[DISCUSSION DRAFT]

112TH CONGRESS
2D SESSION

H. R. _____

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

M__. _____ introduced the following bill; which was referred to the Committee on _____

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 "_____ Act of 2012".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

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 Act 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.

Paragraph (8) of section 735 (21 U.S.C. 379g) is amended to read as follows:

''(8) The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (Washington–Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for October 1996.''.

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)(E), by striking ''subsection (d)'' and inserting ''subsection (d) or (e)'';

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

(I) by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(II) by striking ''subsections (c), (d), (f), and (g)'' and inserting ''subsections (c), (d), (e), (g), and (h)'';

(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 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 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 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 ap-

plications (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 investiga-

tional 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 an-

nual 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, establish, 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.'';

(4) in subsection (d)(4)(A), by striking ''DEFINITION'' and inserting ''SMALL BUSINESS DEFINED'';

(5) by redesignating subsections (e) through (k) as subsections (f) though (l), respectively;

(6) by inserting after subsection (d) the following new subsection:

''(e) FEE WAIVER FOR CERTAIN DRUGS.—The Secretary shall grant a waiver from or reduction of one or more fees established under subsection (a)(1) with respect to a human drug application or supplement if the Secretary finds that—

''(1) such waiver or reduction is necessary to prevent or alleviate a verified or potential drug shortage; and

''(2) the application or supplement is for a drug described in section 506C(a).'';

(7) 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 ''subject to subparagraph (C), shall be retained''; and

(ii) 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 ac-

cordance 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''; and

(8) in subsection (j), as redesignated, by striking ''subsection (d)'' and inserting ''subsection (d) or (e)''.

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; and

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

''(i) the number of applications for approval of a new drug or new molecular entity under section 505(b) of this Act or section 351(a) of the Public Health Service

Act filed per fiscal year by each review division;

''(ii) the percentage of such applications approved by each review division;

''(iii) the total number of review cycles per such approval and the average and median review cycles per such application by each review division;

''(iv) the average and median review times per such application by each review division;

''(v) the percentage of applications that are considered pursuant to accelerated approval by each review division;

''(vi) the percentage of such applications that are approved based on one clinical study by each review division; and

''(vii) the number of full-time equivalent positions and overall budget assigned to 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.—The amendments made by sections 102 and 103 cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendments made by section 104 cease to be effective January 31, 2018.

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 section 106 of the Prescription Drug User Fee Amendments of 2007 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day

before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that 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—FEES RELATING TO DEVICES

SEC. 201. [TO BE SUPPLIED].

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 Administra-

tion 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 when it arrives in the appropriate electronic portal of the Food and Drug Administration or, if in paper form,

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

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—

''(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) except as provided in subsection (o) (relating to waivers) 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 change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

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

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

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

''(d) ANNUAL FEE SETTING.—

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

''(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog

fee for generic drug applications pending on October 1, 2012, the drug master file fee, the 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 REF-

ERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

"(A) the sum of—

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

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

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

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

"(f) IDENTIFICATION OF FACILITIES.—

"(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall cause to be published in the Federal Register a notice requiring each person that owns a

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

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

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

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

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

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

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

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

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

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

''(4) CERTAIN SITES AND ORGANIZATIONS.—

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

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

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

"(ii) a clinical research organization;

"(iii) a contract analytical testing site; or

"(iv) a contract repackager site.

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

"(D) INSPECTION AUTHORITY.—The Secretary's 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 af-

filiate 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 subsection (p)(3) applicable to the fiscal year involved.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the

costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

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

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for

the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

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

''(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

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

''(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

''(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been 'substantially complete' on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.

''(o) FEE WAIVER FOR CERTAIN DRUGS.—The Secretary shall grant a waiver from or reduction of one or more fees established under subsection (a)(1) or (a)(3) with respect to an abbreviated new drug application or a prior approval supplement if the Secretary finds that—

''(1) such waiver or reduction is necessary to prevent or alleviate a verified or potential drug shortage; and

''(2) the application or supplement is for a drug described in section 506C(a).''.

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.—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 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.

''(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.—The amendments made by section 302 cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendments made by section 303 cease to be effective 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 received 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 OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

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 related to human generic drug activities (as defined in section 744A).

"(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are the performance goals with respect to section 744A (regarding assessment and use of human generic drug fees), as set forth in the letters de-

scribed in section 301(b) of the Generic Drug User Fee Amendments of 2012.

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

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

TITLE 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 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 Com-

mittee 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 biosimilar biological product development, biosimilar biological product applications, and supplements:

''(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, bio-

similar 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 're-activation fee') by the earlier of the following:

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

ological 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)(ii), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establish-

ment 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 manufac-

tured at the establishment, subject to clause (ii).

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

''(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

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

''(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before

manufacture of the biosimilar biological product was begun,

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

''(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

''(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (b)(1)(F).

''(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

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

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

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

''(b) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

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

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

''(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal

year shall be equal to 20 percent of the amount of the fee established under section 736(c)(5) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

"(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(5) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

"(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(5) for a prescription drug establishment for that fiscal year.

"(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(5) for a prescription drug product for that fiscal year.

''(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

''(c) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

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

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

''(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in

the same manner as an entity that is not a small business.

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

''(3) SMALL BUSINESS DEFINED.—In this subsection, the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug 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 col-

lected 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 appli-

cations (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 associated with the process for the review of biosimilar biological product applications.

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

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

''(e) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.''.

SEC. 404. SUNSET DATES.

(a) AUTHORIZATION.—The amendment made by section 402 shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendment made by section 403 shall cease to be effective 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 section 106 of the Prescription Drug User Fee Amendments of 2007 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2007, but before October 1, 2012, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 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. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT.

(a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A of the Federal Food, Drug, and Cosmetic Act (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) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(3) 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.'';

(4) in subsection (n)—

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

(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

(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, 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, 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.'';

(5) 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

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

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

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

(ii) in subparagraph (A), by striking ''for a'' and inserting '', including, with respect to a drug, an application for a''; and

(iii) in subparagraph (B), by striking ''for a'' and inserting '', including, with respect to a drug, an application for a''; and

(B) in paragraph (3)—

(i) by redesignating subparagraph (B) as subparagraph (C);

(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).'';

(iii) in subparagraph (C), 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.'';

(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 (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 300 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'';

(3) 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 300 days after the date of submis-

sion 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,'';

(4) 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.'';

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

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

(c) 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), and (p)''.

(d) 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.

SEC. 502. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

(a) IN GENERAL.— Not later than January 1, 2016, and the end of each subsequent 5-year period, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to the Congress a report that evaluates the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested in pediatric populations and properly labeled for use in children.

(b) CONTENTS.—The report under subsection (a) shall include—

(1) the number and importance of drugs and biological products for children that are being tested as a result of the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act;

(2) a description of the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(3) the number and importance of drugs and biological products for children that are not being tested for their use in pediatric populations, notwithstanding the existence of such programs;

(4) the possible reasons for the lack of testing reported under paragraph (3);

(5) the number of drugs and biological products for which testing is being done and labeling changes are required under the programs established by this Act, including—

(A) the date labeling changes are made;

(B) which labeling changes required the use of the dispute resolution process; and

(C) for labeling changes that required such dispute resolution process, a description of—

(i) the disputes;

(ii) the recommendations of the Pediatric Advisory Committee; and

(iii) the outcomes of such process;

(6) any recommendations for modifications to the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act that the Secretary determines to be appropriate, including a detailed rationale for each recommendation;

(7)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe); and

(B) the results of such efforts; and

(8)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act and section 409I of the Public Health Service Act; and

(B) any recommendations for modifications to the programs under such sections that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation.

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

Section 505C of the Federal Food, Drug, and Cosmetic Act (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. FDA'S MISSION.

Section 1003(b) (21 U.S.C. 393(b)) is amended—

(1) in paragraph (2), by striking ''with respect to such products'' and inserting ''with respect to regulated products'';

(2) in paragraph (4), by striking ''(1) through (3)'' and inserting ''(1) through (4)'';

(3) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5); and

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

''(2) establish a regulatory system that—

''(A) advances medical innovation by incorporating modern scientific tools, standards, and approaches to ensure the predictable, consistent, efficient, and reasonable review, clearance, approval, and licensing (as appropriate) of innovative products, including drugs, devices, and biological products;

''(B) protects the public health and enables patients to access novel products while promoting economic growth, innovation, competitiveness, and job creation among the industries regulated by this Act;

''(C) is based on the best available science;

''(D) allows for public participation and an open exchange of ideas;

''(E) promotes predictability, allows flexibility, and reduces uncertainty;

''(F) identifies and uses the most innovative and least burdensome tools for achieving regulatory ends;

''(G) ensures that regulations are accessible, consistent, transparent, written in plain language, and easy to understand;

''(H) measures, and seeks to improve, the actual results of regulatory requirements; and

''(I) incorporates a patient-focused benefit-risk framework that accounts for varying degrees of risk tolerance, including for people living with a life-impacting chronic disease or disability;''.

SEC. 602. 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 shall—

''(I) at least 3 months before issuance of a draft of such guidance document, publish notice in the Federal Register of the Secretary's intent to prepare such guidance document; and

''(II) during preparation and before issuance of the draft of such guidance document, meet with interested stakeholders and solicit public comment;

''(ii) if the Secretary for good cause finds that, with respect to such guidance document, compliance with clause (i) is im-

practicable, 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 3-month period beginning not later than the date of issuance of the draft of such guidance document, the Secretary shall meet with interested stakeholders and solicit public comment;

"(iii) upon issuance of a draft guidance document under clause (i) or (ii), the Secretary shall—

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

"(II) not later than 12 months after the date of issuance of a proposed draft guidance document, issue a final draft of such guidance docu-

ment in accordance with clauses (i) and (ii);

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

''(v) 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) A notice to industry guidance letter, a notice to industry advisory letter, and any similar notice that sets forth initial interpreta-

tions 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 shall be treated as a guidance document for purposes of subparagraph (C).''.

SEC. 603. CONFLICTS OF INTEREST.

Chapter VII is amended by striking section 712 (21 U.S.C. 379d–1).

SEC. 604. 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 SUBMISSION OF APPLICATIONS.

''(a) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under 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.

''(b) GUIDANCE CONTENTS.—In such guidance, the Secretary may provide a timetable for establishment by the Secretary of further standards for such electronic sub-

mission, and set forth criteria for waivers of and exemptions from the requirements of this section.

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

SEC. 605. COSMETICS [TO BE SUPPLIED].

[*Language to be inserted.***]**

TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

SEC. 701. TRACKING AND REVIEW OF APPLICATIONS FOR INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(8)(A) Upon the submission of an application for an exemption for a device under this subsection, the submission of a request to classify a device under section 513, or the submission of a report for a device under section 510(k), whichever occurs first, the Secretary shall assign a tracking number to the device.

''(B) The Secretary shall use such tracking number to record the following interactions between the Secretary and applicant with respect to the device:

''(i) Submission or approval of an application for an exemption under this subsection.

''(ii) Submission of a request to classify the device under section 513.

''(iii) Submission or clearance of a report under section 510(k).

''(iv) Any meeting or meeting request, including in anticipation of the submission of such an application or report.

''(v) Submission or approval of an application under section 515(c).

''(vi) Any formal or informal request by the Secretary for additional information.

''(vii) Any deficiency letter.

''(viii) Any response by the applicant to a request described in clause (v) or a deficiency letter.

''(ix) Any written submission by the applicant to the Food and Drug Administration.

''(x) Any other matter, as determined appropriate by the Secretary.

''(9) Upon the submission of an application for an exemption under this subsection for a device, the Secretary shall assign, to review the application, a reviewer with prior review experience with that type of device or technology or other relevant expertise.''.

SEC. 702. OTHER RULES RELATING TO INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)), as amended by section 701, is further amended—

(1) in paragraph (2)(A), by adding at the end the following: ''Procedures and conditions pursuant to the preceding sentence shall require the Secretary, in determining whether to grant such an exemption, to evaluate whether the investigational study of such a device can be conducted ethically and with reasonable risk.'';

(2) in paragraph (2)(B)(ii), by striking ''evaluate the safety and effectiveness of the device'' and inserting ''evaluate whether the investigational study is being conducted ethically and with reasonable risk'';

(3) in paragraph (4)(B), by adding at the end the following: ''The Secretary may not disapprove an application because the investigation does not or may not meet any requirement, including a data requirement, relating to the approval or clearance of a device because the Secretary believes that a different clinical testing design or plan could produce data more relevant to an approval or clearance decision.'';

(4) in paragraph (7)(A), by striking ''(7)(A) In the case'' and all that follows through the end of paragraph (7)(A) and inserting the following:

''(7)(A)(i) In the case of a person intending to investigate the safety or effectiveness of a class II or a class III device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, information (if available) regarding the expected performance of the device, and a proposed plan (including a clinical protocol) for determining—

''(I) whether there is a reasonable assurance of safety and effectiveness; or

''(II) whether the device is substantially equivalent to or is at least as safe and effective as a legally marketed device that is not subject to approval requirements under section 515.

''(ii) In the case where the Secretary fails to meet the applicant not later than 30 days after receiving a request for a meeting as described under clause (i), the proposed plan submitted in such request shall be deemed to be the agreement reached between the Secretary and the applicant under subparagraph (B) and such agreement shall not be subject to change except as provided in subparagraph (B).''; and

(5) in paragraph (7)(B)(ii), by inserting ''that has emerged since the date of the agreement and that is'' after ''substantial scientific issue''.

SEC. 703. 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 (iv); and

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

''(iii) In carrying out clause (ii), the Secretary—

''(I) shall not request information unrelated or irrelevant to a demonstration of reasonable assurance of device effectiveness;

''(II) shall consider alternative approaches to evaluating device effectiveness in order to reduce the time, effort, and cost of reaching proper resolution of the issue;

''(III) shall use all reasonable mechanisms to lessen review times and render regulatory decisions;

''(IV) shall consider whether preclinical data, such as well-designed bench and animal testing, can meet the statutory threshold for approval; and

''(V) if clinical data are needed, shall consider alternatives to randomized, controlled clinical trials and the use of surrogate endpoints.''.

(b) SUBSTANTIAL EQUIVALENCE DETERMINATION.—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 'information that is necessary to making substantial equivalence determinations' means information that—

''(I) constitutes threshold evidence supporting a determination of substantial equivalence between a new device and the predicate device to which the premarket notification submitter claims substantial equivalence; and

''(II) is relevant and directly related to the substantial equivalence determination.

''(iii) Any request for additional information under clause (i) shall be a complete request for all of the additional information that the Secretary determines would be necessary to support a determination of substantial equivalence.

''(iv) The Secretary shall use all reasonable means to employ mechanisms to increase the efficiency of premarket notification reviews and thereby reduce the time necessary to render appropriate classification determinations of substantial equivalence.''.

SEC. 704. 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) APPEAL RIGHTS AND PROCEDURES.—

''(1) APPEAL TO CENTER DIRECTOR.—Any person may, within 30 days after a significant decision described in subsection (a)(1), appeal such decision to the Director of the Center for Devices and Radio-

logical Health (in this subsection referred to as the 'Center Director').

''(2) PETITION; PROCEDURES.—The Center Director—

''(A) may require that an appeal under paragraph (1) be in writing and set forth the decision being appealed and the grounds for the appeal; and

''(B) subject to paragraph (6), may provide for such procedures as may be necessary with respect to such an appeal.

''(3) RESOLUTION BY CENTER DIRECTOR.—

''(A) MEETING.—The Center Director shall provide, upon the request of any person bringing an appeal under paragraph (1), for at least one meeting, to be held within 45 days after the filing of the appeal, to discuss the significant decision involved, the appeal of such decision, and possible resolutions of the appeal.

''(B) FINAL DECISION.—The Center Director shall issue a final written decision resolving any appeal under paragraph (1), including the grounds for such decision, not later than 90 days after the filing of the appeal.

''(4) APPEAL TO COMMISSIONER.—

''(A) IN GENERAL.—Any person who files an appeal under paragraph (1)—

''(i) within 30 days after receiving any decision of the Center Director resolving the appeal, may appeal such decision to the Commissioner; or

''(ii) if the Center Director has not made a decision resolving the appeal under paragraph (1) within 90 days after the filing of such appeal, may file directly with the Commissioner an appeal of the significant decision subject to such appeal under paragraph (1).

''(B) FINAL DECISION.—The Commissioner shall issue a final written decision resolving any appeal under subparagraph (A), including the grounds for such decision, not later than 30 days after the filing of such appeal under subparagraph (A).

''(5) REPORT.—The Commissioner shall issue a public report on at least an annual basis that sets forth—

''(A) the number of appeals under paragraph (1) and the disposition of those appeals;

''(B) for each appeal under paragraph (1), the number of days taken to reach a final decision under paragraph (3)(B);

''(C) the number of appeals to the Commissioner under paragraph (4)(A), including the number of such appeals under paragraph (4)(A)(ii), and the disposition of those appeals; and

''(D) the number of appeals for which the Commissioner does not issue a final decision within 30 days as required by paragraph (4)(B).

''(6) AUTHORITY OF SECRETARY TO ESTABLISH APPEAL PROCEDURES AND TIMELINES.—

''(A) ESTABLISHMENT.—Subject to subparagraph (B), the Secretary may, by regulation or guidance, establish appeal procedures or timelines applicable to appeals under paragraph (1) or (4).

''(B) LIMITATION.—No procedure or timeline established under subparagraph (A) may alter any requirement or extend or delay any timeline specified in any of paragraphs (1) through (5).''.

SEC. 705. 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).''.

(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. 706. NO 510(K) REPORT REQUIRED FOR CERTAIN MODIFICATIONS.

(a) IN GENERAL.—Section 510(n) (21 U.S.C. 360(n)) is amended—

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

(2) by adding at the end the following:

''(2) A report under subsection (k) is not required for a modification to a device that has been classified into class I or II under section 513 if—

''(A) the device was cleared under subsection (k) prior to such modification; and

''(B) such modification—

''(i) does not significantly affect the safety or effectiveness of the device; and

''(ii) is implemented by the manufacturer of the device.''.

(b) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall promulgate a final regulation to implement section 510(n)(2) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), including to define the phrase ''significantly affect the safety or effectiveness of the device'' in subparagraph (B)(i) of such section.

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) by striking ''under the criteria set forth'' and all that follows and inserting a period; and

(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).

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

''(v) A person submitting a request under clause (i) or (ii) may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.''.

(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 shall, to the maximum extent practicable, enter into agreements with those countries identified in clauses (i) and (ii) of section 802(b)(1)(A) regarding methods and approaches to harmonizing regulatory requirements for 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 listing the agreements entered into under section 803(c)(4) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) and itemizing the methods and approaches that have been harmonized pursuant to such section.

SEC. 732. PARTICIPATION IN INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM.

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 shall participate in the International Medical Device Regulators Forum and shall—

''(i) provide guidance to the Forum on strategies, policies, directions, membership, and other activities of the Forum;

''(ii) ensure that the representatives of the United States on the Forum are made up of an equal representation of international regulators and representatives from the device industry that are subject to regulation

''(iii) in providing guidance under clause (i), solicit, review, and consider comments from industry, academia, health care professionals, and patient groups; and

''(iv) inform the public of the Secretary's activities within the Forum and share with the public any documentation relating to the Forum's strategies, policies, and other activities, including releasing the minutes that record Forum meetings and describing Forum activities.''.

Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

SEC. 741. PERSONS ACCREDITED TO REVIEW REPORTS UNDER SECTION 510(k) AND MAKE RECOMMENDATIONS FOR INITIAL CLASSIFICATION.

(a) TIME PERIOD FOR REVIEW OF RECOMMENDATIONS OF ACCREDITED PERSONS.—Section 523(a) (21 U.S.C. 360m(a)) is amended—

(1) in paragraph (1), by striking ''reviewing reports'' and inserting ''reviewing, and making recommendations to the Secretary regarding, reports''; and

(2) in paragraph (2), by amending subparagraph (B) to read as follows:

''(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation regarding a report submitted under section 510(k) or an initial classification of a device, the Secretary shall make a determination with respect to the recommendation. If the Secretary fails to make such a determina-

tion by the end of such 30-day period, the recommendation is deemed to be accepted by the Secretary.''.

(b) ACCESS TO DEVICE INFORMATION.—Section 523(a)(2) (21 U.S.C. 360m(a)(2)), as amended by subsection (a)(2), is amended by adding at the end the following:

''(D) ACCESS TO DEVICE INFORMATION.—Subject to section 301(j), for the purpose of providing accredited persons with additional information to review reports submitted under section 510(k) and make recommendations regarding the initial classification of devices, the Secretary shall regularly publish—

''(i) detailed decision summaries for each clearance of a device under section 510(k), classification of a device under section 513, approval of an application for a device under section 515, or grant of an exemption for a device under section 520(m), occurring after the date of the enactment of this subparagraph; and

''(ii) total product life cycles information for devices.''.

(c) TYPES OF DEVICES TO BE REVIEWED.—Paragraph (3) of section 523(a) (21 U.S.C. 360m(a)) is amended to read as follows:

''(3) CERTAIN DEVICES.—

''(A) IN GENERAL.—An accredited person may be used to perform a review regarding any report submitted under section 510(k) except that an accredited person—

''(i) may not be used to perform a review of a class III device; and

''(ii) may be used to perform a review of a class II device which is intended to be permanently implantable or life sustaining or supporting only if a notification is submitted under subparagraph (B).

''(B) NOTIFICATION OF INTENT TO PERFORM A REVIEW.—Before performing a review of a report submitted under section 510(k) for a class II device which is intended to be permanently implantable or life sustaining or supporting, an accredited person shall submit to the Secretary a notification of the person's intent to perform the review. If the Secretary does not object within 60 days after receipt of such a notification, the Secretary is deemed to

allow the accredited person to perform such review. If the Secretary objects to performance of the review by the accredited person, the Secretary shall specify in writing the basis for the objection, including any reasons why the accredited person is not capable of performing the review in a manner which provides a reasonable assurance of the safety and effectiveness of the device for its intended purpose.''.

(d) ACCREDITATION.—Section 523(b) (21 U.S.C. 360m(b)) is amended—

(1) in paragraph (2)—

(A) in the heading of subparagraph (C), by inserting ''AND TRAINING'' after ''AUDITING'';

(B) in subparagraph (C)—

(i) in clause (i), by striking ''and'' at the end;

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting after clause (i) the following:

''(ii) provide for the initial training and periodic updating of training of such person; and''; and

(C) by adding at the end 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) for which such persons are reaccredited.'';

(2) in paragraph (3)—

(A) in subparagraph (A), by inserting ''a sole practitioner or'' after ''may not be'';

(B) in subparagraph (B), by striking ''such a manufacturer, supplier, or vendor'' and inserting ''a manufacturer, supplier, or vendor of devices of the type for which such person is accredited''; and

(C) in subparagraph (D), by striking ''devices'' and inserting ''devices of the type for which such person is accredited'';

(3) by striking paragraph (4) (relating to selection of accredited persons); and

(4) by redesignating paragraph (5) as paragraph (4).

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

(f) REPORT.—Section 523(d) (21 U.S.C. 360m(d)) is amended by striking ''January 10, 2007'' and inserting ''January 15, 2015''.

SEC. 742. PERSONS ACCREDITED TO CONDUCT INSPECTIONS.

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

Subtitle G—Humanitarian Device Reform

SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DEVICES.

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

(1) in paragraph (1), by striking ''devices intended to benefit'' and all that follows through the end of paragraph (1) and inserting the following: ''devices intended—

''(A) to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States annually; or

''(B) to benefit patients in the treatment and diagnosis of diseases or conditions that affect greater than 4,000 individuals in the United States annually, if the person requesting the exemption demonstrates that the severity of the disease or condition is such that public health requires a greater availability of the device to treat or diagnose such patients.'';

(2) in paragraph (2)—

(A) by amending subparagraph (A) to read as follows:

''(A)(i) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States annually, or

''(ii) the device is designed to treat or diagnose a disease or condition that affects greater than 4,000 individuals in the United States annually and the criteria in paragraph (1)(B) are met,''; and

(B) in the flush text at the end, by adding at the end the following: ''Any order approving an application for an exemption under this subsection shall not prohibit or in any way limit the number of devices that are medically necessary to treat, diagnose, or monitor individuals with diseases or conditions described in paragraph (1).'';

(3) by striking paragraphs (3) and (6);

(4) in paragraph (5), by striking '', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,'';

(5) by amending paragraph (7) to read as follows:

''(7)(A) The Secretary shall refer any report of an adverse event regarding a device described in subparagraph (B) to the Office of Pediatric Therapeutics. In considering the report, the Director of

the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this Act in response to the report.

''(B) A device is described in this subparagraph if—

''(i) an exemption is granted under paragraph (2) for the device for treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation; and

''(ii) the device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

''(C) In this paragraph:

''(i) The term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

''(ii) The term 'pediatric subpopulation' means any of the following populations:

''(I) Neonates.

''(II) Infants.

''(III) Children.

''(IV) Adolescents.'';

(6) by amending paragraph (8) to read as follows:

''(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (5)(B) to ensure that the exemption under paragraph (2) remains appropriate for pediatric populations.''; and

(7) by redesignating paragraphs (4), (5), (7), and (8) as paragraphs (3), (4), (5) and (6), respectively.

TITLE VIII—DRUG REGULATORY IMPROVEMENTS

Subtitle A—Pharmaceutical Supply Chain

SEC. 801. [TO BE SUPPLIED].

[To be inserted]

Subtitle B—Medical Gas Safety

SEC. 811. REGULATION OF MEDICAL GASES.

(a) ADULTERATION.—

(1) IN GENERAL.—Section 501(a) (21 U.S.C. 351(a)) is amended by striking ''; or (3)'' and in-

serting ''; or (D) if it is a medical gas (as defined in section 575) and it is manufactured, prepared, processed, packed, or held in violation of subchapter G or regulations thereunder; or (3)''.

(2) APPLICABILITY.—The amendment made by paragraph (1) applies beginning on the date that is 2 years after the date of the enactment of this Act.

(b) REGULATION.—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, as defined in the United States Pharmacopeia (or any successor publication).

''(B) Nitrogen, as defined in the National Formulary (or any successor publication).

''(C) Nitrous oxide, as defined in the United States Pharmacopeia (or any successor publication).

''(D) Carbon dioxide, as defined in the United States Pharmacopeia (or any successor publication).

"(E) Helium, as defined in the United States Pharmacopeia (or any successor publication).

"(F) Medical air, as defined in the United States Pharmacopeia (or any successor publication).

"(G) Any other medical gas deemed appropriate by the Secretary.

"(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.

"(3) The term 'Medical Gas Advisory Committee' means the Medical Gas Advisory Committee established under section 577.

"(4) The term 'medical gas manufacturer' means an entity that owns or operates an establishment registered under section 510 that—

"(A) manufactures, prepares, processes, packages, repackages, or labels a medical gas; or

"(B) fills high-pressure medical gas cylinders or cryogenic medical gas containers by

any of the following methods: liquid to liquid, liquid to gas, or gas to gas.

"SEC. 576. REGULATION OF MEDICAL GASES.

"(a) CERTIFICATION OF DESIGNATED MEDICAL GASES.—

"(1) SUBMISSION.—Beginning on the date of the enactment of this section, any person may file with the Secretary a certification that a medical gas is a designated medical gas.

"(2) APPROVAL OF CERTIFICATION.—The Secretary shall approve a certification submitted under paragraph (1) with respect to a medical gas if the certification demonstrates to the Secretary's satisfaction that the medical gas is a designated medical gas.

"(3) EFFECT OF APPROVAL OF CERTIFICATION.—

"(A) IN GENERAL.—A medical gas subject to a certification for which an approval is in effect under paragraph (2) is deemed to be approved pursuant to an application under section 505(b) or 512(b)(1), as applicable, for—

"(i) those indications for which the medical gas has been marketed to a material extent for a material time; or

"(ii) for administration in a supervised clinical setting under the direction of a medical or veterinary professional, as applicable.

"(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—Sections 505(c)(3)(E), 505(j)(5)(F), and 512(c)(2)(F) do not apply with respect to the approval of a designated medical gas under this subsection.

"(4) REGISTRATION AND LISTING UNDER SECTION 510.—To the greatest extent possible, the Secretary shall streamline the certification and approval process under this subsection with the registration and listing process under section 510.

"(b) APPROVAL OF NONDESIGNATED MEDICAL GASES.—

"(1) PROCEDURES.—Not later than 2 years after the date of the enactment of this subchapter, the Secretary, in consultation with the Medical Gas Advisory Committee, shall establish by rule appropriate procedures for the approval of medical gases that are not designated medical gases pursuant to section 505 or 512, as applicable.

"(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall not require the submission of a new drug application or an abbreviated new drug application under subsection (b) or (j) of section 505, or a new animal drug application or an abbreviated new animal drug application under subsection (b)(1) or (b)(2) of section 512, for any medical gas that is not a designated medical gas during the period ending on the later of—

"(i) 4 years after the date of the enactment of this subchapter; or

"(ii) 2 years after the date on which the Secretary establishes applicable procedures under paragraph (1).

"(B) EXCEPTIONS.—Nothing in this subchapter—

"(i) prohibits the voluntary submission of an application under subsection (b) or (j) of section 505 or subsection (b)(1) or (b)(2) of section 512 for a medical gas; or

"(ii) constitutes an exemption from the requirements under section 505(i) or section 512(j) (relating to investigational

new drugs and investigational new animal drugs, respectively).

''(c) SEPARATE REGULATIONS FOR MEDICAL GASES.—

''(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this subchapter, the Secretary, in consultation with the Medical Gas Advisory Committee, shall establish by regulations that are specific to medical gases and separate from other drug regulations—

''(A) appropriate current good manufacturing practice requirements;

''(B) labeling requirements;

''(C) wholesale distribution requirements;

''(D) a streamlined electronic process for registration and listing under section 510 by medical gas manufacturers that are small business concerns (as defined in section 3 of the Small Business Act); and

''(E) appropriate product tracking and anticounterfeiting rules.

''(2) EVALUATION IN RULEMAKING.—In any regulation of the Food and Drug Administration pertaining to drugs or drug manufacturers that is pending finalization as of the date of the enactment

of this subchapter or is proposed after such date, the Secretary shall specifically evaluate the effect of such regulation on, and the suitability of such regulation for, medical gases and medical gas manufacturers. Based on such evaluation, the Secretary shall include in the regulation an accommodation, unique application, or exemption for medical gases and medical gas manufacturers, as appropriate, given the special characteristics of medical gases.

''(3) COORDINATION WITH STATES.—

''(A) IN GENERAL.—The Secretary, in consultation with the Medical Gas Advisory Committee, shall—

''(i) establish a risk-based inspection regime specific to medical gas manufacturers that ensures coordination with State and local inspection activities; and

''(ii) seek to enter into partnership agreements with such States and localities in order to improve the coordination and efficiency of Federal and State efforts to regulate medical gas manufacturers and medical gases.

''(B) CONTENTS OF AGREEMENTS.—The agreements under subparagraph (A)(ii) shall—

''(i) ensure that State and Federal authorities provide consistent training to inspectors;

''(ii) eliminate, to the extent practicable, any overlapping fees or activities between State and Federal inspectors;

''(iii) promote current good manufacturing practice compliance;

''(iv) ensure consistent application of Federal regulations with respect to medical gas manufacturers; and

''(v) include any mechanisms determined by the Secretary, in consultation with the Medical Gas Advisory Committee, to improve the coordination and efficiency of Federal and State efforts to regulate medical gas manufacturers and medical gases.

''(C) DISSEMINATION OF INFORMATION.—The Secretary shall disseminate appropriate information to States regarding the application of Federal regulations to medical gas manufacturers and medical gases in order to improve the consistency of the enforcement of such regulations.

"SEC. 577. MEDICAL GAS ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 6 months after the date of the enactment of this subchapter, the Secretary shall establish a permanent advisory committee to be known as the Medical Gas Advisory Committee.

"(b) MEMBERSHIP.—The Medical Gas Advisory Committee—

"(1) shall include representatives of—

"(A) medical gas manufacturers; and

"(B) organizations that develop medical gas safety standards; and

"(2) may include representatives of—

"(A) patient advocacy groups;

"(B) professional associations;

"(C) physicians;

"(D) scientists;

"(E) other medical professionals licensed to manufacture or use medical gases (such as pulmonologists, respiratory therapists, veterinarians, and anesthesiologists); and

"(F) other stakeholders, as determined appropriate by the Secretary.

"(c) DUTIES.—The Medical Gas Advisory Committee shall provide the Secretary with regular guidance and specific advice on medical gas regulatory initiatives, including with respect to regulations concerning the approval of

medical gases under sections 505 and 512, the manufacture of medical gases, and related activities.

''(d) FACA.—Section 14 of the Federal Advisory Committee Act shall not apply to the duration of the Medical Gas Advisory Committee.''.

SEC. 812. FEES RELATING TO MEDICAL GAS REGULATION.

(a) FINDING.—The Congress finds that the fees authorized by the amendment made in subsection (b) will be dedicated towards the costs of the Food and Drug Administration's regulation of nondesignated medical gases.

(b) AUTHORITY TO ASSESS AND COLLECT FEES.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

''PART 9—FEES RELATING TO MEDICAL GASES

''SEC. 744K. AUTHORITY TO ASSESS AND COLLECT FEES.

''(a) FEES RELATING TO NONDESIGNATED MEDICAL GASES.—For fiscal year 2013 and each subsequent fiscal year, the Secretary, in consultation with the Medical Gas Advisory Committee, shall assess and collect fees under this section from each category of persons that, with respect to drugs that are nondesignated medical gases, would be subject to a fee under section 736(a), 740(a), or 741(a) but for the operation of subsection (c).

''(b) EXEMPTION FOR DESIGNATED MEDICAL GASES.—Subsection (a) does not authorize the assessment

or collection of any fee with respect to drugs that are designated medical gases.

''(c) INAPPLICABILITY OF OTHER DRUG FEES TO MEDICAL GASES.—Fees under sections 736(a), 740(a), and 741(a) shall not be assessed or collected insofar as such fees apply with respect to drugs that are medical gases.

''(d) ESTABLISHMENT.—The Secretary shall, by regulation, establish the amount of fees under this section for a fiscal year so as to generate a total revenue amount not exceeding the Secretary's estimate of 100 percent of the costs of the Food and Drug Administration's regulation of nondesignated medical gases during such year. In establishing the amount under this subsection, the Secretary shall take into consideration the special characteristics of nondesignated medical gases, including the unique manufacturing and distribution system required to produce nondesignated medical gases.

''(e) 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 appropriation 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 costs of the Food and Drug Administration's regulation of nondesignated medical gases.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

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

''(i) shall be retained 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 only be collected and available to pay the costs of the Food and Drug Administration's regulation of nondesignated medical gases.

''(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 the costs of the Food and Drug Administra-

tion's regulation of nondesignated medical gases—

"(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

"(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

"(II) such costs are not more than 5 percent below the level specified in such subparagraph.

"(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 equal to the total revenue amount determined under subsection (d) for the fiscal year.

"(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of fees estimated to be collected under this section for

fiscal year 2016 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2013 through 2016, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.

''(f) DEFINITIONS.—In this section:

''(1) The terms 'designated medical gas' and 'medical gas' have the meanings given to such terms in section 575.

''(2) The term 'nondesignated medical gas' means a medical gas that is not a designated medical gas.''.

(c) REAUTHORIZATION; REPORTING REQUIREMENTS.—Part 9 of subchapter C of chapter VII, as added by subsection (a), is further amended by adding at the end the following:

''SEC. 744L. 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 regulating non-designated medical gases, as described in section 812(a) of the _____ Act 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 the Food and Drug Administration's regulation of nondesignated medical gases 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) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated 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 regulated 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 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.

"(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 regulated 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.''.

(d) SUNSET DATES.—

(1) AUTHORIZATION.—The amendment made by subsection (b) ceases to be effective October 1, 2017.

(2) REPORTING REQUIREMENTS.—The amendment made by subsection (c) ceases to be effective January 31, 2018.

SEC. 813. MISCELLANEOUS PROVISIONS.

(a) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—Subject to paragraph (2), nothing in this subtitle and the amendments made by this subtitle shall apply to a drug (or an active ingredient) that is covered by an approval under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b) prior to the date of the enactment of this Act.

(2) EXCEPTIONS.—The rule of construction under paragraph (1) shall not apply to a listed drug (or active ingredient) that is—

(A) a designated medical gas that is listed in subparagraph (A) through subparagraph (F)

of section 575(1) of the Federal Food, Drug, and Cosmetic Act, as added by section 811; or

(B) a mixture that—

(i) is comprised of any combination of designated medical gases that are listed in subparagraph (A) through subparagraph (F) of such section 575(1);

(ii) is, as of the date of the enactment of this Act, manufactured and distributed by any medical gas manufacturer, to a material extent and for a material period of time.

(b) SAVINGS CLAUSE.—Except as expressly set forth in this Act and the amendments made by this Act, a medical gas (as defined in section 575 of the Federal Food, Drug, and Cosmetic Act, as added by section 811(b) of this Act) shall be subject to all applicable requirements for drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

Subtitle C—Generating Antibiotic Incentives Now

SEC. 821. 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; or

''(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.

"(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 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 ap-

proved 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. 822. ADDITIONAL EXTENSION OF EXCLUSIVITY PERIOD FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS FOR WHICH A QUALIFIED DIAGNOSTIC TEST IS CLEARED OR APPROVED.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by section 821, is further amended by inserting after section 505E the following:

"SEC. 505E–1. ADDITIONAL EXTENSION OF EXCLUSIVITY PERIOD FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS FOR WHICH A QUALIFIED DIAGNOSTIC TEST IS CLEARED OR APPROVED.

''(a) IN GENERAL.—If the sponsor or manufacturer of a qualified infectious disease product identifies in accordance with subsection (b) a qualified diagnostic test described in subsection (c), any period extended under section 505E(a) with respect to such product shall be further extended by 6 months.

''(b) IDENTIFICATION REQUIREMENTS.—For purposes of subsection (a), the identification of a qualified diagnostic test shall—

''(1) be made in such manner as the Secretary may require; and

"(2) occur before the expiration of the period to be extended under subsection (a), not counting any extension to such period under section 505E(a) or 505A.

"(c) QUALIFIED DIAGNOSTIC TEST.—For purposes of subsection (a), a device is a qualified diagnostic test with respect to a qualified infectious disease product if each of the following is met:

"(1) The device is determined by the Secretary under subsection (f) to be a test for diagnosis of a qualifying pathogen.

"(2) The qualified infectious disease product has been determined under section 505E(d) to be for treating, detecting, preventing, or identifying such qualifying pathogen.

"(3) The device is cleared under section 510(k) or approved under section 515.

"(4) The sponsor or manufacturer, as applicable, of the qualified infectious disease product has the exclusive rights to submit an identification under subsection (a) with respect to the device.

"(d) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period with respect to a qualified infectious disease product shall be in addi-

tion to any extension of the period under section 505A of this Act with respect to the product.

''(e) LIMITATIONS.—After the extension of any period under subsection (a) with respect to a qualified infectious disease product pursuant to the identification of a device as a qualified diagnostic test, subsection (a) does not authorize—

''(1) any subsequent extension with respect to such product; or

''(2) any extension with respect to any other product pursuant to identification of such device.

''(f) DETERMINATION.—The sponsor or manufacturer of a drug may request the Secretary to determine that a device is a test for diagnosis of a qualifying pathogen. Such a request shall be made at least 45 days before the submission of a notification under section 510(k) or an application under section 515 for such device. The Secretary shall, not later than 30 days after the submission of such request, determine whether the device is a test for diagnosis of a qualifying pathogen.

''(g) DEFINITIONS.—In this section:

''(1) The term 'qualified infectious disease product' means a drug that is determined to be a qualified infectious disease product under section 505E.

''(2) The term 'qualifying pathogen' has the meaning given to such term in section 505E.''.

SEC. 823. PRIORITY REVIEW.

(a) AMENDMENT.—Chapter V is amended by inserting after section 524 (21 U.S.C. 360n) the following:

''SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''(a) IN GENERAL.—If the Secretary makes a determination under section 505E(c) that a drug is a qualified infectious disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 505(b).

''(b) DEFINITION.—In this section, the term 'priority review', with respect to an application described in subsection (a), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application.''.

(b) APPLICATION.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 824. FAST TRACK PRODUCT.

Paragraph (1) of section 506(a) (21 U.S.C. 356(a)), as amended by section 831, is amended by inserting after

''and it demonstrates the potential to address unmet medical needs for such a disease or condition'' the following: ''or if the Secretary determines under section 505E that the drug is a qualified infectious disease product''.

SEC. 825. 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 821 of this Act.

SEC. 826. 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 guidelines of the Food and Drug Administration for the conduct of clinical trials with respect to antibiotic drugs; and

(B) as appropriate, revise such guidelines to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of an antibiotic 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 appropriate 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 guidelines of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be used to treat, detect, prevent, or identify 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 821 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 821 of this Act.

(4) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

Subtitle D—Accelerated Approval

SEC. 831. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

Section 506 of the Federal Food, Drug, and Cosmetic Act (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 (taking into account the severity or rarity of the disease or condition and the availability of alternative treatments) that the product has an effect on—

''(A) a surrogate endpoint that is reasonably likely to predict clinical benefit; or

''(B) a clinical endpoint, including an endpoint that can be measured earlier than irreversible morbidity or mortality, that is reason-

ably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. 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 appli-

cable 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. 832. 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 amendments made by section 831.

(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 amendments made by section 831; 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 831.

(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 831) 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 prevalence 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 831 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 831.

SEC. 833. INDEPENDENT REVIEW.

(a) IN GENERAL.—The Secretary shall, 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 831, 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.

SEC. 834. RULE OF CONSTRUCTION.

The amendments made to section 506(b) of the Federal Food, Drug and Cosmetic Act by section 831 shall be construed in a manner that encourages the Secretary to utilize innovative approaches for the assessment of products under accelerated approval while maintaining appropriate safety and effectiveness standards for such products.

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—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining; or

''(C) intended for use in the prevention of a debilitating disease or condition;

''(2) for which an application has been approved under section 505(b) or 505(j); and

''(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product;

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 produce a drug shortage, 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 physician and patient organizations, as described in section 506D.''.

(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—

(A) include a list of the drugs that are subject to the requirements of section 506C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(a)), as amended by subsection (a), if the manufacture of such drug is to be discontinued, or an interruption of the manufacture of the drug that is likely to produce a drug shortage; and

(B) define the terms ''life-supporting'', ''life-sustaining'', and ''intended for use in the prevention of a debilitating disease or condition'' for purposes of section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c).

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 verified 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 a nonactive pharmaceutical 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 anticipated 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.".

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) 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.

''(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 holder of the approved application or license for the drug involved certifies (in such certification) that the major manufacturing change for which approval is being sought may prevent or alleviate a verified or anticipated shortage of a drug described in section 506C(a)(1).

''(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.

''(C) GOOD MANUFACTURING PRACTICE.—In approving a major manufacturing change for which a certification described in subparagraph (A) is submitted, the Secretary may, for the purpose of preventing or alleviating the shortage addressed by the certification, deem the change to be in compliance with the requirements of this Act for current good manufacturing practice (within the meaning of section 501(a)(1)(B)) if the manufacturing facilities involved—

''(i) have a plan to achieve full compliance with such requirements, as in effect at the time of the Secretary's determination;

''(ii) have sufficient resources to achieve, and demonstrate adequate progress in achieving, such full compliance; and

''(iii) are implementing adequate interim controls, as determined by the Secretary, in order to ensure the quality of the drug.

''(D) INTERIM CONTROLS.—The interim controls required by subparagraph (C)(iii) for a drug shall include additional testing, such as in-process or release testing of the drug or its active ingredients, excipients, or components.''.

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 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 affected drug shortages?

(5) How does hoarding affect drug shortages?

(6) How would incentives alleviate or prevent drug 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, and drug manufacturers.

(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 Com-

mittee 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 6 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) specifies—

(A) the number of waivers and reductions for human drug applications and supplements requested under section 736(e) of the Federal Food, Drug, and Cosmetic Act, as added by section 103 of this Act, and the number of such waivers and reductions granted; and

(B) the number of waivers and reductions for abbreviated new drug applications and prior approval supplements requested under section 744A(o) of the Federal Food, Drug, and Cosmetic Act, as added by section 302 of this Act, and the number of such waivers and reductions granted;

(11) describes the Secretary's public engagement on drug shortages with stakeholders, including physicians, pharmacists, patients, hospitals, and drug manufacturers; and

(12) contains the Secretary's plan for addressing drug shortages in the upcoming year, including with respect to the issues described in paragraphs (1) through (11).