;

''(B) the request is submitted by the manufacturer of the controlled substance; and

''(C) the controlled substance is in schedule II.''.

SEC. 904. EXPEDITED REVIEW OF MAJOR MANUFACTURING CHANGES FOR POTENTIAL AND VERIFIED SHORTAGES OF DRUGS THAT ARE LIFE-SUPPORTING, LIFE-SUSTAINING, OR INTENDED FOR USE IN THE PREVENTION OF A DEBILITATING DISEASE OR CONDITION.

Subsection (c) of section 506A (21 U.S.C. 356a) is amended by adding at the end the following new paragraph:

''(3) CHANGES ADDRESSING A DRUG SHORTAGE.—

''(A) CERTIFICATION.—

''(i) DESCRIPTION.—A certification is described in this subparagraph if the manufacturer, having notified the Secretary of an interruption or discontinuance of a drug

in accordance with Section 506C, certifies (in such certification) that the major manufacturing change for which approval is being sought may prevent or alleviate a discontinuance or interruption of such drug.

''(ii) BAD FAITH EXCEPTION.—Subparagraphs (B) and (C) do not apply in the case of a certification which the Secretary determines to be made in bad faith.

''(B) EXPEDITED REVIEW.—If a certification described in subparagraph (A) is submitted in connection with a supplemental application for a major manufacturing change, the Secretary shall—

''(i) expedite any technical review or inspection necessary for consideration of the supplemental application;

''(ii) provide any technical assistance necessary to facilitate approval of the supplemental application; and

''(iii) not later than 60 days after receipt of the certification, complete review of the supplemental application.''.

SEC. 905. STUDY ON DRUG SHORTAGES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study to examine the cause of drug shortages and formulate recommendations on how to prevent or alleviate such shortages.

(b) CONSIDERATION.—In conducting the study under this section, the Comptroller General shall consider the following questions:

(1) What are the dominant characteristics of drugs that have gone into actual shortage over the preceding three years?

(2) Are there systemic high-risk factors (such as drug pricing structure, including Federal reimbursements, or the number of manufacturers producing a drug product) that have led to the concentration of drug shortages in certain drug products that have made such products vulnerable to drug shortages?

(3) Is there a reason why drug shortages have occurred primarily in the sterile injectable market and in certain therapeutic areas?

(4) How have regulations, guidance documents, regulatory practices, and other actions of Federal departments and agencies (including the effectiveness of interagency and intraagency coordination,

communication, strategic planning, and decision-making) affected drug shortages?

(5) How does hoarding affect drug shortages?

(6) How would incentives alleviate or prevent drug shortages?

(7) How are healthcare providers, including hospitals and physicians responding to drug shortages, to what extent are such providers able to adjust care effectively to compensate for such shortages, and what impediments exist that hinder provider ability to adjust to such shortages?

(c) CONSULTATION WITH STAKEHOLDERS.—In conducting the study under this section, the Comptroller General shall consult with relevant stakeholders, including physicians, pharmacists, hospitals, patients, drug manufacturers, and other health providers.

(d) REPORT.—Note later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the results of the study under this section.

SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.

Not later than 18 months after the date of the enactment of this Act, and annually thereafter, the Secretary

of Health and Human Services shall 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 drug shortages that—

(1) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

(2) describes the Food and Drug Administration's efforts to expedite the review of new manufacturing sites, new suppliers, and specification changes to prevent or alleviate a drug shortage;

(3) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(4) identifies the number of, and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(5) identifies the number of instances in which the Food and Drug Administration asked firms to increase production to prevent or alleviate a shortage;

(6) identifies the number of notifications submitted to the Secretary under section 506C of the Federal Food, Drug, and Cosmetic Act, as amended by section 901 of this Act, including the percentage of such notifications for a drug that is a sterile injectable;

(7) describes the Food and Drug Administration's implementation of section 506D of the Federal Food, Drug, and Cosmetic Act (relating to a drug shortage list), as added by section 902 of this Act, and identifies—

(A) the name of each drug on the list under such section 506D at any point during the period covered by the report;

(B) the name of each manufacturer of each such drug;

(C) the reason for the shortage of each such drug; and

(D) the anticipated or, if known, actual duration of the shortage of each such drug;

(8) identifies whether, and how, the Food and Drug Administration expedited the review of regulatory submissions to prevent or alleviate shortages, including how the Administration utilized the authority in section 506A(c)(3) of the Federal Food, Drug, and Cosmetic Act, as added by section 904 of this Act;

(9) identifies the number of certifications submitted under such section 506A(c)(3) and, for each such certification, whether the Food and Drug Administration completed expedited review within 60 days as required by subparagraph (B) of such section 506A(c)(3);

(10) describes the Secretary's public engagement on drug shortages with stakeholders, including physicians, pharmacists, patients, hospitals, drug manufacturers, and other health providers; and

(11) contains the Secretary's plan for addressing drug shortages in the upcoming year, including with respect to the issues described in paragraphs (1) through (10).

SEC. 907. ATTORNEY GENERAL REPORT ON DRUG SHORTAGES.

Not later than 6 months after the date of the enactment of this Act, and annually thereafter, the Attorney

General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages that—

(1) identifies the number of requests received under section 306(h) of the Controlled Substances Act (as added by section 903 of this Act), the average review time for such requests, the number of requests granted and denied under such section, and, for each of the requests denied under such section, the basis for such denial;

(2) describes the coordination between the Drug Enforcement Administration and Food and Drug Administration on efforts to prevent or alleviate drug shortages; and

(3) identifies drugs containing a controlled substance subject to section 306 of the Controlled Substances Act when such a drug is determined by the Secretary of Health and Human Services to be in shortage.

SEC. 908. HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE.

Chapter V (21 U.S.C. 351 et seq.), as amended by section 902 of this Act, is further amended by inserting after section 506D the following:

"SEC. 506E. HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE.

''(a) DEFINITIONS.—In this section:

''(1) DRUG.—The term 'drug' excludes any controlled substance (as such term is defined in section 102 of the Controlled Substances Act).

''(2) HEALTH SYSTEM.—The term 'health system' means a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

''(3) REPACKAGE.—For the purposes of this section only, the term 'repackage', with respect to a drug, means to divide the volume of a drug into smaller amounts in order to—

''(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list described in subsection (b); and

''(B) facilitate access to the drug by hospitals within the same health system.

''(b) EXCLUSION FROM REGISTRATION.—Notwithstanding any other provision of this Act, a hospital shall not be considered an establishment for which registration is required under section 510 solely because it repackages a drug and transfers it to another hospital within the same

health system in accordance with the conditions in subsection (c)—

"(1) during any period in which the drug is listed on the Drug Shortage List of the Food and Drug Administration; or

"(2) during the 60-day period following any period described in paragraph (1).

"(c) CONDITIONS.—Subsection (b) shall only apply to a hospital, with respect to the repackaging of a drug for transfers to another hospital within the same health system, if the following conditions are met:

"(1) DRUG FOR INTRASYSTEM USE ONLY.—In no case may a drug that has been repackaged in accordance with this section be sold or otherwise distributed by the health system or a hospital within the system to an entity or individual that is not a hospital within such health system.

"(2) COMPLIANCE WITH STATE RULES.—Repackaging of a drug under this section shall be done in compliance with applicable State requirements in which the health system is located.

"(d) TERMINATION.—This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and

safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage.''.

○