

**Suspend the Rules and Pass the Bill, H. R. 5651, with An
Amendment**

**(The amendment strikes all after the enacting clause and inserts a
new text)**

112TH CONGRESS
2D SESSION

H. R. 5651

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

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2012

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Food and Drug Ad-
3 ministration Reform Act of 2012”.

4 SEC. 2. TABLE OF CONTENTS.

5 The table of contents of this Act is as follows:

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

TITLE I—FEES RELATING TO DRUGS

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

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

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

TITLE III—FEES RELATING TO GENERIC DRUGS

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

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

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

Sec. 407. Conforming amendment.

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

Sec. 501. Permanent extension of Best Pharmaceuticals for Children Act and Pediatric Research Equity Act.

Sec. 502. Food and Drug Administration Report.

Sec. 503. Internal Committee for Review of Pediatric Plans, Assessments, Deferrals, Deferral Extensions, and Waivers.

Sec. 504. Staff of Office of Pediatric Therapeutics.

Sec. 505. Continuation of operation of Pediatric Advisory Committee.

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**TITLE VI—FOOD AND DRUG ADMINISTRATION ADMINISTRATIVE
REFORMS**

Sec. 601. Public participation in issuance of FDA guidance documents.

Sec. 602. Conflicts of interest.

Sec. 603. Electronic submission of applications.

Sec. 604. Notification of FDA intent to regulate laboratory-developed tests.

TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

Sec. 701. Investigational device exemptions.

Sec. 702. Clarification of least burdensome standard.

Sec. 703. Agency documentation and review of significant decisions.

Sec. 704. Transparency in clearance process.

Sec. 705. Device Modifications Requiring Premarket Notification Prior to Marketing.

Subtitle B—Patients Come First

Sec. 711. Establishment of schedule and promulgation of regulation.

Sec. 712. Program to improve the device recall system.

Subtitle C—Novel Device Regulatory Relief

Sec. 721. Modification of de novo application process.

Subtitle D—Keeping America Competitive Through Harmonization

Sec. 731. Harmonization of device premarket review, inspection, and labeling symbols; report.

Sec. 732. Participation in international fora.

Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

Sec. 741. Reauthorization of Third Party Review.

Sec. 742. Reauthorization of third party inspection.

Subtitle F—Humanitarian Device Reform

Sec. 751. Expanded access to humanitarian use devices.

Subtitle G—Records and Reports on Devices

Sec. 761. Unique device identification system regulations.

Sec. 762. Effective device sentinel program.

Subtitle H—Miscellaneous

Sec. 771. Custom devices.

Sec. 772. Pediatric device reauthorization.

Sec. 773. Report on regulation of health information technology.

TITLE VIII—DRUG REGULATORY IMPROVEMENTS

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Sec. 801. Registration of producers of drugs.

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Sec. 806. Administrative detention.

Sec. 807. Enhanced criminal penalty for counterfeit drugs.

Sec. 808. Unique facility identification number.

Sec. 809. Documentation for admissibility of imports.

Sec. 810. Registration of commercial importers.

Sec. 811. Notification.

Sec. 812. Exchange of information.

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Sec. 814. Protection against intentional adulteration.

Sec. 815. Records for inspection.

Subtitle B—Medical Gas Safety

Sec. 821. Regulation of medical gases.

Sec. 822. Changes to regulations.

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Sec. 831. Extension of exclusivity period for drugs.

Sec. 832. Study on incentives for qualified infectious disease biological products.

Sec. 833. Clinical trials.

Sec. 834. Reassessment of qualified infectious disease product incentives in 5 years.

Sec. 835. Guidance on pathogen-focused antibacterial drug development.

Subtitle D—Accelerated Approval

Sec. 841. Expedited approval of drugs for serious or life-threatening diseases or conditions.

Sec. 842. Guidance; amended regulations.

Sec. 843. Independent review.

Subtitle E—Critical Path Reauthorization

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

Subtitle F—Miscellaneous

- Sec. 861. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
- Sec. 862. Extension of period for first applicant To obtain tentative approval without forfeiting 180-day exclusivity period.
- Sec. 863. Final agency action relating to petitions and civil actions.
- Sec. 864. Deadline for determination on certain petitions.
- Sec. 865. Rare pediatric disease priority review voucher incentive program.
- Sec. 866. Combating prescription drug abuse.
- Sec. 867. Assessment and modification of REMS.
- Sec. 868. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
- Sec. 869. Breakthrough therapies.
- Sec. 870. Grants and Contracts for the Development of Orphan Drugs.

TITLE IX—DRUG SHORTAGES

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

1 **SEC. 3. REFERENCES IN ACT.**

2 Except as otherwise specified, amendments made by
3 this Act to a section or other provision of law are amend-
4 ments to such section or other provision of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

6 **TITLE I—FEES RELATING TO** 7 **DRUGS**

8 **SEC. 101. SHORT TITLE; FINDING.**

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

11 (b) FINDING.—The Congress finds that the fees au-
12 thorized by the amendments made in this title will be dedi-
13 cated toward expediting the drug development process and

1 the process for the review of human drug applications, in-
2 cluding postmarket drug safety activities, as set forth in
3 the goals identified for purposes of part 2 of subchapter
4 C of chapter VII of the Federal Food, Drug, and Cosmetic
5 Act, in the letters from the Secretary of Health and
6 Human Services to the Chairman of the Committee on
7 Health, Education, Labor, and Pensions of the Senate and
8 the Chairman of the Committee on Energy and Commerce
9 of the House of Representatives, as set forth in the Con-
10 gressional Record.

11 **SEC. 102. DEFINITIONS.**

12 Section 735(7) (21 U.S.C. 379g) is amended by strik-
13 ing “expenses incurred in connection with” and inserting
14 “expenses in connection with”.

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

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

17 (1) in subsection (a)—

18 (A) in the matter preceding paragraph (1),
19 by striking “fiscal year 2008” and inserting
20 “fiscal year 2013”;

21 (B) in paragraph (1)(A)—

22 (i) in clause (i), by striking “(c)(5)”
23 and inserting “(c)(4)”; and

24 (ii) in clause (ii), by striking “(c)(5)”
25 and inserting “(c)(4)”;

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

3 (i) by striking “(c)(5)” and inserting
4 “(c)(4)”; and

5 (ii) by striking “payable on or before
6 October 1 of each year” and inserting
7 “due on the later of the first business day
8 on or after October 1 of such fiscal year or
9 the first business day after the enactment
10 of an appropriations Act providing for the
11 collection and obligation of fees for such
12 fiscal year under this section”;

13 (D) in paragraph (3)—

14 (i) in subparagraph (A)—

15 (I) by striking “subsection
16 (c)(5)” and inserting “subsection
17 (c)(4)”; and

18 (II) by striking “payable on or
19 before October 1 of each year.” and
20 inserting “due on the later of the first
21 business day on or after October 1 of
22 each such fiscal year or the first busi-
23 ness day after the enactment of an
24 appropriations Act providing for the
25 collection and obligation of fees for

1 each such fiscal year under this sec-
2 tion.”; and

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

5 “(B) EXCEPTION.—A prescription drug
6 product shall not be assessed a fee under sub-
7 paragraph (A) if such product is—

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

11 “(ii) the same product as another
12 product that—

13 “(I) was approved under an ap-
14 plication filed under section 505(b) or
15 505(j); and

16 “(II) is not in the list of discon-
17 tinued products compiled under sec-
18 tion 505(j)(7)(A);

19 “(iii) the same product as another
20 product that was approved under an abbrevi-
21 ated application filed under section 507
22 (as in effect on the day before the date of
23 enactment of the Food and Drug Adminis-
24 tration Modernization Act of 1997); or

1 “(iv) the same product as another
2 product that was approved under an abbrevi-
3 ated new drug application pursuant to
4 regulations in effect prior to the implemen-
5 tation of the Drug Price Competition and
6 Patent Term Restoration Act of 1984.”;

7 (2) in subsection (b)—

8 (A) in paragraph (1)—

9 (i) in the language preceding subpara-
10 graph (A), by striking “fiscal years 2008
11 through 2012” and inserting “fiscal years
12 2013 through 2017”; and

13 (ii) in subparagraph (A), by striking
14 “\$392,783,000; and” and inserting
15 “\$693,099,000;”; and

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

18 “(B) the dollar amount equal to the infla-
19 tion adjustment for fiscal year 2013 (as deter-
20 mined under paragraph (3)(A)); and

21 “(C) the dollar amount equal to the work-
22 load adjustment for fiscal year 2013 (as deter-
23 mined under paragraph (3)(B)).”; and

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

1 “(3) FISCAL YEAR 2013 INFLATION AND WORK-
2 LOAD ADJUSTMENTS.—For purposes of paragraph
3 (1), the dollar amount of the inflation and workload
4 adjustments for fiscal year 2013 shall be determined
5 as follows:

6 “(A) INFLATION ADJUSTMENT.—The infla-
7 tion adjustment for fiscal year 2013 shall be
8 the sum of—

9 “(i) \$652,709,000 multiplied by the
10 result of an inflation adjustment calcula-
11 tion determined using the methodology de-
12 scribed in subsection (c)(1)(B); and

13 “(ii) \$652,709,000 multiplied by the
14 result of an inflation adjustment calcula-
15 tion determined using the methodology de-
16 scribed in subsection (c)(1)(C).

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

20 “(i) \$652,709,000 plus the amount of
21 the inflation adjustment calculated under
22 subparagraph (A); multiplied by

23 “(ii) the amount (if any) by which a
24 percentage workload adjustment for fiscal
25 year 2013, as determined using the meth-

1 odology described in subsection (c)(2)(A),
2 would exceed the percentage workload ad-
3 justment (as so determined) for fiscal year
4 2012, if both such adjustment percentages
5 were calculated using the 5-year base pe-
6 riod consisting of fiscal years 2003
7 through 2007.

8 “(C) LIMITATION.—Under no cir-
9 cumstances shall the adjustment under sub-
10 paragraph (B) result in fee revenues for fiscal
11 year 2013 that are less than the sum of the
12 amount under paragraph (1)(A) and the
13 amount under paragraph (1)(B).”;

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

16 “(c) ADJUSTMENTS.—

17 “(1) INFLATION ADJUSTMENT.—For fiscal year
18 2014 and subsequent fiscal years, the revenues es-
19 tablished in subsection (b) shall be adjusted by the
20 Secretary by notice, published in the Federal Reg-
21 ister, for a fiscal year by the amount equal to the
22 sum of—

23 “(A) one;

24 “(B) the average annual percent change in
25 the cost, per full-time equivalent position of the

1 Food and Drug Administration, of all personnel
2 compensation and benefits paid with respect to
3 such positions for the first 3 years of the pre-
4 ceding 4 fiscal years, multiplied by the propor-
5 tion of personnel compensation and benefits
6 costs to total costs of the process for the review
7 of human drug applications (as defined in sec-
8 tion 735(6)) for the first 3 years of the pre-
9 ceding 4 fiscal years, and

10 “(C) the average annual percent change
11 that occurred in the Consumer Price Index for
12 urban consumers (Washington-Baltimore, DC-
13 MD-VA-WV; Not Seasonally Adjusted; All
14 items; Annual Index) for the first 3 years of the
15 preceding 4 years of available data multiplied
16 by the proportion of all costs other than per-
17 sonnel compensation and benefits costs to total
18 costs of the process for the review of human
19 drug applications (as defined in section 735(6))
20 for the first 3 years of the preceding 4 fiscal
21 years.

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

1 “(2) WORKLOAD ADJUSTMENT.—For fiscal
2 year 2014 and subsequent fiscal years, after the fee
3 revenues established in subsection (b) are adjusted
4 for a fiscal year for inflation in accordance with
5 paragraph (1), the fee revenues shall be adjusted
6 further for such fiscal year to reflect changes in the
7 workload of the Secretary for the process for the re-
8 view of human drug applications. With respect to
9 such adjustment:

10 “(A) The adjustment shall be determined
11 by the Secretary based on a weighted average
12 of the change in the total number of human
13 drug applications (adjusted for changes in re-
14 view activities, as described in the notice that
15 the Secretary is required to publish in the Fed-
16 eral Register under this subparagraph), efficacy
17 supplements, and manufacturing supplements
18 submitted to the Secretary, and the change in
19 the total number of active commercial investiga-
20 tional new drug applications (adjusted for
21 changes in review activities, as so described)
22 during the most recent 12-month period for
23 which data on such submissions is available.
24 The Secretary shall publish in the Federal Reg-
25 ister the fee revenues and fees resulting from

1 the adjustment and the supporting methodolo-
2 gies.

3 “(B) Under no circumstances shall the ad-
4 justment result in fee revenues for a fiscal year
5 that are less than the sum of the amount under
6 subsection (b)(1)(A) and the amount under
7 subsection (b)(1)(B), as adjusted for inflation
8 under paragraph (1).

9 “(C) The Secretary shall contract with an
10 independent accounting or consulting firm to
11 periodically review the adequacy of the adjust-
12 ment and publish the results of those reviews.
13 The first review shall be conducted and pub-
14 lished by the end of fiscal year 2013 (to exam-
15 ine the performance of the adjustment since fis-
16 cal year 2009), and the second review shall be
17 conducted and published by the end of fiscal
18 year 2015 (to examine the continued perform-
19 ance of the adjustment). The reports shall
20 evaluate whether the adjustment reasonably
21 represents actual changes in workload volume
22 and complexity and present options to dis-
23 continue, retain, or modify any elements of the
24 adjustment. The reports shall be published for
25 public comment. After review of the reports and

1 receipt of public comments, the Secretary shall,
2 if warranted, adopt appropriate changes to the
3 methodology. If the Secretary adopts changes to
4 the methodology based on the first report, the
5 changes shall be effective for the first fiscal
6 year for which fees are set after the Secretary
7 adopts such changes and each subsequent fiscal
8 year.

9 “(3) FINAL YEAR ADJUSTMENT.—For fiscal
10 year 2017, the Secretary may, in addition to adjust-
11 ments under this paragraph and paragraphs (1) and
12 (2), further increase the fee revenues and fees estab-
13 lished in subsection (b) if such an adjustment is nec-
14 essary to provide for not more than 3 months of op-
15 erating reserves of carryover user fees for the proc-
16 ess for the review of human drug applications for
17 the first 3 months of fiscal year 2018. If such an
18 adjustment is necessary, the rationale for the
19 amount of the increase shall be contained in the an-
20 nual notice establishing fee revenues and fees for fis-
21 cal year 2017. If the Secretary has carryover bal-
22 ances for such process in excess of 3 months of such
23 operating reserves, the adjustment under this sub-
24 paragraph shall not be made.

1 “(4) ANNUAL FEE SETTING.—The Secretary
2 shall, not later than 60 days before the start of each
3 fiscal year that begins after September 30, 2012, es-
4 tablish, for the next fiscal year, application, product,
5 and establishment fees under subsection (a), based
6 on the revenue amounts established under subsection
7 (b) and the adjustments provided under this sub-
8 section.

9 “(5) LIMIT.—The total amount of fees charged,
10 as adjusted under this subsection, for a fiscal year
11 may not exceed the total costs for such fiscal year
12 for the resources allocated for the process for the re-
13 view of human drug applications.”; and

14 (4) in subsection (g)—

15 (A) in paragraph (1), by striking “Fees
16 authorized” and inserting “Subject to para-
17 graph (2)(C), fees authorized”;

18 (B) in paragraph (2)—

19 (i) in subparagraph (A)(i), by striking
20 “shall be retained” and inserting “shall be
21 collected and available”;

22 (ii) in subparagraph (A)(ii), by strik-
23 ing “shall only be collected and available”
24 and inserting “shall be available”; and

1 (iii) by adding at the end the fol-
2 lowing new subparagraph:

3 “(C) PROVISION FOR EARLY PAYMENTS.—
4 Payment of fees authorized under this section
5 for a fiscal year, prior to the due date for such
6 fees, may be accepted by the Secretary in ac-
7 cordance with authority provided in advance in
8 a prior year appropriations Act.”;

9 (C) in paragraph (3), by striking “fiscal
10 years 2008 through 2012” and inserting “fiscal
11 years 2013 through 2017”; and

12 (D) in paragraph (4)—

13 (i) by striking “fiscal years 2008
14 through 2010” and inserting “fiscal years
15 2013 through 2015”;

16 (ii) by striking “fiscal year 2011” and
17 inserting “fiscal year 2016”;

18 (iii) by striking “fiscal years 2008
19 through 2011” and inserting “fiscal years
20 2013 through 2016”; and

21 (iv) by striking “fiscal year 2012”
22 and inserting “fiscal year 2017”.

23 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

1 (1) by amending subsection (a) to read as fol-
2 lows:

3 “(a) PERFORMANCE REPORT.—

4 “(1) IN GENERAL.—Beginning with fiscal year
5 2013, not later than 120 days after the end of each
6 fiscal year for which fees are collected under this
7 part, the Secretary shall prepare and submit to the
8 Committee on Energy and Commerce of the House
9 of Representatives and the Committee on Health,
10 Education, Labor, and Pensions of the Senate a re-
11 port concerning—

12 “(A) the progress of the Food and Drug
13 Administration in achieving the goals identified
14 in the letters described in section 101(b) of the
15 Prescription Drug User Fee Amendments of
16 2012 during such fiscal year and the future
17 plans of the Food and Drug Administration for
18 meeting the goals, including the status of the
19 independent assessment described in such let-
20 ters; and

21 “(B) the progress of the Center for Drug
22 Evaluation and Research and the Center for
23 Biologics Evaluation and Research in achieving
24 the goals, and future plans for meeting the
25 goals, including, for each review division—

1 “(i) the number of original standard
2 new drug applications and biologics license
3 applications filed per fiscal year for each
4 review division;

5 “(ii) the number of original priority
6 new drug applications and biologics license
7 applications filed per fiscal year for each
8 review division;

9 “(iii) the number of standard efficacy
10 supplements filed per fiscal year for each
11 review division;

12 “(iv) the number of priority efficacy
13 supplements filed per fiscal year for each
14 review division;

15 “(v) the number of applications filed
16 for review under accelerated approval per
17 fiscal year for each review division;

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

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

24 “(2) INCLUSION.—The report under this sub-
25 section for a fiscal year shall include information on

1 all previous cohorts for which the Secretary has not
2 given a complete response on all human drug appli-
3 cations and supplements in the cohort.”.

4 (2) in subsection (b), by striking “2008” and
5 inserting “2013”; and

6 (3) in subsection (d), by striking “2012” each
7 place it appears and inserting “2017”.

8 **SEC. 105. SUNSET DATES.**

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

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

13 (c) PREVIOUS SUNSET PROVISION.—

14 (1) IN GENERAL.—Section 106 of the Prescrip-
15 tion Drug User Fee Amendments of 2007 (Title I
16 of Public Law 110–85) is repealed.

17 (2) CONFORMING AMENDMENT.—The Food and
18 Drug Administration Amendments Act of 2007
19 (Public Law 110–85) is amended in the table of con-
20 tents in section 2, by striking the item relating to
21 section 106.

22 (d) TECHNICAL CLARIFICATIONS.—

23 (1) Effective September 30, 2007—

1 (A) section 509 of the Prescription Drug
2 User Fee Amendments Act of 2002 (Title V of
3 Public Law 107–188) is repealed; and

4 (B) the Public Health Security and Bioter-
5 rorism Preparedness and Response Act of 2002
6 (Public Law 107-188) is amended in the table
7 of contents in section 1(b), by striking the item
8 relating to section 509.

9 (2) Effective September 30, 2002—

10 (A) section 107 of the Food and Drug Ad-
11 ministration Modernization Act of 1997 (Public
12 Law 105–115) is repealed; and

13 (B) the table of contents in section 1(c) of
14 such Act is amended by striking the item re-
15 lated to section 107.

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

19 **SEC. 106. EFFECTIVE DATE.**

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

1 applications received on or after October 1, 2012, regard-
2 less of the date of the enactment of this Act.

3 **SEC. 107. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 2 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act, as in effect on the day before
7 the date of the enactment of this title, shall continue to
8 be in effect with respect to human drug applications and
9 supplements (as defined in such part as of such day) that
10 on or after October 1, 2007, but before October 1, 2012,
11 were accepted by the Food and Drug Administration for
12 filing with respect to assessing and collecting any fee re-
13 quired by such part for a fiscal year prior to fiscal year
14 2012.

15 **TITLE II—MEDICAL DEVICE**
16 **USER FEE AMENDMENTS OF 2012**

17 **SEC. 201. SHORT TITLE; FINDINGS.**

18 (a) **SHORT TITLE.**—This Act may be cited as the
19 “Medical Device User Fee Amendments of 2012”.

20 (b) **FINDINGS.**—The Congress finds that the fees au-
21 thorized under the amendments made by this title will be
22 dedicated toward expediting the process for the review of
23 device applications and for assuring the safety and effec-
24 tiveness of devices, as set forth in the goals identified for
25 purposes of part 3 of subchapter C of chapter VII of the

1 Federal Food, Drug, and Cosmetic Act in the letters from
2 the Secretary of Health and Human Services to the Chair-
3 man of the Committee on Health, Education, Labor, and
4 Pensions of the Senate and the Chairman of the Com-
5 mittee on Energy and Commerce of the House of Rep-
6 resentatives, as set forth in the Congressional Record.

7 **SEC. 202. DEFINITIONS.**

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

9 (1) in paragraph (9), by striking “incurred”
10 after “expenses”;

11 (2) in paragraph (10), by striking “October
12 2001” and inserting “October 2011”; and

13 (3) in paragraph (13), by striking “is required
14 to register” and all that follows through the end of
15 paragraph (13) and inserting the following: “is reg-
16 istered (or is required to register) with the Secretary
17 under section 510 because such establishment is en-
18 gaged in the manufacture, preparation, propagation,
19 compounding, or processing of a device.”.

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

21 (a) TYPES OF FEES.—Section 738(a) (21 U.S.C.
22 379j(a)) is amended—

23 (1) in paragraph (1), by striking “fiscal year
24 2008” and inserting “fiscal year 2013”;

25 (2) in paragraph (2)(A)—

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

2 (i) by striking “subsections (d) and
3 (e)” and inserting “subsections (d), (e),
4 and (f)”;

5 (ii) by striking “October 1, 2002” and
6 inserting “October 1, 2012”; and

7 (iii) by striking “subsection (c)(1)”
8 and inserting “subsection (c)”; and

9 (B) in clause (viii), by striking “1.84” and
10 inserting “2”; and

11 (3) in paragraph (3)—

12 (A) in subparagraph (A), by inserting
13 “and subsection (f)” after “subparagraph (B)”;
14 and

15 (B) in subparagraph (C), by striking “ini-
16 tial registration” and all that follows through
17 “section 510.” and inserting “later of—

18 “(i) the initial or annual registration
19 (as applicable) of the establishment under
20 section 510; or

21 “(ii) the first business day after the
22 date of enactment of an appropriations Act
23 providing for the collection and obligation
24 of fees for such year under this section.”.

1 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.
2 379j(b)) is amended to read as follows:

3 “(b) FEE AMOUNTS.—

4 “(1) IN GENERAL.—Subject to subsections (c),
5 (d), (e), (f), and (i), for each of fiscal years 2013
6 through 2017, fees under subsection (a) shall be de-
7 rived from the base fee amounts specified in para-
8 graph (2), to generate the total revenue amounts
9 specified in paragraph (3).

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

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

13 “(3) TOTAL REVENUE AMOUNTS.—For pur-
14 poses of paragraph (1), the total revenue amounts
15 specified in this paragraph are as follows:

16 “(A) \$97,722,301 for fiscal year 2013.

17 “(B) \$112,580,497 for fiscal year 2014.

18 “(C) \$125,767,107 for fiscal year 2015.

19 “(D) \$129,339,949 for fiscal year 2016.

20 “(E) \$130,184,348 for fiscal year 2017.”.

21 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
22 738(c) (21 U.S.C. 379j(c)) is amended—

1 (1) in the subsection heading, by inserting “;
2 ADJUSTMENTS” after “SETTING”;

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

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

6 (4) by inserting before paragraph (4), as so re-
7 designated, the following:

8 “(1) IN GENERAL.—The Secretary shall, 60
9 days before the start of each fiscal year after Sep-
10 tember 30, 2012, establish fees under subsection (a),
11 based on amounts specified under subsection (b) and
12 the adjustments provided under this subsection, and
13 publish such fees, and the rationale for any adjust-
14 ments to such fees, in the Federal Register.

15 “(2) INFLATION ADJUSTMENTS.—

16 “(A) ADJUSTMENT TO TOTAL REVENUE
17 AMOUNTS.—For fiscal year 2014 and each sub-
18 sequent fiscal year, the Secretary shall adjust
19 the total revenue amount specified in subsection
20 (b)(3) for such fiscal year by multiplying such
21 amount by the applicable inflation adjustment
22 under subparagraph (B) for such year.

23 “(B) APPLICABLE INFLATION ADJUST-
24 MENT TO TOTAL REVENUE AMOUNTS.—The ap-

1 plicable inflation adjustment for a fiscal year
2 is—

3 “(i) for fiscal year 2014, the base in-
4 flation adjustment under subparagraph (C)
5 for such fiscal year; and

6 “(ii) for fiscal year 2015 and each
7 subsequent fiscal year, the product of—

8 “(I) the base inflation adjust-
9 ment under subparagraph (C) for
10 such fiscal year; and

11 “(II) the product of the base in-
12 flation adjustment under subpara-
13 graph (C) for each of the fiscal years
14 preceding such fiscal year, beginning
15 with fiscal year 2014.

16 “(C) BASE INFLATION ADJUSTMENT TO
17 TOTAL REVENUE AMOUNTS.—

18 “(i) IN GENERAL.—Subject to further
19 adjustment under clause (ii), the base in-
20 flation adjustment for a fiscal year is the
21 sum of one plus—

22 “(I) the average annual percent
23 change in the cost, per full-time equiv-
24 alent position of the Food and Drug
25 Administration, of all personnel com-

1 pensation and benefits paid with re-
2 spect to such positions for the first 3
3 years of the preceding 4 fiscal years,
4 multiplied by 0.60; and

5 “(II) the average annual percent
6 change that occurred in the Consumer
7 Price Index for urban consumers
8 (Washington-Baltimore, DC-MD-VA-
9 WV; Not Seasonally Adjusted; All
10 items; Annual Index) for the first 3
11 years of the preceding 4 years of
12 available data multiplied by 0.40.

13 “(ii) LIMITATIONS.—For purposes of
14 subparagraph (B), if the base inflation ad-
15 justment for a fiscal year under clause
16 (i)—

17 “(I) is less than 1, such adjust-
18 ment shall be considered to be equal
19 to 1; or

20 “(II) is greater than 1.04, such
21 adjustment shall be considered to be
22 equal to 1.04.

23 “(D) ADJUSTMENT TO BASE FEE
24 AMOUNTS.—For each of fiscal years 2014
25 through 2017, the base fee amounts specified in

1 subsection (b)(2) shall be adjusted as needed,
2 on a uniform proportionate basis, to generate
3 the total revenue amounts under subsection
4 (b)(3), as adjusted for inflation under subpara-
5 graph (A).

6 “(3) VOLUME-BASED ADJUSTMENTS TO ESTAB-
7 LISHMENT REGISTRATION BASE FEES.—For each of
8 fiscal years 2014 through 2017, after the base fee
9 amounts specified in subsection (b)(2) are adjusted
10 under paragraph (2)(D), the base establishment reg-
11 istration fee amounts specified in such subsection
12 shall be further adjusted, as the Secretary estimates
13 is necessary in order for total fee collections for such
14 fiscal year to generate the total revenue amounts, as
15 adjusted under paragraph (2).”.

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

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

20 (2) by inserting after subsection (e) the fol-
21 lowing new subsection (f):

22 “(f) FEE WAIVER OR REDUCTION.—

23 “(1) IN GENERAL.—The Secretary may, at the
24 Secretary’s sole discretion, grant a waiver or reduc-
25 tion of fees under subsection (a)(2) or (a)(3) if the

1 Secretary finds that such waiver or reduction is in
2 the interest of public health.

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

8 “(3) DURATION.—The authority provided by
9 this subsection terminates October 1, 2017.”.

10 (e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C.
11 379j(h)(1)(A)), as redesignated by subsection (d)(1), is
12 amended by striking “\$205,720,000” and inserting
13 “\$280,587,000”.

14 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
15 tion 738(i) (21 U.S.C. 379j(i)), as redesignated by sub-
16 section (d)(1), is amended—

17 (1) in paragraph (1), by striking “Fees author-
18 ized” and inserting “Subject to paragraph (2)(C),
19 fees authorized”;

20 (2) in paragraph (2)—

21 (A) in subparagraph (A)—

22 (i) in clause (i), by striking “shall be
23 retained” and inserting “subject to sub-
24 paragraph (C), shall be collected and avail-
25 able”; and

1 (ii) in clause (ii)—

2 (I) by striking “collected and”
3 after “shall only be”; and

4 (II) by striking “fiscal year
5 2002” and inserting “fiscal year
6 2009”; and

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

8 “(C) PROVISION FOR EARLY YEAR PAY-
9 MENTS.—Payment of fees authorized under this
10 section for a fiscal year, prior to the due date
11 for such fees, may be accepted by the Secretary
12 in accordance with authority provided in ad-
13 vance in a prior year appropriations Act.”;

14 (3) in paragraph (3), by amending to read as
15 follows:

16 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—
17 For each of the fiscal years 2013 through 2017,
18 there is authorized to be appropriated for fees under
19 this section an amount equal to the total revenue
20 amount specified under subsection (b)(3) for the fis-
21 cal year, as adjusted under subsection (c) and, for
22 fiscal year 2017 only, as further adjusted under
23 paragraph (4).”; and

24 (4) in paragraph (4)—

1 (A) by striking “fiscal years 2008, 2009,
2 and 2010” and inserting “fiscal years 2013,
3 2014, and 2015”;

4 (B) by striking “fiscal year 2011” and in-
5 serting “fiscal year 2016”;

6 (C) by striking “June 30, 2011” and in-
7 serting “June 30, 2016”;

8 (D) by striking “the amount of fees speci-
9 fied in aggregate in” and inserting “the cumu-
10 lative amount appropriated pursuant to”;

11 (E) by striking “aggregate amount in” be-
12 fore “excess shall be credited”; and

13 (F) by striking “fiscal year 2012” and in-
14 serting “fiscal year 2017”.

15 (g) CONFORMING AMENDMENT.—Section
16 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by
17 striking “738(g)” and inserting “738(h)”.

18 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

21 (1) in paragraph (1), by striking “2012” and
22 inserting “2017”; and

23 (2) in paragraph (5), by striking “2012” and
24 inserting “2017”.

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

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

5 “(1) PERFORMANCE REPORT.—

6 “(A) IN GENERAL.—Beginning with fiscal
7 year 2013, for each fiscal year for which fees
8 are collected under this part, the Secretary
9 shall prepare and submit to the Committee on
10 Health, Education, Labor, and Pensions of the
11 Senate and the Committee on Energy and Com-
12 merce of the House of Representatives annual
13 reports concerning the progress of the Food
14 and Drug Administration in achieving the goals
15 identified in the letters described in section
16 201(b) of the Medical Device User Fee Amend-
17 ments of 2012 during such fiscal year and the
18 future plans of the Food and Drug Administra-
19 tion for meeting the goals.

20 “(B) PUBLICATION.—With regard to infor-
21 mation to be reported by the Food and Drug
22 Administration to industry on a quarterly and
23 annual basis pursuant to the letters described
24 in section 201(b) of the Medical Device User
25 Fee Amendments Act of 2012, the Secretary

1 shall make such information publicly available
2 on the Internet Website of the Food and Drug
3 Administration not later than 60 days after the
4 end of each quarter or 120 days after the end
5 of each fiscal year, respectively, to which such
6 information applies. This information shall in-
7 clude the status of the independent assessment
8 identified in the letters described in such sec-
9 tion 201(b).

10 “(C) UPDATES.—The Secretary shall in-
11 clude in each report under subparagraph (A)
12 information on all previous cohorts for which
13 the Secretary has not given a complete response
14 on all device premarket applications and re-
15 ports, supplements, and premarket notifications
16 in the cohort.”; and

17 (2) in paragraph (2), by striking “2008
18 through 2012” and inserting “2013 through 2017”.

19 **SEC. 205. SAVINGS CLAUSE.**

20 Notwithstanding the amendments made by this title,
21 part 3 of subchapter C of chapter VII of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
23 effect on the day before the date of the enactment of this
24 title, shall continue to be in effect with respect to the sub-
25 missions listed in section 738(a)(2)(A) of such Act (as de-

1 fined in such part as of such day) that on or after October
2 1, 2007, but before October 1, 2012, were accepted by
3 the Food and Drug Administration for filing with respect
4 to assessing and collecting any fee required by such part
5 for a fiscal year prior to fiscal year 2013.

6 **SEC. 206. EFFECTIVE DATE.**

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

15 **SEC. 207. SUNSET CLAUSE.**

16 (a) IN GENERAL.—Sections 737 and 738 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j)
18 shall cease to be effective October 1, 2017. Section 738A
19 (21 U.S.C. 739j–1) of the Federal Food, Drug, and Cos-
20 metic Act (regarding reauthorization and reporting re-
21 quirements) is repealed January 31, 2018.

22 (b) PREVIOUS SUNSET PROVISION.—

23 (1) IN GENERAL.—Section 217 of the Medical
24 Device User Fee Amendments of 2007 (Title II of
25 Public Law 110–85) is repealed.

1 (2) CONFORMING AMENDMENT.—The Food and
2 Drug Administration Amendments Act of 2007
3 (Public Law 110-85) is amended in the table of con-
4 tents in section 2, by striking the item relating to
5 section 217.

6 (c) TECHNICAL CLARIFICATION.—Effective Sep-
7 tember 30, 2007—

8 (1) section 107 of the Medical Device User Fee
9 and Modernization Act of 2002 (Public Law 107–
10 250) is repealed; and

11 (2) the table of contents in section 1(b) of such
12 Act is amended by striking the item related to sec-
13 tion 107.

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

17 Subchapter A of chapter VII (21 U.S.C. 371 et seq.)
18 is amended by inserting after section 713 the following
19 new section:

20 **“SEC. 714. STREAMLINED HIRING AUTHORITY.**

21 “(a) IN GENERAL.—In addition to any other per-
22 sonnel authorities under other provisions of law, the Sec-
23 retary may, without regard to the provisions of title 5,
24 United States Code, governing appointments in the com-
25 petitive service, appoint employees to positions in the Food

1 and Drug Administration to perform, administer, or sup-
2 port activities described in subsection (b), if the Secretary
3 determines that such appointments are needed to achieve
4 the objectives specified in subsection (c).

5 “(b) ACTIVITIES DESCRIBED.—The activities de-
6 scribed in this subsection are activities under this Act re-
7 lated to the process for the review of device applications
8 (as defined in section 737(8)).

9 “(c) OBJECTIVES SPECIFIED.—The objectives speci-
10 fied in this subsection are with respect to the activities
11 under subsection (b)(1), the goals referred to in section
12 738A(a)(1).

13 “(d) INTERNAL CONTROLS.—The Secretary shall in-
14 stitute appropriate internal controls for appointments
15 under this section.

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

19 **TITLE III—FEES RELATING TO** 20 **GENERIC DRUGS**

21 **SEC. 301. SHORT TITLE.**

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

24 (b) FINDING.—The Congress finds that the fees au-
25 thorized by the amendments made in this title will be dedi-

1 cated to human generic drug activities, as set forth in the
2 goals identified for purposes of part 7 of subchapter C
3 of chapter VII of the Federal Food, Drug, and Cosmetic
4 Act, in the letters from the Secretary of Health and
5 Human Services to the Chairman of the Committee on
6 Health, Education, Labor, and Pensions of the Senate and
7 the Chairman of the Committee on Energy and Commerce
8 of the House of Representatives, as set forth in the Con-
9 gressional Record.

10 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
11 **NERIC DRUG FEES.**

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

14 **“PART 7—FEES RELATING TO GENERIC DRUGS**

15 **“SEC. 744A. DEFINITIONS.**

16 “For purposes of this part:

17 “(1) The term ‘abbreviated new drug applica-
18 tion’—

19 “(A) means an application submitted
20 under section 505(j), an abbreviated application
21 submitted under section 507 (as in effect on the
22 day before the date of enactment of the Food
23 and Drug Administration Modernization Act of
24 1997), or an abbreviated new drug application
25 submitted pursuant to regulations in effect

1 prior to the implementation of the Drug Price
2 Competition and Patent Term Restoration Act
3 of 1984; and

4 “(B) does not include an application for a
5 positron emission tomography drug.

6 “(2) The term ‘active pharmaceutical ingre-
7 dient’ means—

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

11 “(i) to be used as a component of a
12 drug; and

13 “(ii) to furnish pharmacological activ-
14 ity or other direct effect in the diagnosis,
15 cure, mitigation, treatment, or prevention
16 of disease, or to affect the structure or any
17 function of the human body; or

18 “(B) a substance intended for final crys-
19 tallization, purification, or salt formation, or
20 any combination of those activities, to become a
21 substance or mixture described in subparagraph
22 (A).

23 “(3) The term ‘adjustment factor’ means a fac-
24 tor applicable to a fiscal year that is the Consumer
25 Price Index for all urban consumers (all items;

1 United States city average) for October of the pre-
2 ceding fiscal year divided by such Index for October
3 2011.

4 “(4) The term ‘affiliate’ means a business enti-
5 ty that has a relationship with a second business en-
6 tity if, directly or indirectly—

7 “(A) one business entity controls, or has
8 the power to control, the other business entity;
9 or

10 “(B) a third party controls, or has power
11 to control, both of the business entities.

12 “(5)(A) The term ‘facility’—

13 “(i) means a business or other entity—

14 “(I) under one management, either di-
15 rect or indirect; and

16 “(II) at one geographic location or ad-
17 dress engaged in manufacturing or proc-
18 essing an active pharmaceutical ingredient
19 or a finished dosage form; and

20 “(ii) does not include a business or other
21 entity whose only manufacturing or processing
22 activities are one or more of the following: re-
23 packaging, relabeling, or testing.

24 “(B) For purposes of subparagraph (A), sepa-
25 rate buildings within close proximity are considered

1 to be at one geographic location or address if the ac-
2 tivities in them are—

3 “(i) closely related to the same business
4 enterprise;

5 “(ii) under the supervision of the same
6 local management; and

7 “(iii) capable of being inspected by the
8 Food and Drug Administration during a single
9 inspection.

10 “(C) If a business or other entity would meet
11 the definition of a facility under this paragraph but
12 for being under multiple management, the business
13 or other entity is deemed to constitute multiple fa-
14 cilities, one per management entity, for purposes of
15 this paragraph.

16 “(6) The term ‘finished dosage form’ means—

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

20 “(B) a drug product in a form in which re-
21 constitution is necessary prior to administration
22 to a patient, such as oral suspensions or
23 lyophilized powders; or

24 “(C) any combination of an active pharma-
25 ceutical ingredient with another component of a

1 drug product for purposes of production of a
2 drug product described in subparagraph (A) or
3 (B).

4 “(7) The term ‘generic drug submission’ means
5 an abbreviated new drug application, an amendment
6 to an abbreviated new drug application, or a prior
7 approval supplement to an abbreviated new drug ap-
8 plication.

9 “(8) The term ‘human generic drug activities’
10 means the following activities of the Secretary asso-
11 ciated with generic drugs and inspection of facilities
12 associated with generic drugs:

13 “(A) The activities necessary for the re-
14 view of generic drug submissions, including re-
15 view of drug master files referenced in such
16 submissions.

17 “(B) The issuance of—

18 “(i) approval letters which approve
19 abbreviated new drug applications or sup-
20 plements to such applications; or

21 “(ii) complete response letters which
22 set forth in detail the specific deficiencies
23 in such applications and, where appro-
24 priate, the actions necessary to place such
25 applications in condition for approval.

1 “(C) The issuance of letters related to
2 Type II active pharmaceutical drug master files
3 which—

4 “(i) set forth in detail the specific de-
5 ficiencies in such submissions, and where
6 appropriate, the actions necessary to re-
7 solve those deficiencies; or

8 “(ii) document that no deficiencies
9 need to be addressed.

10 “(D) Inspections related to generic drugs.

11 “(E) Monitoring of research conducted in
12 connection with the review of generic drug sub-
13 missions and drug master files.

14 “(F) Postmarket safety activities with re-
15 spect to drugs approved under abbreviated new
16 drug applications or supplements, including the
17 following activities:

18 “(i) Collecting, developing, and re-
19 viewing safety information on approved
20 drugs, including adverse event reports.

21 “(ii) Developing and using improved
22 adverse-event data-collection systems, in-
23 cluding information technology systems.

24 “(iii) Developing and using improved
25 analytical tools to assess potential safety

1 problems, including access to external data
2 bases.

3 “(iv) Implementing and enforcing sec-
4 tion 505(o) (relating to postapproval stud-
5 ies and clinical trials and labeling changes)
6 and section 505(p) (relating to risk evalua-
7 tion and mitigation strategies) insofar as
8 those activities relate to abbreviated new
9 drug applications.

10 “(v) Carrying out section 505(k)(5)
11 (relating to adverse-event reports and
12 postmarket safety activities).

13 “(G) Regulatory science activities related
14 to generic drugs.

15 “(9) The term ‘positron emission tomography
16 drug’ has the meaning given to the term ‘com-
17 pounded positron emission tomography drug’ in sec-
18 tion 201(ii), except that paragraph (1)(B) of such
19 section shall not apply.

20 “(10) The term ‘prior approval supplement’
21 means a request to the Secretary to approve a
22 change in the drug substance, drug product, produc-
23 tion process, quality controls, equipment, or facilities
24 covered by an approved abbreviated new drug appli-
25 cation when that change has a substantial potential

1 to have an adverse effect on the identity, strength,
2 quality, purity, or potency of the drug product as
3 these factors may relate to the safety or effective-
4 ness of the drug product.

5 “(11) The term ‘resources allocated for human
6 generic drug activities’ means the expenses for—

7 “(A) officers and employees of the Food
8 and Drug Administration, contractors of the
9 Food and Drug Administration, advisory com-
10 mittees, and costs related to such officers and
11 employees and to contracts with such contrac-
12 tors;

13 “(B) management of information, and the
14 acquisition, maintenance, and repair of com-
15 puter resources;

16 “(C) leasing, maintenance, renovation, and
17 repair of facilities and acquisition, maintenance,
18 and repair of fixtures, furniture, scientific
19 equipment, and other necessary materials and
20 supplies; and

21 “(D) collecting fees under subsection (a)
22 and accounting for resources allocated for the
23 review of abbreviated new drug applications and
24 supplements and inspection related to generic
25 drugs.

1 “(12) The term ‘Type II active pharmaceutical
2 ingredient drug master file’ means a submission of
3 information to the Secretary by a person that in-
4 tends to authorize the Food and Drug Administra-
5 tion to reference the information to support approval
6 of a generic drug submission without the submitter
7 having to disclose the information to the generic
8 drug submission applicant.

9 **“SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GE-**
10 **NERIC DRUG FEES.**

11 “(a) TYPES OF FEES.—Beginning in fiscal year
12 2013, the Secretary shall assess and collect fees in accord-
13 ance with this section as follows:

14 “(1) ONE-TIME BACKLOG FEE FOR ABBRE-
15 VIATED NEW DRUG APPLICATIONS PENDING ON OC-
16 TOBER 1, 2012.—

17 “(A) IN GENERAL.—Each person that
18 owns an abbreviated new drug application that
19 is pending on October 1, 2012, and that has
20 not received a tentative approval prior to that
21 date, shall be subject to a fee for each such ap-
22 plication, as calculated under subparagraph
23 (B).

24 “(B) METHOD OF FEE AMOUNT CALCULA-
25 TION.—The amount of each one-time backlog

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

6 “(C) NOTICE.—Not later than October 31,
7 2012, the Secretary shall cause to be published
8 in the Federal Register a notice announcing the
9 amount of the fee required by subparagraph
10 (A).

11 “(D) FEE DUE DATE.—The fee required
12 by subparagraph (A) shall be due no later than
13 30 calendar days after the date of the publica-
14 tion of the notice specified in subparagraph (C).

15 “(2) DRUG MASTER FILE FEE.—

16 “(A) IN GENERAL.—Each person that
17 owns a Type II active pharmaceutical ingre-
18 dient drug master file that is referenced on or
19 after October 1, 2012, in a generic drug sub-
20 mission by any initial letter of authorization
21 shall be subject to a drug master file fee.

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

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

5 “(C) NOTICE.—

6 “(i) FISCAL YEAR 2013.—Not later
7 than October 31, 2012, the Secretary shall
8 cause to be published in the Federal Reg-
9 ister a notice announcing the amount of
10 the drug master file fee for fiscal year
11 2013.

12 “(ii) FISCAL YEAR 2014 THROUGH
13 2017.—Not later than 60 days before the
14 start of each of fiscal years 2014 through
15 2017, the Secretary shall cause to be pub-
16 lished in the Federal Register the amount
17 of the drug master file fee established by
18 this paragraph for such fiscal year.

19 “(D) AVAILABILITY FOR REFERENCE.—

20 “(i) IN GENERAL.—Subject to sub-
21 section (g)(2)(C), for a generic drug sub-
22 mission to reference a Type II active phar-
23 maceutical ingredient drug master file, the
24 drug master file must be deemed available
25 for reference by the Secretary.

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

4 “(I) the person that owns a Type
5 II active pharmaceutical ingredient
6 drug master file has paid the fee re-
7 quired under subparagraph (A) within
8 20 calendar days after the applicable
9 due date under subparagraph (E);
10 and

11 “(II) the drug master file has not
12 failed an initial completeness assess-
13 ment by the Secretary, in accordance
14 with criteria to be published by the
15 Secretary.

16 “(iii) LIST.—The Secretary shall
17 make publicly available on the Internet
18 Web site of the Food and Drug Adminis-
19 tration a list of the drug master file num-
20 bers that correspond to drug master files
21 that have successfully undergone an initial
22 completeness assessment, in accordance
23 with criteria to be published by the Sec-
24 retary, and are available for reference.

25 “(E) FEE DUE DATE.—

1 “(i) IN GENERAL.—Subject to clause
2 (ii), a drug master file fee shall be due no
3 later than the date on which the first ge-
4 neric drug submission is submitted that
5 references the associated Type II active
6 pharmaceutical ingredient drug master file.

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

10 “(I) 30 calendar days after publi-
11 cation of the notice provided for in
12 clause (i) or (ii) of subparagraph (C),
13 as applicable; or

14 “(II) 30 calendar days after the
15 date of enactment of an appropria-
16 tions Act providing for the collection
17 and obligation of fees under this sec-
18 tion.

19 “(3) ABBREVIATED NEW DRUG APPLICATION
20 AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

21 “(A) IN GENERAL.—Each applicant that
22 submits, on or after October 1, 2012, an abbrev-
23 viated new drug application or a prior approval
24 supplement to an abbreviated new drug applica-
25 tion shall be subject to a fee for each such sub-

1 mission in the amount established under sub-
2 section (d).

3 “(B) NOTICE.—

4 “(i) FISCAL YEAR 2013.—Not later
5 than October 31, 2012, the Secretary shall
6 cause to be published in the Federal Reg-
7 ister a notice announcing the amount of
8 the fees under subparagraph (A) for fiscal
9 year 2013.

10 “(ii) FISCAL YEARS 2014 THROUGH
11 2017.—Not later than 60 days before the
12 start of each of fiscal years 2014 through
13 2017, the Secretary shall cause to be pub-
14 lished in the Federal Register the amount
15 of the fees under subparagraph (A) for
16 such fiscal year.

17 “(C) FEE DUE DATE.—

18 “(i) IN GENERAL.—Except as pro-
19 vided in clause (ii), the fees required by
20 subparagraphs (A) and (F) shall be due no
21 later than the date of submission of the
22 abbreviated new drug application or prior
23 approval supplement for which such fee ap-
24 plies.

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

4 “(I) the date on which the fee is
5 due under clause (i);

6 “(II) 30 calendar days after pub-
7 lication of the notice referred to in
8 subparagraph (B)(i); or

9 “(III) if an appropriations Act is
10 not enacted providing for the collec-
11 tion and obligation of fees under this
12 section by the date of submission of
13 the application or prior approval sup-
14 plement for which the fees under sub-
15 paragraphs (A) and (F) apply, 30 cal-
16 endar days after the date that such an
17 appropriations Act is enacted.

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

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

3 “(E) FEE FOR AN APPLICATION THE SEC-
4 RETARY CONSIDERS NOT TO HAVE BEEN RE-
5 CEIVED, OR THAT HAS BEEN WITHDRAWN.—An
6 abbreviated new drug application or prior ap-
7 proval supplement that was submitted on or
8 after October 1, 2012, and that the Secretary
9 considers not to have been received, or that has
10 been withdrawn, shall, upon resubmission of the
11 application or a subsequent new submission fol-
12 lowing the applicant’s withdrawal of the appli-
13 cation, be subject to a full fee under subpara-
14 graph (A).

15 “(F) ADDITIONAL FEE FOR ACTIVE PHAR-
16 MACEUTICAL INGREDIENT INFORMATION NOT
17 INCLUDED BY REFERENCE TO TYPE II ACTIVE
18 PHARMACEUTICAL INGREDIENT DRUG MASTER
19 FILE.—An applicant that submits a generic
20 drug submission on or after October 1, 2012,
21 shall pay a fee, in the amount determined under
22 subsection (d)(3), in addition to the fee re-
23 quired under subparagraph (A), if—

24 “(i) such submission contains infor-
25 mation concerning the manufacture of an

1 active pharmaceutical ingredient at a facil-
2 ity by means other than reference by a let-
3 ter of authorization to a Type II active
4 pharmaceutical drug master file; and

5 “(ii) a fee in the amount equal to the
6 drug master file fee established in para-
7 graph (2) has not been previously paid
8 with respect to such information.

9 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
10 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

11 “(A) IN GENERAL.—Facilities identified,
12 or intended to be identified, in at least one ge-
13 neric drug submission that is pending or ap-
14 proved to produce a finished dosage form of a
15 human generic drug or an active pharma-
16 ceutical ingredient contained in a human ge-
17 neric drug shall be subject to fees as follows:

18 “(i) GENERIC DRUG FACILITY.—Each
19 person that owns a facility which is identi-
20 fied or intended to be identified in at least
21 one generic drug submission that is pend-
22 ing or approved to produce one or more
23 finished dosage forms of a human generic
24 drug shall be assessed an annual fee for
25 each such facility.

1 “(ii) ACTIVE PHARMACEUTICAL IN-
2 GREDIENT FACILITY.—Each person that
3 owns a facility which produces, or which is
4 pending review to produce, one or more ac-
5 tive pharmaceutical ingredients identified,
6 or intended to be identified, in at least one
7 generic drug submission that is pending or
8 approved or in a Type II active pharma-
9 ceutical ingredient drug master file ref-
10 erenced in such a generic drug submission,
11 shall be assessed an annual fee for each
12 such facility.

13 “(iii) FACILITIES PRODUCING BOTH
14 ACTIVE PHARMACEUTICAL INGREDIENTS
15 AND FINISHED DOSAGE FORMS.—Each
16 person that owns a facility identified, or
17 intended to be identified, in at least one
18 generic drug submission that is pending or
19 approved to produce both one or more fin-
20 ished dosage forms subject to clause (i)
21 and one or more active pharmaceutical in-
22 gredients subject to clause (ii) shall be
23 subject to fees under both such clauses for
24 that facility.

1 “(B) AMOUNT.—The amount of fees estab-
2 lished under subparagraph (A) shall be estab-
3 lished under subsection (d).

4 “(C) NOTICE.—

5 “(i) FISCAL YEAR 2013.—For fiscal
6 year 2013, the Secretary shall cause to be
7 published in the Federal Register a notice
8 announcing the amount of the fees pro-
9 vided for in subparagraph (A) within the
10 timeframe specified in subsection
11 (d)(1)(B).

12 “(ii) FISCAL YEARS 2014 THROUGH
13 2017.—Within the timeframe specified in
14 subsection (d)(2), the Secretary shall cause
15 to be published in the Federal Register the
16 amount of the fees under subparagraph
17 (A) for such fiscal year.

18 “(D) FEE DUE DATE.—

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

22 “(I) not later than 45 days after
23 the publication of the notice under
24 subparagraph (B); or

1 “(II) if an appropriations Act is
2 not enacted providing for the collec-
3 tion and obligation of fees under this
4 section by the date of the publication
5 of such notice, 30 days after the date
6 that such an appropriations Act is en-
7 acted.

8 “(ii) FISCAL YEARS 2014 THROUGH
9 2017.—For each of fiscal years 2014
10 through 2017, the fees under subpara-
11 graph (A) for such fiscal year shall be due
12 on the later of—

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

15 “(II) the first business day after
16 the enactment of an appropriations
17 Act providing for the collection and
18 obligation of fees under this section
19 for such year.

20 “(5) DATE OF SUBMISSION.—For purposes of
21 this part, a generic drug submission or Type II
22 pharmaceutical master file is deemed to be ‘sub-
23 mitted’ to the Food and Drug Administration—

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

1 day when transmission to that electronic gate-
2 way is completed, except that a submission or
3 master file that arrives on a weekend, Federal
4 holiday, or day when the Food and Drug Ad-
5 ministration office that will review that submis-
6 sion is not otherwise open for business shall be
7 deemed to be submitted on the next day when
8 that office is open for business; and

9 “(B) if it is submitted in physical media
10 form, on the day it arrives at the appropriate
11 designated document room of the Food and
12 Drug Administration.

13 “(b) FEE REVENUE AMOUNTS.—

14 “(1) IN GENERAL.—

15 “(A) FISCAL YEAR 2013.—For fiscal year
16 2013, fees under subsection (a) shall be estab-
17 lished to generate a total estimated revenue
18 amount under such subsection of \$299,000,000.

19 Of that amount—

20 “(i) \$50,000,000 shall be generated
21 by the one-time backlog fee for generic
22 drug applications pending on October 1,
23 2012, established in subsection (a)(1); and

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

4 “(B) FISCAL YEARS 2014 THROUGH 2017.—
5 For each of the fiscal years 2014 through 2017,
6 fees under paragraphs (2) through (4) of sub-
7 section (a) shall be established to generate a
8 total estimated revenue amount under such sub-
9 section that is equal to \$299,000,000, as ad-
10 justed pursuant to subsection (c).

11 “(2) TYPES OF FEES.—In establishing fees
12 under paragraph (1) to generate the revenue
13 amounts specified in paragraph (1)(A)(ii) for fiscal
14 year 2013 and paragraph (1)(B) for each of fiscal
15 years 2014 through 2017, such fees shall be derived
16 from the fees under paragraphs (2) through (4) of
17 subsection (a) as follows:

18 “(A) 6 percent shall be derived from fees
19 under subsection (a)(2) (relating to drug mas-
20 ter files).

21 “(B) 24 percent shall be derived from fees
22 under subsection (a)(3) (relating to abbreviated
23 new drug applications and supplements). The
24 amount of a fee for a prior approval supplement

1 shall be half the amount of the fee for an ab-
2 breviated new drug application.

3 “(C) 56 percent shall be derived from fees
4 under subsection (a)(4)(A)(i) (relating to ge-
5 neric drug facilities). The amount of the fee for
6 a facility located outside the United States and
7 its territories and possessions shall be not less
8 than \$15,000 and not more than \$30,000 high-
9 er than the amount of the fee for a facility lo-
10 cated in the United States and its territories
11 and possessions, as determined by the Secretary
12 on the basis of data concerning the difference
13 in cost between inspections of facilities located
14 in the United States, including its territories
15 and possessions, and those located outside of
16 the United States and its territories and posses-
17 sions.

18 “(D) 14 percent shall be derived from fees
19 under subsection (a)(4)(A)(ii) (relating to active
20 pharmaceutical ingredient facilities). The
21 amount of the fee for a facility located outside
22 the United States and its territories and posses-
23 sions shall be not less than \$15,000 and not
24 more than \$30,000 higher than the amount of
25 the fee for a facility located in the United

1 States, including its territories and possessions,
2 as determined by the Secretary on the basis of
3 data concerning the difference in cost between
4 inspections of facilities located in the United
5 States and its territories and possessions and
6 those located outside of the United States and
7 its territories and possessions.

8 “(c) ADJUSTMENTS.—

9 “(1) INFLATION ADJUSTMENT.—For fiscal year
10 2014 and subsequent fiscal years, the revenues es-
11 tablished in subsection (b) shall be adjusted by the
12 Secretary by notice, published in the Federal Reg-
13 ister, for a fiscal year, by an amount equal to the
14 sum of—

15 “(A) one;

16 “(B) the average annual percent change in
17 the cost, per full-time equivalent position of the
18 Food and Drug Administration, of all personnel
19 compensation and benefits paid with respect to
20 such positions for the first 3 years of the pre-
21 ceding 4 fiscal years multiplied by the propor-
22 tion of personnel compensation and benefits
23 costs to total costs of human generic drug ac-
24 tivities for the first 3 years of the preceding 4
25 fiscal years; and

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

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

15 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
16 year 2017, the Secretary may, in addition to adjust-
17 ments under paragraph (1), further increase the fee
18 revenues and fees established in subsection (b) if
19 such an adjustment is necessary to provide for not
20 more than 3 months of operating reserves of carry-
21 over user fees for human generic drug activities for
22 the first 3 months of fiscal year 2018. Such fees
23 may only be used in fiscal year 2018. If such an ad-
24 justment is necessary, the rationale for the amount
25 of the increase shall be contained in the annual no-

1 tice establishing fee revenues and fees for fiscal year
2 2017. If the Secretary has carryover balances for
3 such activities in excess of 3 months of such oper-
4 ating reserves, the adjustment under this subpara-
5 graph shall not be made.

6 “(d) ANNUAL FEE SETTING.—

7 “(1) FISCAL YEAR 2013.—For fiscal year
8 2013—

9 “(A) the Secretary shall establish, by Octo-
10 ber 31, 2012, the one-time generic drug backlog
11 fee for generic drug applications pending on Oc-
12 tober 1, 2012, the drug master file fee, the ab-
13 breviated new drug application fee, and the
14 prior approval supplement fee under subsection
15 (a), based on the revenue amounts established
16 under subsection (b); and

17 “(B) the Secretary shall establish, not
18 later than 45 days after the date to comply
19 with the requirement for identification of facili-
20 ties in subsection (f)(2), the generic drug facil-
21 ity fee and active pharmaceutical ingredient fa-
22 cility fee under subsection (a) based on the rev-
23 enue amounts established under subsection (b).

24 “(2) FISCAL YEARS 2014 THROUGH 2017.—Not
25 more than 60 days before the first day of each of

1 fiscal years 2014 through 2017, the Secretary shall
2 establish the drug master file fee, the abbreviated
3 new drug application fee, the prior approval supple-
4 ment fee, the generic drug facility fee, and the active
5 pharmaceutical ingredient facility fee under sub-
6 section (a) for such fiscal year, based on the revenue
7 amounts established under subsection (b) and the
8 adjustments provided under subsection (c).

9 “(3) FEE FOR ACTIVE PHARMACEUTICAL IN-
10 GREDIENT INFORMATION NOT INCLUDED BY REF-
11 ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-
12 GREDIENT DRUG MASTER FILE.—In establishing the
13 fees under paragraphs (1) and (2), the amount of
14 the fee under subsection (a)(3)(F) shall be deter-
15 mined by multiplying—

16 “(A) the sum of—

17 “(i) the total number of such active
18 pharmaceutical ingredients in such submis-
19 sion; and

20 “(ii) for each such ingredient that is
21 manufactured at more than one such facil-
22 ity, the total number of such additional fa-
23 cilities; and

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

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

8 “(f) IDENTIFICATION OF FACILITIES.—

9 “(1) PUBLICATION OF NOTICE; DEADLINE FOR
10 COMPLIANCE.—Not later than October 1, 2012, the
11 Secretary shall cause to be published in the Federal
12 Register a notice requiring each person that owns a
13 facility described in subsection (a)(4)(A), or a site or
14 organization required to be identified by paragraph
15 (4), to submit to the Secretary information on the
16 identity of each such facility, site, or organization.
17 The notice required by this paragraph shall specify
18 the type of information to be submitted and the
19 means and format for submission of such informa-
20 tion.

21 “(2) REQUIRED SUBMISSION OF FACILITY
22 IDENTIFICATION.—Each person that owns a facility
23 described in subsection (a)(4)(A) or a site or organi-
24 zation required to be identified by paragraph (4)
25 shall submit to the Secretary the information re-

1 quired under this subsection each year. Such infor-
2 mation shall—

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

6 “(B) for each subsequent fiscal year, be
7 submitted, updated, or reconfirmed on or before
8 June 1 of the previous year.

9 “(3) CONTENTS OF NOTICE.—At a minimum,
10 the submission required by paragraph (2) shall in-
11 clude for each such facility—

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

15 “(B) whether the facility manufactures ac-
16 tive pharmaceutical ingredients or finished dos-
17 age forms, or both;

18 “(C) whether or not the facility is located
19 within the United States and its territories and
20 possessions;

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

24 “(E) whether the facility manufactures
25 drugs that are not generic drugs.

1 “(4) CERTAIN SITES AND ORGANIZATIONS.—

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

7 “(B) SITES AND ORGANIZATIONS.—A site
8 or organization is described in this subpara-
9 graph if it is identified in a generic drug sub-
10 mission and is—

11 “(i) a site in which a bioanalytical
12 study is conducted;

13 “(ii) a clinical research organization;

14 “(iii) a contract analytical testing site;

15 or

16 “(iv) a contract repackager site.

17 “(C) NOTICE.—The Secretary may, by no-
18 tice published in the Federal Register, specify
19 the means and format for submission of the in-
20 formation under subparagraph (A) and may
21 specify, as necessary for purposes of this sec-
22 tion, any additional information to be sub-
23 mitted.

24 “(D) INSPECTION AUTHORITY.—The Sec-
25 retary’s inspection authority under section

1 704(a)(1) shall extend to all such sites and or-
2 ganizations.

3 “(g) EFFECT OF FAILURE TO PAY FEES.—

4 “(1) GENERIC DRUG BACKLOG FEE.—Failure
5 to pay the fee under subsection (a)(1) shall result in
6 the Secretary placing the person that owns the ab-
7 breviated new drug application subject to that fee on
8 an arrears list, such that no new abbreviated new
9 drug applications or supplement submitted on or
10 after October 1, 2012, from that person, or any af-
11 filiate of that person, will be received within the
12 meaning of section 505(j)(5)(A) until such out-
13 standing fee is paid.

14 “(2) DRUG MASTER FILE FEE.—

15 “(A) Failure to pay the fee under sub-
16 section (a)(2) within 20 calendar days after the
17 applicable due date under subparagraph (E) of
18 such subsection (as described in subsection
19 (a)(2)(D)(ii)(I)) shall result in the Type II ac-
20 tive pharmaceutical ingredient drug master file
21 not being deemed available for reference.

22 “(B)(i) Any generic drug submission sub-
23 mitted on or after October 1, 2012, that ref-
24 erences, by a letter of authorization, a Type II
25 active pharmaceutical ingredient drug master

1 file that has not been deemed available for ref-
2 erence shall not be received within the meaning
3 of section 505(j)(5)(A) unless the condition
4 specified in clause (ii) is met.

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

14 “(C)(i) If an abbreviated new drug applica-
15 tion or supplement to an abbreviated new drug
16 application references a Type II active pharma-
17 ceutical ingredient drug master file for which a
18 fee under subsection (a)(2)(A) has not been
19 paid by the applicable date under subsection
20 (a)(2)(E), the Secretary shall notify the sponsor
21 of the abbreviated new drug application or sup-
22 plement of the failure of the owner of the Type
23 II active pharmaceutical ingredient drug master
24 file to pay the applicable fee.

1 “(ii) If such fee is not paid within 20 cal-
2 endar days of the Secretary providing the noti-
3 fication, the abbreviated new drug application
4 or supplement to an abbreviated new drug ap-
5 plication shall not be received within the mean-
6 ing of 505(j)(5)(A).

7 “(3) ABBREVIATED NEW DRUG APPLICATION
8 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—
9 Failure to pay a fee under subparagraph (A) or (F)
10 of subsection (a)(3) within 20 calendar days of the
11 applicable due date under subparagraph (C) of such
12 subsection shall result in the abbreviated new drug
13 application or the prior approval supplement to an
14 abbreviated new drug application not being received
15 within the meaning of section 505(j)(5)(A) until
16 such outstanding fee is paid.

17 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
18 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

19 “(A) IN GENERAL.—Failure to pay the fee
20 under subsection (a)(4) within 20 calendar days
21 of the due date as specified in subparagraph
22 (D) of such subsection shall result in the fol-
23 lowing:

24 “(i) The Secretary shall place the fa-
25 cility on a publicly available arrears list,

1 such that no new abbreviated new drug ap-
2 plication or supplement submitted on or
3 after October 1, 2012, from the person
4 that is responsible for paying such fee, or
5 any affiliate of that person, will be received
6 within the meaning of section 505(j)(5)(A).

7 “(ii) Any new generic drug submission
8 submitted on or after October 1, 2012,
9 that references such a facility shall not be
10 received, within the meaning of section
11 505(j)(5)(A) if the outstanding facility fee
12 is not paid within 20 calendar days of the
13 Secretary providing the notification to the
14 sponsor of the failure of the owner of the
15 facility to pay the facility fee under sub-
16 section (a)(4)(C).

17 “(iii) All drugs or active pharma-
18 ceutical ingredients manufactured in such
19 a facility or containing an ingredient man-
20 ufactured in such a facility shall be deemed
21 misbranded under section 502(aa).

22 “(B) APPLICATION OF PENALTIES.—The
23 penalties under this paragraph shall apply until
24 the fee established by subsection (a)(4) is paid

1 or the facility is removed from all generic drug
2 submissions that refer to the facility.

3 “(C) NONRECEIVAL FOR NONPAYMENT.—

4 “(i) NOTICE.—If an abbreviated new
5 drug application or supplement to an ab-
6 breviated new drug application submitted
7 on or after October 1, 2012, references a
8 facility for which a facility fee has not been
9 paid by the applicable date under sub-
10 section (a)(4)(C), the Secretary shall notify
11 the sponsor of the generic drug submission
12 of the failure of the owner of the facility
13 to pay the facility fee.

14 “(ii) NONRECEIVAL.—If the facility
15 fee is not paid within 20 calendar days of
16 the Secretary providing the notification
17 under clause (i), the abbreviated new drug
18 application or supplement to an abbrevi-
19 ated new drug application shall not be re-
20 ceived within the meaning of section
21 505(j)(5)(A).

22 “(h) LIMITATIONS.—

23 “(1) IN GENERAL.—Fees under subsection (a)
24 shall be refunded for a fiscal year beginning after
25 fiscal year 2012, unless appropriations for salaries

1 and expenses of the Food and Drug Administration
2 for such fiscal year (excluding the amount of fees
3 appropriated for such fiscal year) are equal to or
4 greater than the amount of appropriations for the
5 salaries and expenses of the Food and Drug Admin-
6 istration for the fiscal year 2009 (excluding the
7 amount of fees appropriated for such fiscal year)
8 multiplied by the adjustment factor (as defined in
9 section 744A) applicable to the fiscal year involved.

10 “(2) AUTHORITY.—If the Secretary does not
11 assess fees under subsection (a) during any portion
12 of a fiscal year and if at a later date in such fiscal
13 year the Secretary may assess such fees, the Sec-
14 retary may assess and collect such fees, without any
15 modification in the rate, for Type II active pharma-
16 ceutical ingredient drug master files, abbreviated
17 new drug applications and prior approval supple-
18 ments, and generic drug facilities and active phar-
19 maceutical ingredient facilities at any time in such
20 fiscal year notwithstanding the provisions of sub-
21 section (a) relating to the date fees are to be paid.

22 “(i) CREDITING AND AVAILABILITY OF FEES.—

23 “(1) IN GENERAL.—Fees authorized under sub-
24 section (a) shall be collected and available for obliga-
25 tion only to the extent and in the amount provided

1 in advance in appropriations Acts, subject to para-
2 graph (2). Such fees are authorized to remain avail-
3 able until expended. Such sums as may be necessary
4 may be transferred from the Food and Drug Admin-
5 istration salaries and expenses appropriation account
6 without fiscal year limitation to such appropriation
7 account for salaries and expenses with such fiscal
8 year limitation. The sums transferred shall be avail-
9 able solely for human generic drug activities.

10 “(2) COLLECTIONS AND APPROPRIATION
11 ACTS.—

12 “(A) IN GENERAL.—The fees authorized
13 by this section—

14 “(i) subject to subparagraphs (C) and
15 (D), shall be collected and available in each
16 fiscal year in an amount not to exceed the
17 amount specified in appropriation Acts, or
18 otherwise made available for obligation for
19 such fiscal year; and

20 “(ii) shall be available for a fiscal year
21 beginning after fiscal year 2012 to defray
22 the costs of human generic drug activities
23 (including such costs for an additional
24 number of full-time equivalent positions in
25 the Department of Health and Human

1 Services to be engaged in such activities),
2 only if the Secretary allocates for such
3 purpose an amount for such fiscal year
4 (excluding amounts from fees collected
5 under this section) no less than
6 \$97,000,000 multiplied by the adjustment
7 factor defined in section 744A(3) applica-
8 ble to the fiscal year involved.

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

16 “(C) FEE COLLECTION DURING FIRST
17 PROGRAM YEAR.—Until the date of enactment
18 of an Act making appropriations through Sep-
19 tember 30, 2013 for the salaries and expenses
20 account of the Food and Drug Administration,
21 fees authorized by this section for fiscal year
22 2013, may be collected and shall be credited to
23 such account and remain available until ex-
24 pended.

1 “(D) PROVISION FOR EARLY PAYMENTS IN
2 SUBSEQUENT YEARS.—Payment of fees author-
3 ized under this section for a fiscal year (after
4 fiscal year 2013), prior to the due date for such
5 fees, may be accepted by the Secretary in ac-
6 cordance with authority provided in advance in
7 a prior year appropriations Act.

8 “(3) AUTHORIZATION OF APPROPRIATIONS.—
9 For each of the fiscal years 2013 through 2017,
10 there is authorized to be appropriated for fees under
11 this section an amount equivalent to the total rev-
12 enue amount determined under subsection (b) for
13 the fiscal year, as adjusted under subsection (c), if
14 applicable, or as otherwise affected under paragraph
15 (2) of this subsection.

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

22 “(k) CONSTRUCTION.—This section may not be con-
23 strued to require that the number of full-time equivalent
24 positions in the Department of Health and Human Serv-
25 ices, for officers, employees, and advisory committees not

1 engaged in human generic drug activities, be reduced to
2 offset the number of officers, employees, and advisory
3 committees so engaged.

4 “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

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

13 “(2) IDENTIFICATION REQUIREMENT.—Facili-
14 ties that produce positron emission tomography
15 drugs or active pharmaceutical ingredients of such
16 drugs are required to be identified pursuant to sub-
17 section (f).

18 “(m) DISPUTES CONCERNING FEES.—To qualify for
19 the return of a fee claimed to have been paid in error
20 under this section, a person shall submit to the Secretary
21 a written request justifying such return within 180 cal-
22 endar days after such fee was paid.

23 “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—
24 An abbreviated new drug application that is not consid-
25 ered to be received within the meaning of section

1 505(j)(5)(A) because of failure to pay an applicable fee
2 under this provision within the time period specified in
3 subsection (g) shall be deemed not to have been ‘substan-
4 tially complete’ on the date of its submission within the
5 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbrevi-
6 ated new drug application that is not substantially com-
7 plete on the date of its submission solely because of failure
8 to pay an applicable fee under the preceding sentence shall
9 be deemed substantially complete and received within the
10 meaning of section 505(j)(5)(A) as of the date such appli-
11 cable fee is received.”.

12 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

16 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**
17 **MENTS.**

18 “(a) PERFORMANCE REPORT.—

19 “(1) IN GENERAL.—Beginning with fiscal year
20 2013, not later than 120 days after the end of each
21 fiscal year for which fees are collected under this
22 part, the Secretary shall prepare and submit to the
23 Committee on Energy and Commerce of the House
24 of Representatives and the Committee on Health,
25 Education, Labor, and Pensions of the Senate a re-

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

7 “(2) REGULATORY SCIENCE ACCOUNTABILITY
8 METRICS.—The report required by paragraph (1)
9 shall describe the amounts spent, data generated,
10 and activities undertaken, including any FDA Advi-
11 sory Committee consideration, by the Secretary for
12 each of the local acting bioequivalence topics (Topics
13 1–3) in the Regulatory Science Plan described in the
14 letters described in section 301(b) of the Generic
15 Drug User Fee Amendments of 2012.

16 “(b) FISCAL REPORT.—Beginning with fiscal year
17 2013, not later than 120 days after the end of each fiscal
18 year for which fees are collected under this part, the Sec-
19 retary shall prepare and submit to the Committee on En-
20 ergy and Commerce of the House of Representatives and
21 the Committee on Health, Education, Labor, and Pen-
22 sions of the Senate a report on the implementation of the
23 authority for such fees during such fiscal year and the
24 use, by the Food and Drug Administration, of the fees
25 collected for such fiscal year.

1 “(c) PUBLIC AVAILABILITY.—The Secretary shall
2 make the reports required under subsections (a) and (b)
3 available to the public on the Internet Web site of the
4 Food and Drug Administration.

5 “(d) REAUTHORIZATION.—

6 “(1) CONSULTATION.—In developing rec-
7 ommendations to present to the Congress with re-
8 spect to the goals, and plans for meeting the goals,
9 for human generic drug activities for the first 5 fis-
10 cal years after fiscal year 2017, and for the reau-
11 thorization of this part for such fiscal years, the Sec-
12 retary shall consult with—

13 “(A) the Committee on Energy and Com-
14 merce of the House of Representatives;

15 “(B) the Committee on Health, Education,
16 Labor, and Pensions of the Senate;

17 “(C) scientific and academic experts;

18 “(D) health care professionals;

19 “(E) representatives of patient and con-
20 sumer advocacy groups; and

21 “(F) the generic drug industry.

22 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
23 negotiations with the generic drug industry on the
24 reauthorization of this part, the Secretary shall—

1 “(A) publish a notice in the Federal Reg-
2 ister requesting public input on the reauthoriza-
3 tion;

4 “(B) hold a public meeting at which the
5 public may present its views on the reauthoriza-
6 tion, including specific suggestions for changes
7 to the goals referred to in subsection (a);

8 “(C) provide a period of 30 days after the
9 public meeting to obtain written comments from
10 the public suggesting changes to this part; and

11 “(D) publish the comments on the Food
12 and Drug Administration’s Internet Web site.

13 “(3) PERIODIC CONSULTATION.—Not less fre-
14 quently than once every month during negotiations
15 with the generic drug industry, the Secretary shall
16 hold discussions with representatives of patient and
17 consumer advocacy groups to continue discussions of
18 their views on the reauthorization and their sugges-
19 tions for changes to this part as expressed under
20 paragraph (2).

21 “(4) PUBLIC REVIEW OF RECOMMENDA-
22 TIONS.—After negotiations with the generic drug in-
23 dustry, the Secretary shall—

1 “(A) present the recommendations devel-
2 oped under paragraph (1) to the congressional
3 committees specified in such paragraph;

4 “(B) publish such recommendations in the
5 Federal Register;

6 “(C) provide for a period of 30 days for
7 the public to provide written comments on such
8 recommendations;

9 “(D) hold a meeting at which the public
10 may present its views on such recommenda-
11 tions; and

12 “(E) after consideration of such public
13 views and comments, revise such recommenda-
14 tions as necessary.

15 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
16 Not later than January 15, 2017, the Secretary
17 shall transmit to the Congress the revised rec-
18 ommendations under paragraph (4), a summary of
19 the views and comments received under such para-
20 graph, and any changes made to the recommenda-
21 tions in response to such views and comments.

22 “(6) MINUTES OF NEGOTIATION MEETINGS.—

23 “(A) PUBLIC AVAILABILITY.—Before pre-
24 senting the recommendations developed under
25 paragraphs (1) through (5) to the Congress, the

1 Secretary shall make publicly available, on the
2 Internet Web site of the Food and Drug Ad-
3 ministration, minutes of all negotiation meet-
4 ings conducted under this subsection between
5 the Food and Drug Administration and the ge-
6 neric drug industry.

7 “(B) CONTENT.—The minutes described
8 under subparagraph (A) shall summarize any
9 substantive proposal made by any party to the
10 negotiations as well as significant controversies
11 or differences of opinion during the negotiations
12 and their resolution.”.

13 **SEC. 304. SUNSET DATES.**

14 (a) AUTHORIZATION.—Sections 744A and 744B, as
15 added by section 302 of this Act, are repealed October
16 1, 2017.

17 (b) REPORTING REQUIREMENTS.—Section 744C, as
18 added by section 303 of this Act, is repealed January 31,
19 2018.

20 **SEC. 305. EFFECTIVE DATE.**

21 The amendments made by this title shall take effect
22 on October 1, 2012, or the date of the enactment of this
23 title, whichever is later, except that fees under section 302
24 shall be assessed for all human generic drug submissions
25 and Type II active pharmaceutical drug master files re-

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

3 **SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.**

4 Section 502 (21 U.S.C. 352) is amended by adding
5 at the end the following:

6 “(aa) If it is a drug, or an active pharmaceutical in-
7 gredient, and it was manufactured, prepared, propagated,
8 compounded, or processed in a facility for which fees have
9 not been paid as required by section 744A(a)(4) or for
10 which identifying information required by section 744B(f)
11 has not been submitted, or it contains an active pharma-
12 ceutical ingredient that was manufactured, prepared,
13 propagated, compounded, or processed in such a facility.”.

14 **SEC. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT**
15 **ACTIVITIES RELATED TO HUMAN GENERIC**
16 **DRUGS.**

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

19 (1) by amending subsection (b) to read as fol-
20 lows:

21 “(b) **ACTIVITIES DESCRIBED.**—The activities de-
22 scribed in this subsection are—

23 “(1) activities under this Act related to the
24 process for the review of device applications (as de-
25 fined in section 737(8)); and

1 “(2) activities under this Act related to human
2 generic drug activities (as defined in section
3 744A).”; and

4 (2) by amending subsection (c) to read as fol-
5 lows:

6 “(c) OBJECTIVES SPECIFIED.—The objectives speci-
7 fied in this subsection are—

8 “(1) with respect to the activities under sub-
9 section (b)(1), the goals referred to in section
10 738A(a)(1); and

11 “(2) with respect to the activities under sub-
12 section (b)(2), the goals referred to in section
13 744C(a).”.

14 **TITLE IV—FEES RELATING TO** 15 **BIOSIMILAR BIOLOGICAL** 16 **PRODUCTS**

17 **SEC. 401. SHORT TITLE; FINDING.**

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

20 (b) FINDING.—The Congress finds that the fees au-
21 thorized by the amendments made in this title will be dedi-
22 cated to expediting the process for the review of biosimilar
23 biological product applications, including postmarket safe-
24 ty activities, as set forth in the goals identified for pur-
25 poses of part 8 of subchapter C of chapter VII of the Fed-

1 eral Food, Drug, and Cosmetic Act, in the letters from
2 the Secretary of Health and Human Services to the Chair-
3 man of the Committee on Health, Education, Labor, and
4 Pensions of the Senate and the Chairman of the Com-
5 mittee on Energy and Commerce of the House of Rep-
6 resentatives, as set forth in the Congressional Record.

7 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
8 **PRODUCTS.**

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

12 **“PART 8—FEES RELATING TO BIOSIMILAR**
13 **BIOLOGICAL PRODUCTS**

14 **“SEC. 744G. DEFINITIONS.**

15 “For purposes of this part:

16 “(1) The term ‘adjustment factor’ applicable to
17 a fiscal year that is the Consumer Price Index for
18 all urban consumers (Washington-Baltimore, DC–
19 MD–VA–WV; Not Seasonally Adjusted; All items) of
20 the preceding fiscal year divided by such Index for
21 September 2011.

22 “(2) The term ‘affiliate’ means a business enti-
23 ty that has a relationship with a second business en-
24 tity if, directly or indirectly—

1 “(A) one business entity controls, or has
2 the power to control, the other business entity;
3 or

4 “(B) a third party controls, or has power
5 to control, both of the business entities.

6 “(3) The term ‘biosimilar biological product’
7 means a product for which a biosimilar biological
8 product application has been approved.

9 “(4)(A) Subject to subparagraph (B), the term
10 ‘biosimilar biological product application’ means an
11 application for licensure of a biological product
12 under section 351(k) of the Public Health Service
13 Act.

14 “(B) Such term does not include—

15 “(i) a supplement to such an application;

16 “(ii) an application filed under section
17 351(k) of the Public Health Service Act that
18 cites as the reference product a bovine blood
19 product for topical application licensed before
20 September 1, 1992, or a large volume paren-
21 teral drug product approved before such date;

22 “(iii) an application filed under section
23 351(k) of the Public Health Service Act with
24 respect to—

1 “(I) whole blood or a blood component
2 for transfusion;

3 “(II) an allergenic extract product;

4 “(III) an in vitro diagnostic biological
5 product; or

6 “(IV) a biological product for further
7 manufacturing use only; or

8 “(iv) an application for licensure under
9 section 351(k) of the Public Health Service Act
10 that is submitted by a State or Federal Govern-
11 ment entity for a product that is not distributed
12 commercially.

13 “(5) The term ‘biosimilar biological product de-
14 velopment meeting’ means any meeting, other than
15 a biosimilar initial advisory meeting, regarding the
16 content of a development program, including a pro-
17 posed design for, or data from, a study intended to
18 support a biosimilar biological product application.

19 “(6) The term ‘biosimilar biological product de-
20 velopment program’ means the program under this
21 part for expediting the process for the review of sub-
22 missions in connection with biosimilar biological
23 product development.

1 “(7)(A) The term ‘biosimilar biological product
2 establishment’ means a foreign or domestic place of
3 business—

4 “(i) that is at one general physical location
5 consisting of one or more buildings, all of which
6 are within five miles of each other; and

7 “(ii) at which one or more biosimilar bio-
8 logical products are manufactured in final dos-
9 age form.

10 “(B) For purposes of subparagraph (A)(ii), the
11 term ‘manufactured’ does not include packaging.

12 “(8) The term ‘biosimilar initial advisory meet-
13 ing’—

14 “(A) means a meeting, if requested, that is
15 limited to—

16 “(i) a general discussion regarding
17 whether licensure under section 351(k) of
18 the Public Health Service Act may be fea-
19 sible for a particular product; and

20 “(ii) if so, general advice on the ex-
21 pected content of the development pro-
22 gram; and

23 “(B) does not include any meeting that in-
24 volves substantive review of summary data or
25 full study reports.

1 “(9) The term ‘costs of resources allocated for
2 the process for the review of biosimilar biological
3 product applications’ means the expenses in connec-
4 tion with the process for the review of biosimilar bio-
5 logical product applications for—

6 “(A) officers and employees of the Food
7 and Drug Administration, contractors of the
8 Food and Drug Administration, advisory com-
9 mittees, and costs related to such officers em-
10 ployees and committees and to contracts with
11 such contractors;

12 “(B) management of information, and the
13 acquisition, maintenance, and repair of com-
14 puter resources;

15 “(C) leasing, maintenance, renovation, and
16 repair of facilities and acquisition, maintenance,
17 and repair of fixtures, furniture, scientific
18 equipment, and other necessary materials and
19 supplies; and

20 “(D) collecting fees under section 744H
21 and accounting for resources allocated for the
22 review of submissions in connection with bio-
23 similar biological product development, bio-
24 similar biological product applications, and sup-
25 plements.

1 “(10) The term ‘final dosage form’ means, with
2 respect to a biosimilar biological product, a finished
3 dosage form which is approved for administration to
4 a patient without substantial further manufacturing
5 (such as lyophilized products before reconstitution).

6 “(11) The term ‘financial hold’—

7 “(A) means an order issued by the Sec-
8 retary to prohibit the sponsor of a clinical in-
9 vestigation from continuing the investigation if
10 the Secretary determines that the investigation
11 is intended to support a biosimilar biological
12 product application and the sponsor has failed
13 to pay any fee for the product required under
14 subparagraph (A), (B), or (D) of section
15 744H(a)(1); and

16 “(B) does not mean that any of the bases
17 for a ‘clinical hold’ under section 505(i)(3) have
18 been determined by the Secretary to exist con-
19 cerning the investigation.

20 “(12) The term ‘person’ includes an affiliate of
21 such person.

22 “(13) The term ‘process for the review of bio-
23 similar biological product applications’ means the
24 following activities of the Secretary with respect to
25 the review of submissions in connection with bio-

1 similar biological product development, biosimilar bi-
2 ological product applications, and supplements:

3 “(A) The activities necessary for the re-
4 view of submissions in connection with bio-
5 similar biological product development, bio-
6 similar biological product applications, and sup-
7 plements.

8 “(B) Actions related to submissions in con-
9 nection with biosimilar biological product devel-
10 opment, the issuance of action letters which ap-
11 prove biosimilar biological product applications
12 or which set forth in detail the specific defi-
13 ciencies in such applications, and where appro-
14 priate, the actions necessary to place such ap-
15 plications in condition for approval.

16 “(C) The inspection of biosimilar biological
17 product establishments and other facilities un-
18 dertaken as part of the Secretary’s review of
19 pending biosimilar biological product applica-
20 tions and supplements.

21 “(D) Activities necessary for the release of
22 lots of biosimilar biological products under sec-
23 tion 351(k) of the Public Health Service Act.

1 “(E) Monitoring of research conducted in
2 connection with the review of biosimilar biological
3 product applications.

4 “(F) Postmarket safety activities with re-
5 spect to biologics approved under biosimilar bio-
6 logical product applications or supplements, in-
7 cluding the following activities:

8 “(i) Collecting, developing, and re-
9 viewing safety information on biosimilar bi-
10 ological products, including adverse-event
11 reports.

12 “(ii) Developing and using improved
13 adverse-event data-collection systems, in-
14 cluding information technology systems.

15 “(iii) Developing and using improved
16 analytical tools to assess potential safety
17 problems, including access to external data
18 bases.

19 “(iv) Implementing and enforcing sec-
20 tion 505(o) (relating to postapproval stud-
21 ies and clinical trials and labeling changes)
22 and section 505(p) (relating to risk evalua-
23 tion and mitigation strategies).

1 “(v) Carrying out section 505(k)(5)
2 (relating to adverse-event reports and
3 postmarket safety activities).

4 “(14) The term ‘supplement’ means a request
5 to the Secretary to approve a change in a biosimilar
6 biological product application which has been ap-
7 proved, including a supplement requesting that the
8 Secretary determine that the biosimilar biological
9 product meets the standards for interchangeability
10 described in section 351(k)(4) of the Public Health
11 Service Act.

12 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
13 **BIOLOGICAL PRODUCT FEES.**

14 “(a) TYPES OF FEES.—Beginning in fiscal year
15 2013, the Secretary shall assess and collect fees in accord-
16 ance with this section as follows:

17 “(1) BIOSIMILAR DEVELOPMENT PROGRAM
18 FEES.—

19 “(A) INITIAL BIOSIMILAR BIOLOGICAL
20 PRODUCT DEVELOPMENT FEE.—

21 “(i) IN GENERAL.—Each person that
22 submits to the Secretary a meeting request
23 described under clause (ii) or a clinical
24 protocol for an investigational new drug
25 protocol described under clause (iii) shall

1 pay for the product named in the meeting
2 request or the investigational new drug ap-
3 plication the initial biosimilar biological
4 product development fee established under
5 subsection (b)(1)(A).

6 “(ii) MEETING REQUEST.—The meet-
7 ing request defined in this clause is a re-
8 quest for a biosimilar biological product
9 development meeting for a product.

10 “(iii) CLINICAL PROTOCOL FOR IND.—
11 A clinical protocol for an investigational
12 new drug protocol described in this clause
13 is a clinical protocol consistent with the
14 provisions of section 505(i), including any
15 regulations promulgated under section
16 505(i), (referred to in this section as ‘in-
17 vestigational new drug application’) de-
18 scribing an investigation that the Secretary
19 determines is intended to support a bio-
20 similar biological product application for a
21 product.

22 “(iv) DUE DATE.—The initial bio-
23 similar biological product development fee
24 shall be due by the earlier of the following:

1 “(I) Not later than 5 days after
2 the Secretary grants a request for a
3 biosimilar biological product develop-
4 ment meeting.

5 “(II) The date of submission of
6 an investigational new drug applica-
7 tion describing an investigation that
8 the Secretary determines is intended
9 to support a biosimilar biological
10 product application.

11 “(v) TRANSITION RULE.—Each per-
12 son that has submitted an investigational
13 new drug application prior to the date of
14 enactment of the Biosimilars User Fee Act
15 of 2012 shall pay the initial biosimilar bio-
16 logical product development fee by the ear-
17 lier of the following:

18 “(I) Not later than 60 days after
19 the date of the enactment of the
20 Biosimilars User Fee Act of 2012, if
21 the Secretary determines that the in-
22 vestigational new drug application de-
23 scribes an investigation that is in-
24 tended to support a biosimilar biologi-
25 cal product application.

1 “(II) Not later than 5 days after
2 the Secretary grants a request for a
3 biosimilar biological product develop-
4 ment meeting.

5 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
6 PRODUCT DEVELOPMENT FEE.—

7 “(i) IN GENERAL.—A person that
8 pays an initial biosimilar biological product
9 development fee for a product shall pay for
10 such product, beginning in the fiscal year
11 following the fiscal year in which the initial
12 biosimilar biological product development
13 fee was paid, an annual fee established
14 under subsection (b)(1)(B) for biosimilar
15 biological product development (referred to
16 in this section as ‘annual biosimilar bio-
17 logical product development fee’).

18 “(ii) DUE DATE.—The annual bio-
19 similar biological product development pro-
20 gram fee for each fiscal year will be due on
21 the later of—

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

24 “(II) the first business day after
25 the enactment of an appropriations

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

4 “(iii) EXCEPTION.—The annual bio-
5 similar development program fee for each
6 fiscal year will be due on the date specified
7 in clause (ii), unless the person has—

8 “(I) submitted a marketing appli-
9 cation for the biological product that
10 was accepted for filing; or

11 “(II) discontinued participation
12 in the biosimilar biological product de-
13 velopment program for the product
14 under subparagraph (C).

15 “(C) DISCONTINUATION OF FEE OBLIGA-
16 TION.—A person may discontinue participation
17 in the biosimilar biological product development
18 program for a product effective October 1 of a
19 fiscal year by, not later than August 1 of the
20 preceding fiscal year—

21 “(i) if no investigational new drug ap-
22 plication concerning the product has been
23 submitted, submitting to the Secretary a
24 written declaration that the person has no
25 present intention of further developing the

1 product as a biosimilar biological product;
2 or

3 “(ii) if an investigational new drug
4 application concerning the product has
5 been submitted, by withdrawing the inves-
6 tigational new drug application in accord-
7 ance with part 312 of title 21, Code of
8 Federal Regulations (or any successor reg-
9 ulations).

10 “(D) REACTIVATION FEE.—

11 “(i) IN GENERAL.—A person that has
12 discontinued participation in the biosimilar
13 biological product development program for
14 a product under subparagraph (C) shall
15 pay a fee (referred to in this section as ‘re-
16 activation fee’) by the earlier of the fol-
17 lowing:

18 “(I) Not later than 5 days after
19 the Secretary grants a request for a
20 biosimilar biological product develop-
21 ment meeting for the product (after
22 the date on which such participation
23 was discontinued).

24 “(II) Upon the date of submis-
25 sion (after the date on which such

1 participation was discontinued) of an
2 investigational new drug application
3 describing an investigation that the
4 Secretary determines is intended to
5 support a biosimilar biological product
6 application for that product.

7 “(ii) APPLICATION OF ANNUAL
8 FEE.—A person that pays a reactivation
9 fee for a product shall pay for such prod-
10 uct, beginning in the next fiscal year, the
11 annual biosimilar biological product devel-
12 opment fee under subparagraph (B).

13 “(E) EFFECT OF FAILURE TO PAY BIO-
14 SIMILAR DEVELOPMENT PROGRAM FEES.—

15 “(i) NO BIOSIMILAR BIOLOGICAL
16 PRODUCT DEVELOPMENT MEETINGS.—If a
17 person has failed to pay an initial or an-
18 nual biosimilar biological product develop-
19 ment fee as required under subparagraph
20 (A) or (B), or a reactivation fee as re-
21 quired under subparagraph (D), the Sec-
22 retary shall not provide a biosimilar bio-
23 logical product development meeting relat-
24 ing to the product for which fees are owed.

1 “(ii) NO RECEIPT OF INVESTIGA-
2 TIONAL NEW DRUG APPLICATIONS.—Ex-
3 cept in extraordinary circumstances, the
4 Secretary shall not consider an investiga-
5 tional new drug application to have been
6 received under section 505(i)(2) if—

7 “(I) the Secretary determines
8 that the investigation is intended to
9 support a biosimilar biological product
10 application; and

11 “(II) the sponsor has failed to
12 pay an initial or annual biosimilar bio-
13 logical product development fee for
14 the product as required under sub-
15 paragraph (A) or (B), or a reactiva-
16 tion fee as required under subpara-
17 graph (D).

18 “(iii) FINANCIAL HOLD.—Notwith-
19 standing section 505(i)(2), except in ex-
20 traordinary circumstances, the Secretary
21 shall prohibit the sponsor of a clinical in-
22 vestigation from continuing the investiga-
23 tion if—

24 “(I) the Secretary determines
25 that the investigation is intended to

1 support a biosimilar biological product
2 application; and

3 “(II) the sponsor has failed to
4 pay an initial or annual biosimilar bio-
5 logical product development fee for
6 the product as required under sub-
7 paragraph (A) or (B), or a reactiva-
8 tion fee for the product as required
9 under subparagraph (D).

10 “(iv) NO ACCEPTANCE OF BIOSIMILAR
11 BIOLOGICAL PRODUCT APPLICATIONS OR
12 SUPPLEMENTS.—If a person has failed to
13 pay an initial or annual biosimilar biologi-
14 cal product development fee as required
15 under subparagraph (A) or (B), or a reac-
16 tivation fee as required under subpara-
17 graph (D), any biosimilar biological prod-
18 uct application or supplement submitted by
19 that person shall be considered incomplete
20 and shall not be accepted for filing by the
21 Secretary until all such fees owed by such
22 person have been paid.

23 “(F) LIMITS REGARDING BIOSIMILAR DE-
24 VELOPMENT PROGRAM FEES.—

1 “(i) NO REFUNDS.—The Secretary
2 shall not refund any initial or annual bio-
3 similar biological product development fee
4 paid under subparagraph (A) or (B), or
5 any reactivation fee paid under subpara-
6 graph (D).

7 “(ii) NO WAIVERS, EXEMPTIONS, OR
8 REDUCTIONS.—The Secretary shall not
9 grant a waiver, exemption, or reduction of
10 any initial or annual biosimilar biological
11 product development fee due or payable
12 under subparagraph (A) or (B), or any re-
13 activation fee due or payable under sub-
14 paragraph (D).

15 “(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
16 CATION AND SUPPLEMENT FEE.—

17 “(A) IN GENERAL.—Each person that sub-
18 mits, on or after October 1, 2012, a biosimilar
19 biological product application or a supplement
20 shall be subject to the following fees:

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

23 “(I) the amount of the fee estab-
24 lished under subsection (b)(1)(D) for
25 a biosimilar biological product applica-

1 tion for which clinical data (other
2 than comparative bioavailability stud-
3 ies) with respect to safety or effective-
4 ness are required for approval; minus
5 “(II) the cumulative amount of
6 fees paid, if any, under subparagraphs
7 (A), (B), and (D) of paragraph (1)
8 for the product that is the subject of
9 the application.

10 “(ii) A fee for a biosimilar biological
11 product application for which clinical data
12 (other than comparative bioavailability
13 studies) with respect to safety or effective-
14 ness are not required, that is equal to—

15 “(I) half of the amount of the fee
16 established under subsection (b)(1)(D)
17 for a biosimilar biological product ap-
18 plication; minus

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

23 “(iii) A fee for a supplement for which
24 clinical data (other than comparative bio-
25 availability studies) with respect to safety

1 or effectiveness are required, that is equal
2 to half of the amount of the fee established
3 under subsection (b)(1)(D) for a biosimilar
4 biological product application.

5 “(B) REDUCTION IN FEES.—Notwith-
6 standing section 404 of the Biosimilars User
7 Fee Act of 2012, any person who pays a fee
8 under subparagraph (A), (B), or (D) of para-
9 graph (1) for a product before October 1, 2017,
10 but submits a biosimilar biological product ap-
11 plication for that product after such date, shall
12 be entitled to the reduction of any biosimilar bi-
13 ological product application fees that may be
14 assessed at the time when such biosimilar bio-
15 logical product application is submitted, by the
16 cumulative amount of fees paid under subpara-
17 graphs (A), (B), and (D) of paragraph (1) for
18 that product.

19 “(C) PAYMENT DUE DATE.—Any fee re-
20 quired by subparagraph (A) shall be due upon
21 submission of the application or supplement for
22 which such fee applies.

23 “(D) EXCEPTION FOR PREVIOUSLY FILED
24 APPLICATION OR SUPPLEMENT.—If a biosimilar
25 biological product application or supplement

1 was submitted by a person that paid the fee for
2 such application or supplement, was accepted
3 for filing, and was not approved or was with-
4 drawn (without a waiver), the submission of a
5 biosimilar biological product application or a
6 supplement for the same product by the same
7 person (or the person's licensee, assignee, or
8 successor) shall not be subject to a fee under
9 subparagraph (A).

10 “(E) REFUND OF APPLICATION FEE IF AP-
11 PPLICATION REFUSED FOR FILING OR WITH-
12 DRAWN BEFORE FILING.—The Secretary shall
13 refund 75 percent of the fee paid under this
14 paragraph for any application or supplement
15 which is refused for filing or withdrawn without
16 a waiver before filing.

17 “(F) FEES FOR APPLICATIONS PRE-
18 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
19 BEFORE FILING.—A biosimilar biological prod-
20 uct application or supplement that was sub-
21 mitted but was refused for filing, or was with-
22 drawn before being accepted or refused for fil-
23 ing, shall be subject to the full fee under sub-
24 paragraph (A) upon being resubmitted or filed

1 over protest, unless the fee is waived under sub-
2 section (c).

3 “(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTAB-
4 LISHMENT FEE.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (E), each person that is named
7 as the applicant in a biosimilar biological prod-
8 uct application shall be assessed an annual fee
9 established under subsection (b)(1)(E) for each
10 biosimilar biological product establishment that
11 is listed in the approved biosimilar biological
12 product application as an establishment that
13 manufactures the biosimilar biological product
14 named in such application.

15 “(B) ASSESSMENT IN FISCAL YEARS.—The
16 establishment fee shall be assessed in each fis-
17 cal year for which the biosimilar biological prod-
18 uct named in the application is assessed a fee
19 under paragraph (4) unless the biosimilar bio-
20 logical product establishment listed in the appli-
21 cation does not engage in the manufacture of
22 the biosimilar biological product during such
23 fiscal year.

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

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

3 “(ii) the first business day after the
4 enactment of an appropriations Act pro-
5 viding for the collection and obligation of
6 fees for such fiscal year under this section.

7 “(D) APPLICATION TO ESTABLISHMENT.—

8 “(i) Each biosimilar biological product
9 establishment shall be assessed only one
10 fee per biosimilar biological product estab-
11 lishment, notwithstanding the number of
12 biosimilar biological products manufac-
13 tured at the establishment, subject to
14 clause (ii).

15 “(ii) In the event an establishment is
16 listed in a biosimilar biological product ap-
17 plication by more than one applicant, the
18 establishment fee for the fiscal year shall
19 be divided equally and assessed among the
20 applicants whose biosimilar biological prod-
21 ucts are manufactured by the establish-
22 ment during the fiscal year and assessed
23 biosimilar biological product fees under
24 paragraph (4).

1 “(E) EXCEPTION FOR NEW PRODUCTS.—

2 If, during the fiscal year, an applicant initiates
3 or causes to be initiated the manufacture of a
4 biosimilar biological product at an establish-
5 ment listed in its biosimilar biological product
6 application—

7 “(i) that did not manufacture the bio-
8 similar biological product in the previous
9 fiscal year; and

10 “(ii) for which the full biosimilar bio-
11 logical product establishment fee has been
12 assessed in the fiscal year at a time before
13 manufacture of the biosimilar biological
14 product was begun,

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

19 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

20 “(A) IN GENERAL.—Each person who is
21 named as the applicant in a biosimilar biologi-
22 cal product application shall pay for each such
23 biosimilar biological product the annual fee es-
24 tablished under subsection (b)(1)(F).

1 “(B) DUE DATE.—The biosimilar biologi-
2 cal product fee for a fiscal year shall be due on
3 the later of—

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

6 “(ii) the first business day after the
7 enactment of an appropriations Act pro-
8 viding for the collection and obligation of
9 fees for such year under this section.

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

14 “(b) FEE SETTING AND AMOUNTS.—

15 “(1) IN GENERAL.—Subject to paragraph (2),
16 the Secretary shall, 60 days before the start of each
17 fiscal year that begins after September 30, 2012, es-
18 tablish, for the next fiscal year, the fees under sub-
19 section (a). Except as provided in subsection (c),
20 such fees shall be in the following amounts:

21 “(A) INITIAL BIOSIMILAR BIOLOGICAL
22 PRODUCT DEVELOPMENT FEE.—The initial bio-
23 similar biological product development fee under
24 subsection (a)(1)(A) for a fiscal year shall be
25 equal to 10 percent of the amount established

1 under section 736(c)(4) for a human drug ap-
2 plication described in section 736(a)(1)(A)(i)
3 for that fiscal year.

4 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
5 PRODUCT DEVELOPMENT FEE.—The annual
6 biosimilar biological product development fee
7 under subsection (a)(1)(B) for a fiscal year
8 shall be equal to 10 percent of the amount es-
9 tablished under section 736(c)(4) for a human
10 drug application described in section
11 736(a)(1)(A)(i) for that fiscal year.

12 “(C) REACTIVATION FEE.—The reactiva-
13 tion fee under subsection (a)(1)(D) for a fiscal
14 year shall be equal to 20 percent of the amount
15 of the fee established under section 736(c)(4)
16 for a human drug application described in sec-
17 tion 736(a)(1)(A)(i) for that fiscal year.

18 “(D) BIOSIMILAR BIOLOGICAL PRODUCT
19 APPLICATION FEE.—The biosimilar biological
20 product application fee under subsection (a)(2)
21 for a fiscal year shall be equal to the amount
22 established under section 736(c)(4) for a
23 human drug application described in section
24 736(a)(1)(A)(i) for that fiscal year.

1 “(E) BIOSIMILAR BIOLOGICAL PRODUCT
2 ESTABLISHMENT FEE.—The biosimilar biological
3 product establishment fee under subsection
4 (a)(3) for a fiscal year shall be equal to the
5 amount established under section 736(c)(4) for
6 a prescription drug establishment for that fiscal
7 year.

8 “(F) BIOSIMILAR BIOLOGICAL PRODUCT
9 FEE.—The biosimilar biological product fee
10 under subsection (a)(4) for a fiscal year shall be
11 equal to the amount established under section
12 736(c)(4) for a prescription drug product for
13 that fiscal year.

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

19 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-
20 NESS.—

21 “(1) WAIVER OF APPLICATION FEE.—The Sec-
22 retary shall grant to a person who is named in a bio-
23 similar biological product application a waiver from
24 the application fee assessed to that person under
25 subsection (a)(2)(A) for the first biosimilar biologi-

1 cal product application that a small business or its
2 affiliate submits to the Secretary for review. After a
3 small business or its affiliate is granted such a waiver,
4 er, the small business or its affiliate shall pay—

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

10 “(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in
11 the same manner as an entity that is not a
12 small business.

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

20 “(3) SMALL BUSINESS DEFINED.—In this subsection, the term ‘small business’ means an entity
21 that has fewer than 500 employees, including employees of affiliates, and does not have a drug product
22 that has been approved under a human drug application (as defined in section 735) or a biosimilar
23
24
25

1 biological product application (as defined in section
2 744G(4)) and introduced or delivered for introduc-
3 tion into interstate commerce.

4 “(d) EFFECT OF FAILURE TO PAY FEES.—A bio-
5 similar biological product application or supplement sub-
6 mitted by a person subject to fees under subsection (a)
7 shall be considered incomplete and shall not be accepted
8 for filing by the Secretary until all fees owed by such per-
9 son have been paid.

10 “(e) CREDITING AND AVAILABILITY OF FEES.—

11 “(1) IN GENERAL.—Subject to paragraph (2),
12 fees authorized under subsection (a) shall be col-
13 lected and available for obligation only to the extent
14 and in the amount provided in advance in appropria-
15 tions Acts. Such fees are authorized to remain avail-
16 able until expended. Such sums as may be necessary
17 may be transferred from the Food and Drug Admin-
18 istration salaries and expenses appropriation account
19 without fiscal year limitation to such appropriation
20 account for salaries and expenses with such fiscal
21 year limitation. The sums transferred shall be avail-
22 able solely for the process for the review of bio-
23 similar biological product applications.

24 “(2) COLLECTIONS AND APPROPRIATION
25 ACTS.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graphs (C) and (D), the fees authorized by this
3 section shall be collected and available in each
4 fiscal year in an amount not to exceed the
5 amount specified in appropriation Acts, or oth-
6 erwise made available for obligation for such
7 fiscal year.

8 “(B) USE OF FEES AND LIMITATION.—
9 The fees authorized by this section shall be
10 available for a fiscal year beginning after fiscal
11 year 2012 to defray the costs of the process for
12 the review of biosimilar biological product appli-
13 cations (including such costs for an additional
14 number of full-time equivalent positions in the
15 Department of Health and Human Services to
16 be engaged in such process), only if the Sec-
17 retary allocates for such purpose an amount for
18 such fiscal year (excluding amounts from fees
19 collected under this section) no less than
20 \$20,000,000, multiplied by the adjustment fac-
21 tor applicable to the fiscal year involved.

22 “(C) FEE COLLECTION DURING FIRST
23 PROGRAM YEAR.—Until the date of enactment
24 of an Act making appropriations through Sep-
25 tember 30, 2013, for the salaries and expenses

1 account of the Food and Drug Administration,
2 fees authorized by this section for fiscal year
3 2013 may be collected and shall be credited to
4 such account and remain available until ex-
5 pended.

6 “(D) PROVISION FOR EARLY PAYMENTS IN
7 SUBSEQUENT YEARS.—Payment of fees author-
8 ized under this section for a fiscal year (after
9 fiscal year 2013), prior to the due date for such
10 fees, may be accepted by the Secretary in ac-
11 cordance with authority provided in advance in
12 a prior year appropriations Act.

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

18 “(f) COLLECTION OF UNPAID FEES.—In any case
19 where the Secretary does not receive payment of a fee as-
20 sessed under subsection (a) within 30 days after it is due,
21 such fee shall be treated as a claim of the United States
22 Government subject to subchapter II of chapter 37 of title
23 31, United States Code.

24 “(g) WRITTEN REQUESTS FOR WAIVERS AND RE-
25 FUNDS.—To qualify for consideration for a waiver under

1 subsection (c), or for a refund of any fee collected in ac-
2 cordance with subsection (a)(2)(A), a person shall submit
3 to the Secretary a written request for such waiver or re-
4 fund not later than 180 days after such fee is due.

5 “(h) CONSTRUCTION.—This section may not be con-
6 strued to require that the number of full-time equivalent
7 positions in the Department of Health and Human Serv-
8 ices, for officers, employers, and advisory committees not
9 engaged in the process of the review of biosimilar biologi-
10 cal product applications, be reduced to offset the number
11 of officers, employees, and advisory committees so en-
12 gaged.”.

13 **SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.**

14 Part 8 of subchapter C of chapter VII, as added by
15 section 402 of this Act, is further amended by inserting
16 after section 744H the following:

17 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**
18 **MENTS.**

19 “(a) PERFORMANCE REPORT.—Beginning with fiscal
20 year 2013, not later than 120 days after the end of each
21 fiscal year for which fees are collected under this part,
22 the Secretary shall prepare and submit to the Committee
23 on Energy and Commerce of the House of Representatives
24 and the Committee on Health, Education, Labor, and
25 Pensions of the Senate a report concerning the progress

1 of the Food and Drug Administration in achieving the
2 goals identified in the letters described in section 401(b)
3 of the Biosimilar User Fee Act of 2012 during such fiscal
4 year and the future plans of the Food and Drug Adminis-
5 tration for meeting such goals. The report for a fiscal year
6 shall include information on all previous cohorts for which
7 the Secretary has not given a complete response on all
8 biosimilar biological product applications and supplements
9 in the cohort.

10 “(b) FISCAL REPORT.—Not later than 120 days after
11 the end of fiscal year 2013 and each subsequent fiscal year
12 for which fees are collected under this part, the Secretary
13 shall prepare and submit to the Committee on Energy and
14 Commerce of the House of Representatives and the Com-
15 mittee on Health, Education, Labor, and Pensions of the
16 Senate a report on the implementation of the authority
17 for such fees during such fiscal year and the use, by the
18 Food and Drug Administration, of the fees collected for
19 such fiscal year.

20 “(c) PUBLIC AVAILABILITY.—The Secretary shall
21 make the reports required under subsections (a) and (b)
22 available to the public on the Internet Web site of the
23 Food and Drug Administration.

24 “(d) STUDY.—

1 “(1) IN GENERAL.—The Secretary shall con-
2 tract with an independent accounting or consulting
3 firm to study the workload volume and full costs as-
4 sociated with the process for the review of biosimilar
5 biological product applications.

6 “(2) INTERIM RESULTS.—Not later than June
7 1, 2015, the Secretary shall publish, for public com-
8 ment, interim results of the study described under
9 paragraph (1).

10 “(3) FINAL RESULTS.—Not later than Sep-
11 tember 30, 2016, the Secretary shall publish, for
12 public comment, the final results of the study de-
13 scribed under paragraph (1).

14 “(e) REAUTHORIZATION.—

15 “(1) CONSULTATION.—In developing rec-
16 ommendations to present to the Congress with re-
17 spect to the goals described in subsection (a), and
18 plans for meeting the goals, for the process for the
19 review of biosimilar biological product applications
20 for the first 5 fiscal years after fiscal year 2017, and
21 for the reauthorization of this part for such fiscal
22 years, the Secretary shall consult with—

23 “(A) the Committee on Energy and Com-
24 merce of the House of Representatives;

1 “(B) the Committee on Health, Education,
2 Labor, and Pensions of the Senate;

3 “(C) scientific and academic experts;

4 “(D) health care professionals;

5 “(E) representatives of patient and con-
6 sumer advocacy groups; and

7 “(F) the regulated industry.

8 “(2) PUBLIC REVIEW OF RECOMMENDA-
9 TIONS.—After negotiations with the regulated indus-
10 try, the Secretary shall—

11 “(A) present the recommendations devel-
12 oped under paragraph (1) to the congressional
13 committees specified in such paragraph;

14 “(B) publish such recommendations in the
15 Federal Register;

16 “(C) provide for a period of 30 days for
17 the public to provide written comments on such
18 recommendations;

19 “(D) hold a meeting at which the public
20 may present its views on such recommenda-
21 tions; and

22 “(E) after consideration of such public
23 views and comments, revise such recommenda-
24 tions as necessary.

1 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
2 Not later than January 15, 2017, the Secretary
3 shall transmit to the Congress the revised rec-
4 ommendations under paragraph (2), a summary of
5 the views and comments received under such para-
6 graph, and any changes made to the recommenda-
7 tions in response to such views and comments.”.

8 **SEC. 404. SUNSET DATES.**

9 (a) AUTHORIZATION.—Sections 744G and 744H, as
10 added by section 402 of this Act, are repealed October
11 1, 2017.

12 (b) REPORTING REQUIREMENTS.—Section 744I, as
13 added by section 403 of this Act, is repealed January 31,
14 2018.

15 **SEC. 405. EFFECTIVE DATE.**

16 (a) IN GENERAL.—Except as provided under sub-
17 section (b), the amendments made by this title shall take
18 effect on the later of—

19 (1) October 1, 2012; or

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

21 (b) EXCEPTION.—Fees under part 8 of subchapter
22 C of chapter VII of the Federal Food, Drug, and Cosmetic
23 Act, as added by this title, shall be assessed for all bio-
24 similar biological product applications received on or after

1 October 1, 2012, regardless of the date of the enactment
2 of this title.

3 **SEC. 406. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 2 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act, as in effect on the day before
7 the date of the enactment of this title, shall continue to
8 be in effect with respect to human drug applications and
9 supplements (as defined in such part as of such day) that
10 were accepted by the Food and Drug Administration for
11 filing on or after October 1, 2007, but before October 1,
12 2012, with respect to assessing and collecting any fee re-
13 quired by such part for a fiscal year prior to fiscal year
14 2013.

15 **SEC. 407. CONFORMING AMENDMENT.**

16 Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amend-
17 ed by striking “or (k)”.

1 **TITLE V—REAUTHORIZATION OF**
2 **BEST PHARMACEUTICALS**
3 **FOR CHILDREN ACT AND PE-**
4 **DIATRIC RESEARCH EQUITY**
5 **ACT**

6 **SEC. 501. PERMANENT EXTENSION OF BEST PHARMA-**
7 **CEUTICALS FOR CHILDREN ACT AND PEDI-**
8 **ATRIC RESEARCH EQUITY ACT.**

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

12 (1) in subsection (c)(1)—

13 (A) in the matter preceding subparagraph
14 (A), by inserting “or section 351(m) of this
15 Act,” after “Cosmetic Act,”;

16 (B) in subparagraph (A)(i), by inserting
17 “or section 351(k) of this Act” after “Cosmetic
18 Act”; and

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

21 “(B)(i) there remains no patent listed pur-
22 suant to section 505(b)(1) of the Federal Food,
23 Drug, and Cosmetic Act; and

24 “(ii) every three-year and five-year period
25 referred to in subsection (c)(3)(E)(ii),

1 (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii),
2 (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of
3 the Federal Food, Drug and Cosmetic Act, or
4 applicable twelve-year period referred to in sec-
5 tion 351(k)(7) of this Act, and any seven-year
6 period referred to in section 527 of the Federal
7 Food, Drug, and Cosmetic Act, has ended for
8 at least one form of the drug; and”;

9 (2) in subsection (c)(2)—

10 (A) in the heading of paragraph (2), by
11 striking “FOR DRUGS LACKING EXCLUSIVITY”;

12 (B) by striking “under section 505 of the
13 Federal Food, Drug, and Cosmetic Act”; and

14 (C) by striking “505A of such Act” and
15 inserting “505A of the Federal Food, Drug,
16 and Cosmetic Act or section 351(m) of this
17 Act”; and

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

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

24 (1) in subsection (d)(1)(A), by adding at the
25 end the following: “If a request under this subpara-

1 graph does not request studies in neonates, such re-
2 quest shall include a statement describing the ra-
3 tionale for not requesting studies in neonates.”;

4 (2) by amending subsection (h) to read as fol-
5 lows:

6 “(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-
7 QUIREMENTS.—Exclusivity under this section shall only be
8 granted for the completion of a study or studies that are
9 the subject of a written request and for which reports are
10 submitted and accepted in accordance with subsection
11 (d)(3). Written requests under this section may consist of
12 a study or studies required under section 505B.”;

13 (3) in subsection (k)(2), by striking “subsection
14 (f)(3)(F)” and inserting “subsection (f)(6)(F)”;

15 (4) in subsection (l)—

16 (A) in paragraph (1)—

17 (i) in the paragraph heading, by strik-
18 ing “YEAR ONE” and inserting “FIRST 18-
19 MONTH PERIOD”; and

20 (ii) by striking “one-year” and insert-
21 ing “18-month”;

22 (B) in paragraph (2)—

23 (i) in the paragraph heading, by strik-
24 ing “YEARS” and inserting “PERIODS”;
25 and

1 (ii) by striking “one-year period” and
2 inserting “18-month period”;

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

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

7 “(3) PRESERVATION OF AUTHORITY.—Nothing
8 in this subsection shall prohibit the Office of Pedi-
9 atric Therapeutics from providing for the review of
10 adverse event reports by the Pediatric Advisory
11 Committee prior to the 18-month period referred to
12 in paragraph (1), if such review is necessary to en-
13 sure safe use of a drug in a pediatric population.”;

14 (5) in subsection (n)—

15 (A) in the subsection heading, by striking
16 “COMPLETED” and inserting “SUBMITTED”;
17 and

18 (B) in paragraph (1)—

19 (i) in the text preceding subparagraph
20 (A), by striking “have not been completed”
21 and inserting “have not been submitted by
22 the date specified in the written request
23 issued and agreed upon”; and

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

1 “(A) For a drug for which there remains
2 any listed patent or exclusivity protection eligi-
3 ble for extension under subsection (b)(1) or
4 (c)(1) of this section, or any exclusivity protec-
5 tion eligible for extension under subsection
6 (m)(2) or (m)(3) of section 351 of the Public
7 Health Service Act, the Secretary shall make a
8 determination regarding whether an assessment
9 shall be required to be submitted under section
10 505B(b).

11 “(B) For a drug that has no remaining
12 listed patents or exclusivity protection eligible
13 for extension under subsection (b)(1) or (c)(1)
14 of this section, or any exclusivity protection eli-
15 gible for extension under subsection (m)(2) or
16 (m)(3) of section 351 of the Public Health
17 Service Act, the Secretary shall refer the drug
18 for inclusion on the list established under sec-
19 tion 409I of the Public Health Service Act for
20 the conduct of studies.”;

21 (6) in subsection (o)(2), by amending subpara-
22 graph (B) to read as follows:

23 “(B) a statement of any appropriate pedi-
24 atric contraindications, warnings, precautions,

1 or other information that the Secretary con-
2 siderers necessary to assure safe use.”; and

3 (7) by striking subsection (q) (relating to a sun-
4 set).

5 (c) RESEARCH INTO PEDIATRIC USES FOR DRUGS
6 AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B
7 (21 U.S.C. 355c) is amended—

8 (1) in subsection (a)—

9 (A) in paragraph (1), in the matter before
10 subparagraph (A), by inserting “for a drug”
11 after “(or supplement to an application)”;

12 (B) in paragraph (3)—

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

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

17 “(B) DEFERRAL EXTENSION.—On the ini-
18 tiative of the Secretary or at the request of the
19 applicant, the Secretary may grant an extension
20 of a deferral under subparagraph (A) if—

21 “(i) the Secretary finds that the cri-
22 teria specified in subclause (II) or (III) of
23 subparagraph (A)(i) continue to be met;
24 and

1 “(ii) the applicant submits the mate-
2 rials required under subparagraph (A)(ii).

3 “(C) CONSIDERATION DURING DEFERRAL
4 PERIOD.—If the Secretary has under this para-
5 graph deferred the date by which an assessment
6 must be submitted, then until the date specified
7 in the deferral under subparagraph (A) (includ-
8 ing any extension of such date under subpara-
9 graph (B))—

10 “(i) the assessment shall not be con-
11 sidered late or delayed; and

12 “(ii) the Secretary shall not classify
13 the assessment as late or delayed in any
14 report, database, or public posting.”; and

15 (iii) in subparagraph (D), as redesign-
16 nated, by amending clause (ii) to read as
17 follows:

18 “(ii) PUBLIC AVAILABILITY.—Not
19 later than 60 days after the submission to
20 the Secretary of the information submitted
21 through the annual review under clause (i),
22 the Secretary shall make available to the
23 public in an easily accessible manner, in-
24 cluding through the Web site of the Food
25 and Drug Administration—

1 “(I) such information;

2 “(II) the name of the applicant
3 for the product subject to the assess-
4 ment;

5 “(III) the date on which the
6 product was approved; and

7 “(IV) the date of each deferral or
8 deferral extension under this para-
9 graph for the product.”; and

10 (C) in paragraph (4)(C)—

11 (i) in the first sentence, by inserting
12 “partial” before “waiver is granted”; and

13 (ii) in the second sentence, by striking
14 “either a full or partial waiver” and insert-
15 ing “a partial waiver”;

16 (2) in subsection (b)(1), by striking “After pro-
17 viding notice in the form of a letter (that, for a drug
18 approved under section 505, references a declined
19 written request under section 505A for a labeled in-
20 dication which written request is not referred under
21 section 505A(n)(1)(A) to the Foundation of the Na-
22 tional Institutes of Health for the pediatric studies),
23 the Secretary” and inserting “The Secretary”;

24 (3) by amending subsection (d) to read as fol-
25 lows:

1 “(d) FAILURE TO MEET REQUIREMENTS.—If a per-
2 son fails to submit a required assessment described in sub-
3 section (a)(2), fails to meet the applicable requirements
4 in subsection (a)(3), or fails to submit a request for ap-
5 proval of a pediatric formulation described in subsection
6 (a) or (b), in accordance with applicable provisions of sub-
7 sections (a) and (b)—

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

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

14 “(C) not later than 45 calendar days after the
15 issuance of a letter under subparagraph (A), the
16 Secretary shall make such letter, and any response
17 to such letter under subparagraph (B), available to
18 the public on the Web site of the Food and Drug
19 Administration, with appropriate redactions made to
20 protect trade secrets and confidential commercial in-
21 formation, except that, if the Secretary determines
22 that the letter under subparagraph (A) was issued
23 in error, the requirements of this subparagraph shall
24 not apply with respect to such letter; and

1 “(2)(A) the drug or biological product that is
2 the subject of the required assessment, applicable re-
3 quirements in subsection (a)(3), or required request
4 for approval of a pediatric formulation may be con-
5 sidered misbranded solely because of that failure and
6 subject to relevant enforcement action (except that
7 the drug or biological product shall not be subject to
8 action under section 303); but

9 “(B) the failure to submit the required assess-
10 ment, meet the applicable requirements in subsection
11 (a)(3), or submit the required request for approval
12 of a pediatric formulation shall not be the basis for
13 a proceeding—

14 “(i) to withdraw approval for a drug under
15 section 505(e); or

16 “(ii) to revoke the license for a biological
17 product under section 351 of the Public Health
18 Service Act.”;

19 (4) by amending subsection (e) to read as fol-
20 lows:

21 “(e) INITIAL PEDIATRIC PLAN.—

22 “(1) IN GENERAL.—

23 “(A) SUBMISSION.—An applicant who is
24 required to submit an assessment under sub-

1 section (a)(1) shall submit an initial pediatric
2 plan.

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

5 “(i) before the date on which the ap-
6 plicant submits the assessments under sub-
7 section (a)(2); and

8 “(ii) not later than—

9 “(I) 60 calendar days after the
10 date of end-of-Phase 2 meeting (as
11 such term is used in section 312.47 of
12 title 21, Code of Federal Regulations,
13 or successor regulations); or

14 “(II) such other time as may be
15 agreed upon between the Secretary
16 and the applicant.

17 Nothing in this section shall preclude the Sec-
18 retary from accepting the submission of an ini-
19 tial pediatric plan earlier than the date other-
20 wise applicable under this subparagraph.

21 “(C) CONTENTS.—The initial pediatric
22 plan shall include—

23 “(i) an outline of the pediatric studies
24 that the applicant plans to conduct;

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

4 “(iii) other information the Secretary
5 determines necessary, including any infor-
6 mation specified in regulations under para-
7 graph (5).

8 “(2) MEETING.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (B), not later than 90 calendar days
11 after receiving an initial pediatric plan under
12 paragraph (1), the Secretary shall meet with
13 the applicant to discuss the plan.

14 “(B) WRITTEN RESPONSE.—If the Sec-
15 retary determines that a written response to the
16 initial pediatric plan is sufficient to commu-
17 nicate comments on the initial pediatric plan,
18 and that no meeting is necessary the Secretary
19 shall, not later than 90 days after receiving an
20 initial pediatric plan under paragraph (1)—

21 “(i) notify the applicant of such deter-
22 mination; and

23 “(ii) provide to the applicant the Sec-
24 retary’s written comments on the plan.

25 “(3) AGREED INITIAL PEDIATRIC PLAN.—

1 “(A) SUBMISSION.—The applicant shall
2 submit to the Secretary a document reflecting
3 the agreement between the Secretary and the
4 applicant on the initial pediatric plan (referred
5 to in this subsection as an ‘agreed initial pedi-
6 atric plan’).

7 “(B) CONFIRMATION.—Not later than 30
8 days after receiving the agreed initial pediatric
9 plan under subparagraph (A), the Secretary
10 shall provide written confirmation to the appli-
11 cant that such plan reflects the agreement of
12 the Secretary.

13 “(C) DEFERRAL AND WAIVER.—If the
14 agreed initial pediatric plan contains a request
15 from the applicant for a deferral, partial waiver,
16 or waiver under this section, the written con-
17 firmation under subparagraph (B) shall include
18 a recommendation from the Secretary as to
19 whether such request meets the standards
20 under paragraphs (3) or (4) of subsection (a).

21 “(D) AMENDMENTS TO THE PLAN.—At
22 the initiative of the Secretary or the applicant,
23 the agreed initial pediatric plan may be amend-
24 ed at any time. The requirements of paragraph
25 (2) shall apply to any such proposed amend-

1 ment in the same manner and to the same ex-
2 tent as such requirements apply to an initial pe-
3 diatric plan under paragraph (1). The require-
4 ments of subparagraphs (A) through (C) of this
5 paragraph shall apply to any agreement result-
6 ing from such proposed amendment in the same
7 manner and to the same extent as such require-
8 ments apply to an agreed initial pediatric plan.

9 “(4) INTERNAL COMMITTEE.—The Secretary
10 shall consult the internal committee under section
11 505C on the review of the initial pediatric plan,
12 greed initial pediatric plan, and any amendments to
13 such plans.

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

20 “(6) EFFECTIVE DATE.—The provisions of this
21 subsection shall take effect 180 calendar days after
22 the date of enactment of the Food and Drug Admin-
23 istration Reform Act of 2012, irrespective of wheth-
24 er the Secretary has promulgated final regulations
25 to carry out this subsection by such date.”;

1 (5) in subsection (f)—

2 (A) in the subsection heading, by inserting
3 “DEFERRAL EXTENSIONS,” after “DEFER-
4 RALS,”;

5 (B) in paragraph (4)—

6 (i) in the paragraph heading, by in-
7 serting “DEFERRAL EXTENSIONS,” after
8 “DEFERRALS,”; and

9 (ii) in the second sentence, by insert-
10 ing “, deferral extensions,” after “defer-
11 rals”; and

12 (C) in paragraph (6)(D)—

13 (i) by inserting “and deferral exten-
14 sions” before “requested and granted”;
15 and

16 (ii) by inserting “and deferral exten-
17 sions” after “the reasons for such defer-
18 rals”;

19 (6) in subsection (g)—

20 (A) in paragraph (1)(A), by striking “after
21 the date of the submission of the application or
22 supplement” and inserting “after the date of
23 the submission of an application or supplement
24 that receives a priority review or 330 days after
25 the date of the submission of an application or

1 supplement that receives a standard review”;
2 and

3 (B) in paragraph (2), by striking “the
4 label of such product” and inserting “the label-
5 ing of such product”;

6 (7) in subsection (h)(1)—

7 (A) by inserting “an application (or sup-
8 plement to an application) that contains” after
9 “date of submission of”; and

10 (B) by inserting “if the application (or
11 supplement) receives a priority review, or not
12 later than 330 days after the date of submis-
13 sion of an application (or supplement to an ap-
14 plication) that contains a pediatric assessment
15 under this section, if the application (or supple-
16 ment) receives a standard review,” after “under
17 this section,”;

18 (8) in subsection (i)—

19 (A) in paragraph (1)—

20 (i) in the paragraph heading, by strik-
21 ing “YEAR ONE” and inserting “FIRST 18-
22 MONTH PERIOD”; and

23 (ii) by striking “one-year” and insert-
24 ing “18-month”;

25 (B) in paragraph (2)—

1 (i) in the paragraph heading, by strik-
2 ing “YEARS” and inserting “PERIODS”;
3 and

4 (ii) by striking “one-year period” and
5 inserting “18-month period”;

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

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

10 “(3) PRESERVATION OF AUTHORITY.—Nothing
11 in this subsection shall prohibit the Office of Pedi-
12 atric Therapeutics from providing for the review of
13 adverse event reports by the Pediatric Advisory
14 Committee prior to the 18-month period referred to
15 in paragraph (1), if such review is necessary to en-
16 sure safe use of a drug in a pediatric population.”;

17 (9) by striking subsection (m) (relating to inte-
18 gration with other pediatric studies); and

19 (10) by redesignating subsection (n) as sub-
20 section (m).

21 (d) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS
22 IN PHSA.—Section 351(m)(1) of the Public Health Serv-
23 ice Act (42 U.S.C. 262(m)(1)) is amended by striking “(f),
24 (i), (j), (k), (l), (p), and (q)” and inserting “(f), (h), (i),
25 (j), (k), (l), (n), and (p)”.

1 (e) APPLICATION; TRANSITION RULE.—

2 (1) APPLICATION.—Notwithstanding any provi-
3 sion of section 505A and 505B of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355a, 355c)
5 stating that a provision applies beginning on the
6 date of the enactment of the Best Pharmaceuticals
7 for Children Act of 2007 or the date of the enact-
8 ment of the Pediatric Research Equity Act of 2007,
9 any amendment made by this Act to such a provi-
10 sion applies beginning on the date of the enactment
11 of this Act.

12 (2) TRANSITIONAL RULE FOR ADVERSE EVENT
13 REPORTING.—With respect to a drug for which a la-
14 beling change described under section 505A(l)(1) or
15 505B(i)(1) of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved
17 or made, respectively, during the one-year period
18 that ends on the day before the date of enactment
19 of this Act, the Secretary shall apply section 505A(l)
20 and section 505B(i), as applicable, to such drug, as
21 such sections were in effect on such day.

22 (f) CONFORMING AMENDMENT.—Section
23 499(c)(1)(C) of the Public Health Service Act (42 U.S.C.
24 290b(c)(1)(C)) is amended by striking “for which the Sec-
25 retary issues a certification in the affirmative under sec-

1 tion 505A(n)(1)(A) of the Federal Food, Drug, and Cos-
2 metic Act”.

3 (g) PUBLIC MEETING ON PEDIATRIC CANCERS.—
4 Not later than December 31, 2013, the Secretary of
5 Health and Human Services shall hold a public meeting
6 on the impact of sections 505A and 505B of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c)
8 on the development of new therapies for children with can-
9 cer.

10 **SEC. 502. FOOD AND DRUG ADMINISTRATION REPORT.**

11 (a) IN GENERAL.—Not later than four years after
12 the date of enactment of this Act and every five years
13 thereafter, the Secretary of Health and Human Services
14 shall prepare and submit to the Committee on Health,
15 Education, Labor and Pensions of the Senate and the
16 Committee on Energy and Commerce of the House of
17 Representatives, and make publicly available, including
18 through posting on the Web site of the Food and Drug
19 Administration, a report on the implementation of section
20 505A and 505B.

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

23 (1) an assessment of the effectiveness of sec-
24 tions 505A and 505B in improving information
25 about pediatric uses for approved drugs and bio-

1 logics, including the number and type of labeling
2 changes made since the date of enactment of this
3 Act;

4 (2) the number of waivers and partial waivers
5 granted under section 505B since the date of enact-
6 ment of this Act, and the reasons such waivers and
7 partial waivers were granted;

8 (3) the number of deferrals and deferral exten-
9 sions granted under section 505B since the date of
10 enactment of this Act, and the reasons such defer-
11 rals and deferral extensions were granted;

12 (4) the number of letters issued under section
13 505B(d);

14 (5) an assessment of the timeliness and effec-
15 tiveness of pediatric study planning since the date of
16 enactment of this Act, including the number of pedi-
17 atric plans not submitted in accordance with the re-
18 quirements of section 505B(e) and any resulting
19 rulemaking;

20 (6) the number of written requests issued, ac-
21 cepted, and declined under section 505A since the
22 date of enactment of this Act, and a listing of any
23 important gaps in pediatric information as a result
24 of such declined requests;

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

3 (8) an assessment of the effectiveness of study-
4 ing drugs for rare diseases under 505A;

5 (9) an assessment of the effectiveness of study-
6 ing drugs for children with cancer under 505A and
7 505B, and any recommendations for modifications
8 to the programs under such sections that would lead
9 to new and better therapies for children with cancer;

10 (10) an assessment of the effectiveness of
11 studying drugs in the neonate population under
12 505A and 505B;

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

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

19 (13) any suggestions for modification to the
20 programs that would improve pediatric drug re-
21 search and increase pediatric labeling of drugs and
22 biologics that the Secretary determines to be appro-
23 priate.

24 (c) STAKEHOLDER COMMENT.—At least 180 days
25 prior to the submission of the report required in para-

1 graph (1), the Secretary shall consult with representatives
2 of patient groups, including pediatric patient groups, con-
3 sumer groups, regulated industry, academia, and other in-
4 terested parties to obtain any recommendations or infor-
5 mation relevant to the study and report including sugges-
6 tions for modifications that would improve pediatric drug
7 research and pediatric labeling of drugs and biologics.

8 **SEC. 503. INTERNAL COMMITTEE FOR REVIEW OF PEDI-**
9 **ATRIC PLANS, ASSESSMENTS, DEFERRALS,**
10 **DEFERRAL EXTENSIONS, AND WAIVERS.**

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

12 (1) in the section heading, by inserting “**DE-**
13 **FERRAL EXTENSIONS,**” after “**DEFERRALS,**”;
14 and

15 (2) by inserting “neonatology” after “pediatric
16 ethics”.

17 **SEC. 504. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.**

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

20 (1) in paragraph (1), by striking “and” at the
21 end;

22 (2) by redesignating paragraph (2) as para-
23 graph (4);

24 (3) by inserting after paragraph (1) the fol-
25 lowing:

1 “(2) one or more additional individuals with ex-
2 pertise in neonatology;

3 “(3) one or more additional individuals with ex-
4 pertise in pediatric epidemiology; and”.

5 **SEC. 505. CONTINUATION OF OPERATION OF PEDIATRIC**
6 **ADVISORY COMMITTEE.**

7 Section 14(d) of the Best Pharmaceuticals for Chil-
8 dren Act (42 U.S.C. 284m note) is amended by striking
9 “during the five-year period beginning on the date of the
10 enactment of the Best Pharmaceuticals for Children Act
11 of 2007” and inserting “to carry out the advisory commit-
12 tee’s responsibilities under sections 505A, 505B, and
13 520(m) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355a, 355c, and 360j(m))”.

15 **SEC. 506. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**
16 **DRUGS ADVISORY COMMITTEE.**

17 Section 15(a) of the Best Pharmaceuticals for Chil-
18 dren Act (Public Law 107–109), as amended by section
19 502(e) of the Food and Drug Administration Amendments
20 Act of 2007 (Public Law 110–85), is amended—

21 (1) in paragraph (1)(D), by striking “section
22 505B(f)” and inserting “section 505C”; and

23 (2) in paragraph (3), by striking “during the
24 five-year period beginning on the date of the enact-
25 ment of the Best Pharmaceuticals for Children Act

1 of 2007” and inserting “to carry out the Sub-
2 committee’s responsibilities under this section”.

3 **TITLE VI—FOOD AND DRUG AD-**
4 **MINISTRATION ADMINISTRATIVE REFORMS**
5

6 **SEC. 601. PUBLIC PARTICIPATION IN ISSUANCE OF FDA**
7 **GUIDANCE DOCUMENTS.**

8 Section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended
9 by striking subparagraph (C) and inserting the following:
10 “(C) For any guidance document that sets forth ini-
11 tial interpretations of a statute or regulation, sets forth
12 changes in interpretation or policy that are of more than
13 a minor nature, includes complex scientific issues, or cov-
14 ers highly controversial issues—

15 “(i) the Secretary—

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

20 “(II) during preparation and before
21 issuance of such guidance document, may meet
22 with interested stakeholders, including industry,
23 medical, and scientific experts and others, and
24 solicit public comment;

1 “(ii) if the Secretary for good cause finds that,
2 with respect to such guidance document, compliance
3 with clause (i) is impracticable, unnecessary, or con-
4 trary to the public interest—

5 “(I) the Secretary shall publish such find-
6 ing and a brief statement of the reasons for
7 such finding in the Federal Register;

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

10 “(III) during a 90-day period beginning
11 not later than the date of issuance of such guid-
12 ance document, the Secretary may meet with
13 interested stakeholders, including industry,
14 medical, and scientific experts and others, and
15 shall solicit public comment;

16 “(iii) beginning on the date of enactment of the
17 Food and Drug Administration Reform Act of 2012,
18 upon issuance of a draft guidance document under
19 clause (i) or (ii), the Secretary shall—

20 “(I) designate the document as draft or
21 final; and

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

1 “(iv) the Secretary may extend the deadline for
2 issuing final guidance under clause (iii)(II) by not
3 more than 180 days upon submission by the Sec-
4 retary of a notification of such extension in the Fed-
5 eral Register;

6 “(v) if the Secretary issues a draft guidance
7 document and fails to finalize the draft by the dead-
8 line determined under clause (iii)(II), as extended
9 under clause (iv), the Secretary shall, beginning on
10 the date of such deadline, treat the draft as null and
11 void; and

12 “(vi) not less than every 5 years after the
13 issuance of a final guidance document in accordance
14 with clause (iii), the Secretary shall—

15 “(I) conduct a retrospective analysis of
16 such guidance document to ensure it is not out-
17 moded, ineffective, insufficient, or excessively
18 burdensome; and

19 “(II) based on such analysis, modify,
20 streamline, expand, or repeal the guidance doc-
21 ument in accordance with what has been
22 learned.

23 “(D) With respect to devices, a notice to industry
24 guidance letter, a notice to industry advisory letter, and
25 any similar notice that sets forth initial interpretations of

1 a statute or regulation or sets forth changes in interpreta-
2 tion or policy shall be treated as a guidance document for
3 purposes of subparagraph (C).

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

6 “(i) Any document that does not set forth an
7 initial interpretation or a reinterpretation of a stat-
8 ute or regulation.

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

12 “(iii) Agency reports, general information docu-
13 ments provided to consumers or health professionals,
14 speeches, journal articles and editorials, media inter-
15 views, press materials, warning letters, memoranda
16 of understanding, or communications directed to in-
17 dividual persons or firms.”.

18 **SEC. 602. CONFLICTS OF INTEREST.**

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

21 (1) by striking subsections (b) and (c) and in-
22 serting the following subsections:

23 “(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

24 “(1) IN GENERAL.—The Secretary shall—

1 “(A) develop and implement strategies on
2 effective outreach to potential members of advisory
3 committees at universities, colleges, other
4 academic research centers, professional and
5 medical societies, and patient and consumer
6 groups;

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

10 “(C) at least every 180 days, request referrals for potential
11 members of advisory committees from a variety of stakeholders, including—
12 tees from a variety of stakeholders, including—

13 “(i) product developers, patient
14 groups, and disease advocacy organizations; and
15 tions; and

16 “(ii) relevant—

17 “(I) professional societies;

18 “(II) medical societies;

19 “(III) academic organizations;

20 and

21 “(IV) governmental organizations;
22 tions; and

23 “(D) in carrying out subparagraphs (A)
24 and (B), take into account the levels of activity
25 (including the numbers of annual meetings) and

1 the numbers of vacancies of the advisory com-
2 mittees.

3 “(2) RECRUITMENT ACTIVITIES.—The recruit-
4 ment activities under paragraph (1) may include—

5 “(A) advertising the process for becoming
6 an advisory committee member at medical and
7 scientific society conferences;

8 “(B) making widely available, including by
9 using existing electronic communications chan-
10 nels, the contact information for the Food and
11 Drug Administration point of contact regarding
12 advisory committee nominations; and

13 “(C) developing a method through which
14 an entity receiving funding from the National
15 Institutes of Health, the Agency for Healthcare
16 Research and Quality, the Centers for Disease
17 Control and Prevention, or the Veterans Health
18 Administration can identify a person whom the
19 Food and Drug Administration can contact re-
20 garding the nomination of individuals to serve
21 on advisory committees.

22 “(3) EXPERTISE.—In carrying out this sub-
23 section, the Secretary shall seek to ensure that the
24 Secretary has access to the most current expert ad-
25 vice.

1 “(c) DISCLOSURE OF DETERMINATIONS AND CER-
2 TIFICATIONS.—Notwithstanding section 107(a)(2) of the
3 Ethics in Government Act of 1978, the following shall
4 apply:

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

18 “(A) the type, nature, and magnitude of
19 the financial interests of the advisory committee
20 member to which such determination or certifi-
21 cation applies; and

22 “(B) the reasons of the Secretary for such
23 determination or certification, including, as ap-
24 propriate, the public health interest in having
25 the expertise of the member with respect to the

1 particular matter before the advisory com-
2 mittee.

3 “(2) LESS THAN 30 DAYS IN ADVANCE.—In the
4 case of a financial interest that becomes known to
5 the Secretary less than 30 days prior to a meeting
6 of an advisory committee to which a written deter-
7 mination as referred to in section 208(b)(1) of title
8 18, United States Code, or a written certification as
9 referred to in section 208(b)(3) of such title applies,
10 the Secretary shall disclose (other than information
11 exempted from disclosure under section 552 or 552a
12 of title 5, United States Code) on the Internet
13 Website of the Food and Drug Administration, the
14 information described in subparagraphs (A) and (B)
15 of paragraph (1) as soon as practicable after the
16 Secretary makes such determination or certification,
17 but in no case later than the date of such meeting.”;

18 (2) in subsection (d), by striking “subsection
19 (c)(3)” and inserting “subsection (c)”;

20 (3) by amending subsection (e) to read as fol-
21 lows:

22 “(e) ANNUAL REPORT.—

23 “(1) IN GENERAL.—Not later than February 1
24 of each year, the Secretary shall submit to the Com-
25 mittee on Appropriations and the Committee on

1 Health, Education, Labor, and Pensions of the Sen-
2 ate, and the Committee on Appropriations and the
3 Committee on Energy and Commerce of the House
4 of Representatives, a report that describes—

5 “(A) with respect to the fiscal year that
6 ended on September 30 of the previous year,
7 the number of persons nominated for participa-
8 tion at meetings for each advisory committee,
9 the number of persons so nominated, and will-
10 ing to serve, the number of vacancies on each
11 advisory committee, and the number of persons
12 contacted for service as members on each advi-
13 sory committee meeting for each advisory com-
14 mittee who did not participate because of the
15 potential for such participation to constitute a
16 disqualifying financial interest under section
17 208 of title 18, United States Code;

18 “(B) with respect to such year, the number
19 of persons contacted for services as members
20 for each advisory committee meeting for each
21 advisory committee who did not participate be-
22 cause of reasons other than the potential for
23 such participation to constitute a disqualifying
24 financial interest under section 208 of title 18,
25 United States Code;

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

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

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

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

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

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

1 tise, with due consideration of the requirements of
2 such section 208.”.

3 (b) APPLICABILITY.—The amendments made by sub-
4 section (a) apply beginning on October 1, 2012.

5 **SEC. 603. ELECTRONIC SUBMISSION OF APPLICATIONS.**

6 Subchapter D of chapter VII (21 U.S.C. 379k et
7 seq.) is amended by inserting after section 745 the fol-
8 lowing:

9 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

10 “(a) DRUGS AND BIOLOGICS.—

11 “(1) IN GENERAL.—Beginning no earlier than
12 24 months after the issuance of a final guidance
13 issued after public notice and opportunity for com-
14 ment, submissions under subsection (b), (i), or (j) of
15 section 505 of this Act or subsection (a) or (k) of
16 section 351 of the Public Health Service Act shall
17 be submitted in such electronic format as specified
18 by the Secretary in such guidance.

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

21 “(A) provide a timetable for establishment
22 by the Secretary of further standards for elec-
23 tronic submission as required by such para-
24 graph; and

1 “(B) set forth criteria for waivers of and
2 exemptions from the requirements of this sub-
3 section.

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

6 “(b) DEVICES.—

7 “(1) IN GENERAL.—Beginning after the
8 issuance of final guidance implementing this para-
9 graph, pre-submissions and submissions for devices
10 under section 510(k), 513(f)(2)(A), 515(c), 515(d),
11 515(f), 520(g), 520(m), or 564 of this Act or section
12 351 of the Public Health Service Act, and any sup-
13 plements to such pre-submissions or submissions,
14 shall include an electronic copy of such pre-submis-
15 sions or submissions.

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

18 “(A) provide standards for the electronic
19 copy required under such paragraph; and

20 “(B) set forth criteria for waivers of and
21 exemptions from the requirements of this sub-
22 section.”.

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

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

8 (1) notifying the Committee on Energy and
9 Commerce of the House of Representatives and the
10 Committee on Health, Education, Labor, and Pen-
11 sions of the Senate of the Administration’s intent to
12 take such action; and

13 (2) including in such notification the antici-
14 pated details of such action.

15 **TITLE VII—MEDICAL DEVICE**
16 **REGULATORY IMPROVEMENTS**
17 **Subtitle A—Premarket**
18 **Predictability**

19 **SEC. 701. INVESTIGATIONAL DEVICE EXEMPTIONS.**

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

21 (1) in paragraph (2)(B)(ii), by inserting “safety
22 or effectiveness” before “data obtained”; and

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

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

4 “(i) the investigation may not support a sub-
5 stantial equivalence or de novo classification deter-
6 mination or approval of the device;

7 “(ii) the investigation may not meet a require-
8 ment, including a data requirement, relating to the
9 approval or clearance of a device; or

10 “(iii) an additional or different investigation
11 may be necessary to support clearance or approval
12 of the device.”.

13 **SEC. 702. CLARIFICATION OF LEAST BURDENSOME STAND-**
14 **ARD.**

15 (a) **PREMARKET APPROVAL.**—Section 513(a)(3)(D)
16 (21 U.S.C. 360c(a)(3)(D)) is amended—

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

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

20 “(iii) For purposes of clause (ii), the term ‘necessary’
21 means the minimum required information that would sup-
22 port a determination by the Secretary that an application
23 provides reasonable assurance of the effectiveness of the
24 device.

1 “(iv) Nothing in this subparagraph shall alter the cri-
2 teria for evaluating an application for premarket approval
3 of a device.”.

4 (b) PREMARKET NOTIFICATION UNDER SECTION
5 510(k).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D))
6 is amended—

7 (1) by striking “(D) Whenever” and inserting
8 “(D)(i) Whenever”; and

9 (2) by adding at the end the following:

10 “(ii) For purposes of clause (i), the term ‘necessary’
11 means the minimum required information that would sup-
12 port a determination of substantial equivalence between
13 a new device and a predicate device.

14 “(iii) Nothing in this subparagraph shall alter the
15 standard for determining substantial equivalence between
16 a new device and a predicate device.”.

17 **SEC. 703. AGENCY DOCUMENTATION AND REVIEW OF SIG-**
18 **NIFICANT DECISIONS.**

19 Chapter V is amended by inserting after section 517
20 (21 U.S.C. 360g) the following:

21 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**
22 **SIGNIFICANT DECISIONS REGARDING DE-**
23 **VICES.**

24 “(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-
25 CANT DECISIONS.—

1 “(1) IN GENERAL.—The Secretary shall com-
2 pletely document the scientific and regulatory ration-
3 ale for any significant decision of the Center for De-
4 vices and Radiological Health regarding submission
5 or review of a report under section 510(k), an appli-
6 cation under section 515, or an application for an
7 exemption under section 520(g), including docu-
8 mentation of significant controversies or differences
9 of opinion and the resolution of such controversies
10 or differences of opinion.

11 “(2) PROVISION OF DOCUMENTATION.—Upon
12 request, the Secretary shall furnish such complete
13 documentation to the person who is seeking to sub-
14 mit, or who has submitted, such report or applica-
15 tion.

16 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

17 “(1) REQUEST FOR SUPERVISORY REVIEW OF
18 SIGNIFICANT DECISION.—Any person may request a
19 supervisory review of the significant decision de-
20 scribed in subsection (a)(1). Such review may be
21 conducted at the next supervisory level or higher
22 above the individual who made the significant deci-
23 sion.

24 “(2) SUBMISSION OF REQUEST.—A person re-
25 questing a supervisory review under paragraph (1)

1 shall submit such request to the Secretary not later
2 than 30 days after such decision and shall indicate
3 in the request whether such person seeks an in-per-
4 son meeting or a teleconference review.

5 “(3) TIMEFRAME.—

6 “(A) IN GENERAL.—Except as provided in
7 subparagraph (B), the Secretary shall schedule
8 an in-person or teleconference review, if so re-
9 quested, not later than 30 days after such re-
10 quest is made. The Secretary shall issue a deci-
11 sion to the person requesting a review under
12 this subsection not later than 45 days after the
13 request is made under paragraph (1), or, in the
14 case of a person who requests an in-person
15 meeting or teleconference, 30 days after such
16 meeting or teleconference.

17 “(B) EXCEPTION.—Subparagraph (A)
18 shall not apply in cases that are referred to ex-
19 perts outside of the Food and Drug Adminis-
20 tration.”.

21 **SEC. 704. TRANSPARENCY IN CLEARANCE PROCESS.**

22 (a) PUBLICATION OF DETAILED DECISION SUM-
23 MARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended
24 by adding at the end the following:

1 “(5) Subject to subsection (c) and section 301(j), the
2 Secretary shall regularly publish detailed decision sum-
3 maries for each clearance of a device under section 510(k)
4 requiring clinical data.”.

5 (b) APPLICATION.—The requirement of section
6 520(h)(5) of the Federal Food, Drug, and Cosmetic Act,
7 as added by subsection (a), applies only with respect to
8 clearance of a device occurring after the date of the enact-
9 ment of this Act.

10 **SEC. 705. DEVICE MODIFICATIONS REQUIRING PREMARKET**
11 **NOTIFICATION PRIOR TO MARKETING.**

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

13 (1) striking “(n) The Secretary” and inserting
14 “(n)(1) The Secretary”; and

15 (2) by adding at the end the following:

16 “(2)(A) Not later than 18 months after the en-
17 actment of this paragraph, the Secretary shall sub-
18 mit to the Committee on Energy and Commerce of
19 the House of Representatives and the Committee on
20 Health, Education, Labor, and Pensions of the Sen-
21 ate a report regarding when a premarket notification
22 under subsection (k) should be submitted for a
23 modification or change to a legally marketed device.
24 The report shall include the Secretary’s interpreta-
25 tion of the following terms: ‘could significantly affect

1 the safety or effectiveness of the device’, ‘a signifi-
2 cant change or modification in design, material,
3 chemical composition, energy source, or manufac-
4 turing process,’ and ‘major change or modification
5 in the intended use of the device’. The report also
6 shall discuss possible processes for industry to use to
7 determine whether a new submission under sub-
8 section (k) is required and shall analyze how to le-
9 verage existing quality system requirements to re-
10 duce premarket burden, facilitate continual device
11 improvement. and provide reasonable assurance of
12 safety and effectiveness of modified devices. In de-
13 veloping such report, the Secretary shall consider the
14 input of interested stakeholders.

15 “(B) The Secretary shall withdraw the Food
16 and Drug Administration draft guidance entitled
17 ‘Guidance for Industry and FDA Staff—510(k) De-
18 vice Modifications: Deciding When to Submit a
19 510(k) for a Change to an Existing Device’, dated
20 July 27, 2011, and shall not use this draft guidance
21 as part of, or for the basis of, any premarket review
22 or any compliance or enforcement decisions or ac-
23 tions. The Secretary shall not issue—

24 “(i) any draft guidance or proposed regula-
25 tion that addresses when to submit a premarket

1 notification submission for changes and modi-
2 fications made to a manufacturer's previously
3 cleared device before the receipt by the Com-
4 mittee on Energy and Commerce of the House
5 of Representatives and the Committee on
6 Health, Education, Labor, and Pensions of the
7 Senate of the report required in subparagraph
8 (A); and

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

15 “(C) The Food and Drug Administration guid-
16 ance entitled ‘Deciding When to Submit a 510(k) for
17 a Change to an Existing Device’, dated January 10,
18 1997, shall be in effect until the subsequent issuance
19 of guidance or promulgation, if appropriate, of a
20 regulation described in subparagraph (B), and the
21 Secretary shall interpret such guidance in a manner
22 that is consistent with the manner in which the Sec-
23 retary has interpreted such guidance since 1997.”.

1 **Subtitle B—Patients Come First**

2 **SEC. 711. ESTABLISHMENT OF SCHEDULE AND PROMULGA-**
3 **TION OF REGULATION.**

4 (a) ESTABLISHMENT OF SCHEDULE.—Not later than
5 90 days after the date of enactment of this Act, the Sec-
6 retary of Health and Human Services shall establish the
7 schedule referred to in section 515(i)(3) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

9 (b) REGULATION.—Not later than one year after the
10 date that the schedule is established under such section
11 515(i)(3) (as required by subsection (a)) the Secretary
12 shall issue a final regulation under section 515(b) of such
13 Act for each device that the Secretary requires to remain
14 in class III through a determination under section
15 515(i)(2) of such Act.

16 **SEC. 712. PROGRAM TO IMPROVE THE DEVICE RECALL SYS-**
17 **TEM.**

18 Chapter V is amended by inserting after section 518
19 (21 U.S.C. 360h) the following:

20 **“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**
21 **SYSTEM.**

22 “(a) IN GENERAL.—The Secretary shall—

23 “(1) establish a program to routinely and sys-
24 tematically assess information relating to device re-
25 calls and use such information to proactively identify

1 strategies for mitigating health risks presented by
2 defective or unsafe devices;

3 “(2) clarify procedures for conducting device re-
4 call audit checks to improve the ability of investiga-
5 tors to perform those checks in a consistent manner;

6 “(3) develop detailed criteria for assessing
7 whether a person performing a device recall has per-
8 formed an effective correction or action plan for the
9 recall; and

10 “(4) document the basis for each termination
11 by the Food and Drug Administration of a device re-
12 call.

13 “(b) ASSESSMENT CONTENT.—The program estab-
14 lished under subsection (a)(1) shall, at a minimum, iden-
15 tify—

16 “(1) trends in the number and types of device
17 recalls;

18 “(2) devices that are most frequently the sub-
19 ject of a recall; and

20 “(3) underlying causes of device recalls.

21 “(c) DEFINITION.—In this section, the term ‘recall’
22 means—

23 “(1) the removal from the market of a device
24 pursuant to an order of the Secretary under sub-
25 section (b) or (e) of section 518; or

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

5 **Subtitle C—Novel Device** 6 **Regulatory Relief**

7 **SEC. 721. MODIFICATION OF DE NOVO APPLICATION PROC-** 8 **ESS.**

9 (a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.
10 360c(f)(2)) is amended—

11 (1) by inserting “(i)” after “(2)(A)”;

12 (2) in subparagraph (A)(i), as so designated by
13 paragraph (1), by striking “under the criteria set
14 forth” and all that follows through the end of sub-
15 paragraph (A) and inserting a period;

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

18 “(ii) In lieu of submitting a report under section
19 510(k) and submitting a request for classification under
20 clause (i) for a device, if a person determines there is no
21 legally marketed device upon which to base a determina-
22 tion of substantial equivalence (as defined in subsection
23 (i)), a person may submit a request under this clause for
24 the Secretary to classify the device.

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

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

8 “(I) identifies a legally marketed device that
9 would permit a substantial equivalence determina-
10 tion under paragraph (1) for the device; or

11 “(II) determines that the device submitted is
12 not of low-moderate risk or special controls to miti-
13 gate the risks cannot be developed for the device.

14 “(v) The person submitting the request for classifica-
15 tion under this subparagraph may recommend to the Sec-
16 retary a classification for the device and shall, if recom-
17 mending classification in class II, include in the request
18 an initial draft proposal for applicable special controls, as
19 described in subsection (a)(1)(B), that are necessary, in
20 conjunction with general controls, to provide reasonable
21 assurance of safety and effectiveness and a description of
22 how the special controls provide such assurance. Any such
23 request shall describe the device and provide detailed in-
24 formation and reasons for the recommended classifica-
25 tion.”; and

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

5 (b) CONFORMING AMENDMENTS.—Section 513(f) of
6 such Act (21 U.S.C. 360c(f)) is amended in paragraph
7 (1)—

8 (1) in subparagraph (A), by striking “, or” at
9 the end and inserting a semicolon;

10 (2) in subparagraph (B), by striking the period
11 and inserting “; or”; and

12 (3) by inserting after subparagraph (B) the fol-
13 lowing:

14 “(C) the device is classified pursuant to a re-
15 quest submitted under paragraph (2).”.

16 **Subtitle D—Keeping America Com-**
17 **petitive Through Harmonization**

18 **SEC. 731. HARMONIZATION OF DEVICE PREMARKET RE-**
19 **VIEW, INSPECTION, AND LABELING SYMBOLS;**
20 **REPORT.**

21 (a) IN GENERAL.—Paragraph (4) of section 803(c)
22 (21 U.S.C. 383(c)) is amended to read as follows:

23 “(4) With respect to devices, the Secretary may,
24 when appropriate, enter into arrangements with nations
25 regarding methods and approaches to harmonizing regu-

latory requirements for activities, including inspections
and common international labeling symbols.”.

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

SEC. 732. PARTICIPATION IN INTERNATIONAL FORA.

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

(1) by striking “(3)” and inserting “(3)(A)”;
and

(2) by adding at the end the following:

“(B) In carrying out subparagraph (A), the Secretary
may participate in appropriate fora, including the Inter-
national Medical Device Regulators Forum, and may—

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

1 “(ii) to the extent appropriate, solicit, review,
2 and consider comments from industry, academia,
3 health care professionals, and patient groups regard-
4 ing the activities of such fora; and

5 “(iii) to the extent appropriate, inform the pub-
6 lic of the Secretary’s activities within such fora, and
7 share with the public any documentation relating to
8 a forum’s strategies, policies, and other activities of
9 such fora.”.

10 **Subtitle E—FDA Renewing Effi-**
11 **ciency From Outside Reviewer**
12 **Management**

13 **SEC. 741. REAUTHORIZATION OF THIRD PARTY REVIEW.**

14 (a) PERIODIC REACCREDITATION.—Section
15 523(b)(2) (21 U.S.C. 360m(b)(2)) is amended by adding
16 at the end of the following:

17 “(E) PERIODIC REACCREDITATION.—

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

23 “(ii) RESPONSE TO REACCREDITATION
24 REQUEST.—Upon the submission of a re-
25 quest by an accredited person for re-

1 accreditation under this section, the Sec-
2 retary shall approve or deny such request
3 not later than 60 days after receipt of the
4 request.

5 “(iii) CRITERIA.—Not later than 120
6 days after the date of the enactment of
7 this subparagraph, the Secretary shall es-
8 tablish and publish in the Federal Register
9 criteria to reaccredit or deny reaccredita-
10 tion to persons under this section. The re-
11 accreditation of persons under this section
12 shall specify the particular activities under
13 subsection (a), and the devices, for which
14 such persons are reaccredited.”.

15 (b) DURATION OF AUTHORITY.—Section 523(c) (21
16 U.S.C. 360m(c)) is amended by striking “October 1,
17 2012” and inserting “October 1, 2017”.

18 **SEC. 742. REAUTHORIZATION OF THIRD PARTY INSPEC-**
19 **TION.**

20 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-
21 ed by striking “October 1, 2012” and inserting “October
22 1, 2017”.

1 **Subtitle F—Humanitarian Device**
2 **Reform**

3 **SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DE-**
4 **VICES.**

5 (a) IN GENERAL.—Section 520(m) (21 U.S.C.
6 360j(m)) is amended—

7 (1) in paragraph (6)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),
10 by striking “subparagraph (D)” and in-
11 serting “subparagraph (C)”;

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

14 “(i) The device with respect to which the ex-
15 emption is granted—

16 “(I) is intended for the treatment or diag-
17 nosis of a disease or condition that occurs in
18 pediatric patients or in a pediatric subpopula-
19 tion, and such device is labeled for use in pedi-
20 atric patients or in a pediatric subpopulation in
21 which the disease or condition occurs; or

22 “(II) is intended for the treatment or diag-
23 nosis of a disease or condition that does not
24 occur in pediatric patients or that occurs in pe-
25 diatric patients in such numbers that the devel-

1 opment of the device for such patients is impos-
2 sible, highly impracticable, or unsafe.”;

3 (iii) by striking clause (ii) and insert-
4 ing the following:

5 “(ii) During any calendar year, the number of
6 such devices distributed during that year under each
7 exemption granted under this subsection does not
8 exceed the number of such devices needed to treat,
9 diagnose, or cure a population of 4,000 individuals
10 in the United States (referred to in this paragraph
11 as the ‘annual distribution number’).”; and

12 (iv) in clause (iv), by striking “2012”
13 and inserting “2017”;

14 (B) by striking subparagraph (C);

15 (C) by redesignating subparagraphs (D)
16 and (E) as subparagraphs (C) and (D), respec-
17 tively; and

18 (D) in subparagraph (C), as so redesign-
19 ated, by striking “and modified under sub-
20 paragraph (C), if applicable,”;

21 (2) in paragraph (7), by striking “regarding a
22 device” and inserting “regarding a device described
23 in paragraph (6)(A)(i)(I)”; and

1 (3) in paragraph (8), by striking “of all devices
2 described in paragraph (6)” and inserting “of all de-
3 vices described in paragraph (6)(A)(i)(I)”.

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

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

19 (1) the effectiveness of the amendments made
20 by subsection (a) in stimulating innovation with re-
21 spect to medical devices, including any favorable or
22 adverse impact on pediatric device development;

23 (2) the impact of such amendments on pediatric
24 device approvals for devices that received a humani-
25 tarian use designation under section 520(m) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 360j(m)) prior to the date of enactment of this Act;

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

7 (4) the impact that paragraph (4) of such sec-
8 tion 520(m) has had on access to and insurance cov-
9 erage of devices granted an exemption under para-
10 graph (2) of such section 520(m); and

11 (5) the effect of the amendments made by sub-
12 section (a) on patients described in such section
13 520(m).

14 **Subtitle G—Records and Reports** 15 **on Devices**

16 **SEC. 761. UNIQUE DEVICE IDENTIFICATION SYSTEM REGU-** 17 **LATIONS.**

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

23 **SEC. 762. EFFECTIVE DEVICE SENTINEL PROGRAM.**

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

1 (21 U.S.C. 360i) is amended by adding at the end the
2 following:

3 “(h) INCLUSION OF DEVICES IN POSTMARKET RISK
4 IDENTIFICATION AND ANALYSIS SYSTEM.—

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

11 “(2) DATA.—In expanding the system as de-
12 scribed in paragraph (1), the Secretary shall use rel-
13 evant data with respect to devices cleared under sec-
14 tion 510(k) or approved under section 515, which
15 may include claims data, patient survey data, and
16 standardized analytic files that allow for the pooling
17 and analysis of data from disparate data environ-
18 ments.

19 “(3) STAKEHOLDER INPUT.—To help ensure ef-
20 fective implementation of the system as described in
21 paragraph (1) with respect to devices, the Secretary
22 shall engage outside stakeholders in development of
23 the system, and gather information from outside
24 stakeholders regarding the content of an effective
25 sentinel program, through a public hearing, advisory

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

3 “(4) VOLUNTARY SURVEYS.—Chapter 35 of
4 title 44, United States Code, shall not apply to the
5 collection of voluntary information from health care
6 providers, such as voluntary surveys or question-
7 naires, initiated by the Secretary for purposes of
8 postmarket risk identification, mitigation, and anal-
9 ysis for devices.”.

10 (b) AMENDMENTS TO POSTMARKET RISK IDENTI-
11 FICATION AND ANALYSIS SYSTEM.—Section
12 505(k)(3)(C)(i) (21 U.S.C. 355(k)(3)(C)(i)) is amended—

13 (1) by striking subclause (II);

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

17 (3) in item (bb) of subclause (II), as so redesign-
18 nated, by striking “pharmaceutical purchase data
19 and health insurance claims data” and inserting
20 “medical device utilization data, health insurance
21 claims data, and procedure and device registries”.

22 **Subtitle H—Miscellaneous**

23 **SEC. 771. CUSTOM DEVICES.**

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

1 “(b) CUSTOM DEVICES.—

2 “(1) IN GENERAL.—The requirements of sec-
3 tions 514 and 515 shall not apply to a device that—

4 “(A) is created or modified in order to
5 comply with the order of an individual physician
6 or dentist (or any other specially qualified per-
7 son designated under regulations promulgated
8 by the Secretary after an opportunity for an
9 oral hearing);

10 “(B) in order to comply with an order de-
11 scribed in subparagraph (A), necessarily devi-
12 ates from an otherwise applicable performance
13 standard under section 514 or requirement
14 under section 515;

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

19 “(D) is designed to treat a unique pathol-
20 ogy or physiological condition that no other de-
21 vice is domestically available to treat;

22 “(E)(i) is intended to meet the special
23 needs of such physician or dentist (or other spe-
24 cially qualified person so designated) in the
25 course of the professional practice of such phy-

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

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

7 “(F) is assembled from components or
8 manufactured and finished on a case-by-case
9 basis to accommodate the unique needs of indi-
10 viduals described in clause (i) or (ii) of subpara-
11 graph (E); and

12 “(G) may have common, standardized de-
13 sign characteristics, chemical and material com-
14 positions, and manufacturing processes as com-
15 mercially distributed devices.

16 “(2) LIMITATIONS.—Paragraph (1) shall apply
17 to a device only if—

18 “(A) such device is for the purpose of
19 treating a sufficiently rare condition, such that
20 conducting clinical investigations on such device
21 would be impractical;

22 “(B) production of such device under para-
23 graph (1) is limited to no more than 5 units per
24 year of a particular device type, provided that

1 such replication otherwise complies with this
2 section; and

3 “(C) the manufacturer of such device noti-
4 fies the Secretary on an annual basis, in a man-
5 ner prescribed by the Secretary, of the manu-
6 facture of such device.

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

11 **SEC. 772. PEDIATRIC DEVICE REAUTHORIZATION.**

12 (a) FINAL RULE RELATING TO TRACKING OF PEDI-
13 ATRIC USES OF DEVICES.—The Secretary of Health and
14 Human Services shall issue—

15 (1) a proposed rule implementing section
16 515A(a)(2) of the Federal Food, Drug and Cosmetic
17 Act (21 U.S.C. 360e–1(a)(2)) not later than Decem-
18 ber 31, 2012; and

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

21 (b) DEMONSTRATION GRANTS TO IMPROVE PEDI-
22 ATRIC DEVICE AVAILABILITY.—Section 305(e) of the Pe-
23 diatric Medical Device Safety and Improvement Act of
24 2007 (Title III of Public Law 110–85) is amended by

1 striking “2008 through 2012” and inserting “2013
2 through 2017”.

3 **SEC. 773. REPORT ON REGULATION OF HEALTH INFORMA-**
4 **TION TECHNOLOGY.**

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

14 (1) a strategy for coordinating the regulation of
15 health information technology in order to avoid regu-
16 latory duplication; and

17 (2) recommendations on an appropriate regu-
18 latory framework for health information technology,
19 including a risk-based framework.

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

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

3 **TITLE VIII—DRUG REGULATORY** 4 **IMPROVEMENTS**

5 **Subtitle A—Drug Supply Chain**

6 **SEC. 801. REGISTRATION OF PRODUCERS OF DRUGS.**

7 (a) TIMING.—Section 510 (21 U.S.C. 360) is amend-
8 ed—

9 (1) in subsection (b)(1), by striking “On or be-
10 fore” and inserting “During the period beginning on
11 October 1 and ending on”; and

12 (2) in subsection (i)(1)(B)(i), by striking “on or
13 before” and inserting “during the period beginning
14 on October 1 and ending on”.

15 (b) ESTABLISHMENTS NOT DULY REGISTERED; MIS-
16 BRANDING.—Section 502(o) (21 U.S.C. 352(o)) is amend-
17 ed by striking “in any State”.

18 **SEC. 802. INSPECTION OF DRUGS.**

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

21 (1) by striking “(h)” and inserting “(h)(1)”;

22 (2) by inserting “with respect to the manufac-
23 ture, preparation, propagation, compounding, or
24 processing of a device” after “registered with the
25 Secretary pursuant to this section”;

1 (3) by striking “of a drug or drugs or”; and

2 (4) by adding at the end the following:

3 “(2) INSPECTIONS WITH RESPECT TO DRUG ESTAB-
4 LISHMENTS.—With respect to the manufacture, prepara-
5 tion, propagation, compounding, or processing of a drug:

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

10 “(B) RISK-BASED SCHEDULE.—In the case of
11 an establishment that is engaged in the manufac-
12 ture, preparation, propagation, compounding, or
13 processing of a drug or drugs (referred to in this
14 subsection as a ‘drug establishment’), the inspec-
15 tions required under subparagraph (A) shall be con-
16 ducted by officers or employees duly designated by
17 the Secretary, on a risk-based schedule established
18 by the Secretary.

19 “(C) RISK FACTORS.—In establishing the risk-
20 based schedule under subparagraph (B), the Sec-
21 retary shall allocate resources to inspect establish-
22 ments according to the known safety risks of such
23 establishments, based on the following factors:

24 “(i) The compliance history of the estab-
25 lishment.

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

5 “(iii) The record, history, and nature of re-
6 calls linked to the establishment.

7 “(iv) The inherent risk of the drug manu-
8 factured, prepared, propagated, compounded, or
9 processed at the establishment.

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

13 “(D) EFFECT OF STATUS.—In determining the
14 risk associated with an establishment for purposes of
15 establishing a risk-based schedule under subpara-
16 graph (B), the Secretary shall not consider whether
17 the drugs manufactured, prepared, propagated, com-
18 pounded, or processed by such establishment are
19 drugs described in section 503(b)(1).

20 “(E) ANNUAL REPORT ON INSPECTIONS OF ES-
21 TABLISHMENTS.—Not later than February 1 of each
22 year, the Secretary shall submit to Congress a re-
23 port that contains the following:

1 “(i) The number of domestic and foreign
2 establishments registered pursuant to this sec-
3 tion in the previous calendar year.

4 “(ii) The number of such registered domes-
5 tic and foreign establishments that the Sec-
6 retary inspected in the previous calendar year.

7 “(iii) The number of such registered estab-
8 lishments that list one or more drugs approved
9 pursuant to an application filed under section
10 505(j).

11 “(iv) The number of such registered estab-
12 lishments that list one or more drugs approved
13 pursuant to an application filed under section
14 505(b).

15 “(v) The number of registered establish-
16 ments that list both drug products approved
17 pursuant to an application filed under section
18 505(j) and drug products approved pursuant to
19 an application filed under section 505(b).

20 “(vi) A description of how the Secretary
21 implemented the risk-based schedule under sub-
22 paragraph (B) utilizing the factors under sub-
23 paragraph (C).

24 “(F) PUBLIC AVAILABILITY OF ANNUAL RE-
25 PORTS.—The Secretary shall make the report re-

1 quired under subparagraph (E) available to the pub-
2 lic on the Internet Web site of the Food and Drug
3 Administration.”.

4 **SEC. 803. DRUG SUPPLY QUALITY AND SAFETY.**

5 Paragraph (a) of section 501 (21 U.S.C. 351) is
6 amended by adding at the end the following: “For pur-
7 poses of subparagraph (2)(B), the term ‘current good
8 manufacturing practice’ includes the implementation of
9 oversight and controls over the manufacture of drugs to
10 ensure quality, including managing the risk of and estab-
11 lishing the safety of raw materials, materials used in the
12 manufacturing of drugs, and finished drug products.”.

13 **SEC. 804. PROHIBITION AGAINST DELAYING, DENYING, LIM-**
14 **ITING, OR REFUSING INSPECTION.**

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

17 “(j) If it is a drug and it has been manufactured,
18 processed, packed, or held in any factory, warehouse, or
19 establishment and the owner, operator, or agent of such
20 factory, warehouse, or establishment delays, denies, or
21 limits an inspection, or refuses to permit entry or inspec-
22 tion.”.

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

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

5 **SEC. 805. DESTRUCTION OF ADULTERATED, MISBRANDED,**
6 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
7 **PORT.**

8 (a) IN GENERAL.—The sixth sentence of section
9 801(a) (21 U.S.C. 381(a)) is amended by inserting before
10 the period at the end the following: “, except that the Sec-
11 retary of Health and Human Services, in consultation with
12 the Secretary of Homeland Security, may cause the de-
13 struction, without the opportunity for export, of any drug
14 refused admission that has reasonable probability of caus-
15 ing serious adverse health consequences or death, as deter-
16 mined by the Secretary of Health and Human Services,
17 or that is valued at an amount that is \$2,000 or less (or
18 such higher amount as the Secretary of Homeland Secu-
19 rity may set by regulation pursuant to section 498 of the
20 Tariff Act of 1930 (19 U.S.C. 1498))”.

21 (b) NOTICE.—Section 801(a) (21 U.S.C. 381(a)), as
22 amended by subsection (a), is further amended by insert-
23 ing after the sixth sentence the following: “The Secretary
24 of Health and Human Services shall issue regulations pro-
25 viding for notice and an opportunity for a hearing on the

1 destruction of a drug under the previous sentence. For a
2 drug with a value less than and or equal to \$2,000 (or,
3 as described in the sixth sentence of this subsection, such
4 higher amount as the Secretary of Homeland Security
5 may set by regulation pursuant to section 498 of the Tar-
6 iff Act of 1930 (19 U.S.C. 1498)) the regulations under
7 the previous sentence shall provide for prompt notice and
8 an opportunity for a hearing for the owner or consignee
9 before or after the destruction has occurred. For a drug
10 with a value greater than \$2,000 (or, as described in the
11 sixth sentence of this subsection, such higher amount as
12 the Secretary of Homeland Security may set by regulation
13 pursuant to section 498 of the Tariff Act of 1930 (19
14 U.S.C. 1498)) that has reasonable probability of causing
15 serious adverse health consequences or death as deter-
16 mined by the Secretary of Health and Human Services,
17 the regulations under the seventh sentence of this sub-
18 section shall provide for notice and an opportunity for a
19 hearing to the owner or consignee before the destruction
20 occurs.”.

21 (c) RESTITUTION.—In the regulations described in
22 the seventh sentence of section 801(a) of the Federal
23 Food, Drug, and Cosmetic Act (as added by subsection
24 (b)), the Secretary of Health and Human Services shall
25 establish an administrative process whereby an owner or

1 consignee of a drug destroyed without an opportunity for
2 a hearing on destruction may obtain restitution for the
3 value of the drug destroyed under the sixth sentence of
4 such section upon demonstration that such drug was
5 wrongfully destroyed.

6 (d) CONFORMING AMENDMENT.—The first sentence
7 of section 801(a) (21 U.S.C. 381(a)) is amended by insert-
8 ing “, except as otherwise described in the sixth and sev-
9 enth sentences of this subsection,” after “giving notice
10 thereof”.

11 **SEC. 806. ADMINISTRATIVE DETENTION.**

12 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
13 335a(g)) is amended—

14 (1) in paragraph (1), by inserting “, drug,”
15 after “device”, each place it appears;

16 (2) in paragraph (2)(A), by inserting “, drug,”
17 after “(B), a device”; and

18 (3) in paragraph (2)(B), by inserting “or drug”
19 after “device” each place it appears.

20 (b) REGULATION.—Not later than 2 years after the
21 date of the enactment of this Act, the Secretary of Health
22 and Human Services shall promulgate regulations to im-
23 plement administrative detention authority with respect to
24 drugs, as authorized by the amendments made by sub-
25 section (a). Before promulgating such regulations, the

1 Secretary shall consult with stakeholders, including manu-
2 facturers of drugs.

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

6 **SEC. 807. ENHANCED CRIMINAL PENALTY FOR COUNTER-**
7 **FEIT DRUGS.**

8 (a) IN GENERAL.—Section 303(a) (21 U.S.C.
9 333(a)) is amended by adding at the end the following:
10 “(3) Notwithstanding paragraph (2), any person who
11 engages in any conduct described in section 301(i)(2)
12 knowing or having reason to know that the conduct con-
13 cerns the rendering of a drug as a counterfeit drug, or
14 who engages in conduct described in section 301(i)(3)
15 knowing or having reason to know that the conduct will
16 cause a drug to be a counterfeit drug or knowing or having
17 reason to know that a drug held, sold, or dispensed is a
18 counterfeit drug, shall be fined in accordance with title
19 18, United States Code, or imprisoned not more than 20
20 years, or both, except that if the use of the counterfeit
21 drug by a consumer is the proximate cause of the death
22 of the consumer, the term of imprisonment shall be any
23 term of years or for life.”.

24 (b) CONFORMING AMENDMENT.—Section 201(g)(2)
25 (21 U.S.C. 321(g)(2)) is amended by adding at the end

1 the following sentence: “The term ‘counterfeit drug’ shall
2 not include a drug or placebo intended for use in a clinical
3 trial that is intentionally labeled or marked to maintain
4 proper blinding of the study.”.

5 **SEC. 808. UNIQUE FACILITY IDENTIFICATION NUMBER.**

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

8 (1) in subsection (b)(1), by striking “and all
9 such establishments” and inserting “all such estab-
10 lishments, and the unique facility identifier of each
11 such establishment”; and

12 (2) in subsection (c), by striking “and such es-
13 tablishment” and inserting “such establishment, and
14 the unique facility identifier of such establishment”.

15 (b) FOREIGN ESTABLISHMENTS.—Subparagraph (A)
16 of section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by
17 inserting “the unique facility identifier of the establish-
18 ment,” after “the name and place of business of the estab-
19 lishment,”.

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

22 “(q) GUIDANCE ON SUBMISSION OF UNIQUE FACIL-
23 ITY IDENTIFIERS.—

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

4 “(A) the unique facility identifier system
5 to be used to meet the requirements of—

6 “(i) subsections (b)(1), (c), and
7 (i)(1)(A) of this section; and

8 “(ii) section 801(s) (relating to reg-
9 istration of commercial importers); and

10 “(B) the form, manner, and timing of sub-
11 missions of unique facility identifiers under the
12 provisions specified in subparagraph (A).

13 “(2) CONSIDERATION.—In developing the guid-
14 ance under paragraph (1), the Secretary shall take
15 into account the utilization of existing unique identi-
16 fication schemes and compatibility with customs
17 automated systems.”.

18 (d) IMPORTATION.—Section 801(a) (21 U.S.C.
19 381(a)) is amended by inserting “or (5) for an article that
20 is a drug, the appropriate unique facility identifiers under
21 subsection (s) (relating to commercial importers) and sec-
22 tion 510(i) (relating to foreign establishments), as speci-
23 fied by the Secretary, are not provided,” before “then such
24 article shall be refused admission”.

1 **SEC. 809. DOCUMENTATION FOR ADMISSIBILITY OF IM-**
2 **PORTS.**

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

5 “(r) DOCUMENTATION.—

6 “(1) SUBMISSION.—The Secretary may require,
7 in consultation with the Secretary of Homeland Se-
8 curity acting through U.S. Customs and Border Pro-
9 tection as determined appropriate by the Secretary,
10 the submission of documentation or other informa-
11 tion for a drug that is imported or offered for im-
12 port into the United States.

13 “(2) REFUSAL OF ADMISSION.—A drug im-
14 ported or offered for import into the United States
15 shall be refused admission unless all documentation
16 and information the Secretary requires under this
17 Act, the Public Health Service Act, or both, as ap-
18 propriate, for such article is submitted.

19 “(3) REGULATIONS.—

20 “(A) DOCUMENTS AND INFORMATION.—

21 The Secretary shall issue a regulation to specify
22 the documentation or other information that is
23 described in paragraph (1). Such information
24 may include—

25 “(i) information demonstrating the
26 regulatory status of the drug, such as the

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

4 “(ii) facility information, such as
5 proof of registration and the unique facility
6 identifier; and

7 “(iii) indication of compliance with
8 current good manufacturing practice, such
9 as satisfactory testing results, certifi-
10 cations relating to satisfactory inspections,
11 and compliance with the country of export
12 regulations.

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

18 “(4) EFFECTIVE DATE.—The final rule under
19 paragraph (3)(A) shall take effect not less than 180
20 days after the Secretary promulgates such final
21 rule.”.

22 **SEC. 810. REGISTRATION OF COMMERCIAL IMPORTERS.**

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

1 “(aaa) The failure to register in accordance with sec-
2 tion 801(s).”.

3 (b) REGISTRATION.—Section 801 (21 U.S.C. 381),
4 as amended by section 809, is further amended by adding
5 at the end the following:

6 “(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

7 “(1) REGISTRATION.—The Secretary shall re-
8 quire a commercial importer of drugs—

9 “(A) to be registered with the Secretary in
10 a form and manner specified by the Secretary;
11 and

12 “(B) consistent with the guidance under
13 section 510(q), to submit, at the time of reg-
14 istration, a unique identifier for the principal
15 place of business for which the importer is re-
16 quired to register under this subsection.

17 “(2) REGULATIONS.—

18 “(A) IN GENERAL.—The Secretary, in con-
19 sultation with the Secretary of Homeland Secu-
20 rity acting through U.S. Customs and Border
21 Protection, shall promulgate regulations to es-
22 tablish good importer practices that specify the
23 measures an importer shall take to ensure im-
24 ported drugs are in compliance with the re-

1 quirements of this Act and the Public Health
2 Service Act.

3 “(B) EXPEDITED CLEARANCE FOR CER-
4 TAIN IMPORTERS.—In promulgating good im-
5 porter practice regulations under subparagraph
6 (A), the Secretary may, as appropriate, take
7 into account differences among importers and
8 types of imports, and, based on the level of risk
9 posed by the imported drug, provide for expe-
10 dited clearance for those importers that volun-
11 teer to participate in partnership programs for
12 highly compliant companies.

13 “(3) DISCONTINUANCE OF REGISTRATION.—
14 The Secretary shall discontinue the registration of
15 any commercial importer of drugs that fails to com-
16 ply with the regulations promulgated under this sub-
17 section.

18 “(4) EXEMPTIONS.—The Secretary, by notice
19 in the Federal Register, may establish exemptions
20 from the requirements of this subsection.”.

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

1 (d) REGULATIONS.—

2 (1) IN GENERAL.—Not later than 36 months
3 after the date of the enactment of this Act, the Sec-
4 retary of Health and Human Services, in consulta-
5 tion with the Secretary of Homeland Security acting
6 through U.S. Customs and Border Protection, shall
7 promulgate the regulations required to carry out sec-
8 tion 801(s) of the Federal Food, Drug, and Cos-
9 metic Act, as added by subsection (b).

10 (2) EFFECTIVE DATE.—In establishing the ef-
11 fective date of the regulations under paragraph (1),
12 the Secretary of Health and Human Services shall,
13 in consultation with the Secretary of Homeland Se-
14 curity acting through U.S. Customs and Border Pro-
15 tection, as determined appropriate by the Secretary
16 of Health and Human Services, provide a reasonable
17 period of time for an importer of a drug to comply
18 with good importer practices, taking into account
19 differences among importers and types of imports,
20 including based on the level of risk posed by the im-
21 ported product.

22 **SEC. 811. NOTIFICATION.**

23 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
24 331), as amended by section 810, is further amended by
25 adding at the end the following:

1 “(bbb) The failure to notify the Secretary in violation
2 of section 568.”.

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

6 **“SEC. 568. NOTIFICATION.**

7 “(a) NOTIFICATION TO SECRETARY.—With respect
8 to a drug, the Secretary may require notification to the
9 Secretary by a regulated person if the regulated person
10 knows—

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

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

15 “(3) that—

16 “(A) such drug has been or is being coun-
17 terfeited; and

18 “(B)(i) the counterfeit product is in com-
19 merce in the United States or could be reason-
20 ably expected to be introduced into commerce;
21 or

22 “(ii) such drug has been or is being im-
23 ported into the United States or may reason-
24 ably be expected to be offered for import into
25 the United States.

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

5 “(c) SAVINGS CLAUSE.—Nothing in this section shall
6 be construed as limiting any other authority of the Sec-
7 retary to require notifications related to a drug under any
8 other provision of this Act or the Public Health Service
9 Act.

10 “(d) DEFINITION.—In this section, the term ‘regu-
11 lated person’ means—

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

14 “(2) a wholesale distributor of a drug product;
15 or

16 “(3) any other person that distributes drugs ex-
17 cept a person that distributes drugs exclusively for
18 retail sale.”.

19 **SEC. 812. EXCHANGE OF INFORMATION.**

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

21 (1) by striking “The Secretary may provide”
22 and inserting the following:

23 “(a) CONTRACTORS.—The Secretary may provide”;
24 and

25 (2) by adding at the end the following:

1 “(b) ABILITY TO RECEIVE AND PROTECT CON-
2 FIDENTIAL INFORMATION.—Except pursuant to an order
3 of a court of the United States, the Secretary shall not
4 be required to disclose under section 552 of title 5, United
5 States Code, or any other provision of law, any informa-
6 tion relating to drugs obtained from a Federal, State, or
7 local government agency, or from a foreign government
8 agency, if the agency has requested that the information
9 be kept confidential. For purposes of section 552 of title
10 5, United States Code, this subsection shall be considered
11 a statute described in section 552(b)(3)(B).

12 “(c) AUTHORITY TO ENTER INTO MEMORANDA OF
13 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-
14 CHANGE.—The Secretary may enter into written agree-
15 ments regarding the exchange of information referenced
16 in section 301(j) subject to the following criteria:

17 “(1) CERTIFICATION.—The Secretary may only
18 enter into written agreements under this subsection
19 with foreign governments that the Secretary has cer-
20 tified as having the authority and demonstrated abil-
21 ity to protect trade secret information from disclo-
22 sure. Responsibility for this certification shall not be
23 delegated to any officer or employee other than the
24 Commissioner of Food and Drugs.

1 “(2) WRITTEN AGREEMENT.—The written
2 agreement under this subsection shall include a com-
3 mitment by the foreign government to protect infor-
4 mation exchanged under this subsection from disclo-
5 sure unless and until the sponsor gives written per-
6 mission for disclosure or the Secretary makes a dec-
7 laration of a public health emergency pursuant to
8 section 319 of the Public Health Service Act that is
9 relevant to the information.

10 “(3) INFORMATION EXCHANGE.—The Secretary
11 may provide to a foreign government that has been
12 certified under paragraph (1), and that has executed
13 a written agreement under paragraph (2), informa-
14 tion referenced in section 301(j) in the following cir-
15 cumstances:

16 “(A) Information concerning the inspection
17 of a facility may be provided if—

18 “(i) the Secretary reasonably believes,
19 or the written agreement described in
20 paragraph (2) establishes, that the govern-
21 ment has authority to otherwise obtain
22 such information; and

23 “(ii) the written agreement executed
24 under paragraph (2) limits the recipient’s

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

3 “(B) Information not described in sub-
4 paragraph (A) may be provided as part of an
5 investigation, or to alert the foreign government
6 to the potential need for an investigation, if the
7 Secretary has reasonable grounds to believe
8 that a drug has a reasonable probability of
9 causing serious adverse health consequences or
10 death.

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

14 **SEC. 813. EXTRATERRITORIAL JURISDICTION.**

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

17 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

18 “There is extraterritorial jurisdiction over any viola-
19 tion of this Act relating to any article regulated under this
20 Act if such article was intended for import into the United
21 States or if any act in furtherance of the violation was
22 committed in the United States.”.

1 **SEC. 814. PROTECTION AGAINST INTENTIONAL ADULTERA-**
2 **TION.**

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

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

13 **SEC. 815. RECORDS FOR INSPECTION.**

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

16 “(4)(A) Any records or other information that the
17 Secretary may inspect under this section from a person
18 that owns or operates an establishment that is engaged
19 in the manufacture, preparation, propagation,
20 compounding, or processing of a drug shall, upon the re-
21 quest of the Secretary, be provided to the Secretary by
22 such person, in advance of or in lieu of an inspection, with-
23 in a reasonable timeframe, within reasonable limits, and
24 in a reasonable manner, and in either electronic or phys-
25 ical form, at the expense of such person. The Secretary’s

1 request shall include a sufficient description of the records
2 requested.

3 “(B) Upon receipt of the records requested under
4 subparagraph (A), the Secretary shall provide to the per-
5 son confirmation of receipt.

6 “(C) Nothing in this paragraph supplants the author-
7 ity of the Secretary to conduct inspections otherwise per-
8 mitted under this Act in order to ensure compliance with
9 this Act.”.

10 **Subtitle B—Medical Gas Safety**

11 **SEC. 821. REGULATION OF MEDICAL GASES.**

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

14 **“Subchapter G—Medical Gases**

15 **“SEC. 575. DEFINITIONS.**

16 “In this subchapter:

17 “(1) The term ‘designated medical gas’ means
18 any of the following:

19 “(A) Oxygen that meets the standards set
20 forth in an official compendium.

21 “(B) Nitrogen that meets the standards
22 set forth in an official compendium.

23 “(C) Nitrous oxide that meets the stand-
24 ards set forth in an official compendium.

1 “(D) Carbon dioxide that meets the stand-
2 ards set forth in an official compendium.

3 “(E) Helium that meets the standards set
4 forth in an official compendium.

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

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

9 “(H) Any other medical gas deemed appro-
10 priate by the Secretary, after taking into ac-
11 count any investigational new drug application
12 or investigational new animal drug application
13 for the same medical gas submitted in accord-
14 ance with regulations applicable to such appli-
15 cations in title 21 of the Code of Federal Regu-
16 lations, unless any period of exclusivity under
17 section 505(c)(3)(E)(ii) or section
18 505(j)(5)(F)(ii), or the extension of any such
19 period under section 505A, applicable to such
20 medical gas has not expired.

21 “(2) The term ‘medical gas’ means a drug
22 that—

23 “(A) is manufactured or stored in a lique-
24 fied, nonliquefied, or cryogenic state; and

25 “(B) is administered as a gas.

1 **“SEC. 576. REGULATION OF MEDICAL GASES.**

2 “(a) CERTIFICATION OF DESIGNATED MEDICAL
3 GASES.—

4 “(1) SUBMISSION.—Beginning 180 days after
5 the date of enactment of this section, any person
6 may file with the Secretary a request for certifi-
7 cation of a medical gas as a designated medical gas.
8 Any such request shall contain the following infor-
9 mation:

10 “(A) A description of the medical gas.

11 “(B) The name and address of the spon-
12 sor.

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

16 “(D) Any other information deemed appro-
17 priate by the Secretary to determine whether
18 the medical gas is a designated medical gas.

19 “(2) GRANT OF CERTIFICATION.—The certifi-
20 cation requested under paragraph (1) is deemed to
21 be granted unless, within 60 days of the filing of
22 such request, the Secretary finds that—

23 “(A) the medical gas subject to the certifi-
24 cation is not a designated medical gas;

25 “(B) the request does not contain the in-
26 formation required under paragraph (1) or oth-

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

4 “(C) denying the request is necessary to
5 protect the public health.

6 “(3) EFFECT OF CERTIFICATION.—

7 “(A) IN GENERAL.—

8 “(i) APPROVED USES.—A designated
9 medical gas for which a certification is
10 granted under paragraph (2) is deemed,
11 alone or in combination, as medically ap-
12 propriate, with another designated medical
13 gas or gases for which a certification or
14 certifications have been granted, to have in
15 effect an approved application under sec-
16 tion 505 or 512, subject to all applicable
17 post-approval requirements, for the fol-
18 lowing indications for use:

19 “(I) In the case of oxygen, the
20 treatment or prevention of hypoxemia
21 or hypoxia.

22 “(II) In the case of nitrogen, use
23 in hypoxic challenge testing.

24 “(III) In the case of nitrous
25 oxide, analgesia.

1 “(IV) In the case of carbon diox-
2 ide, use in extracorporeal membrane
3 oxygenation therapy or respiratory
4 stimulation.

5 “(V) In the case of helium, the
6 treatment of upper airway obstruction
7 or increased airway resistance.

8 “(VI) In the case of medical air,
9 to reduce the risk of hyperoxia.

10 “(VII) In the case of carbon
11 monoxide, use in lung diffusion test-
12 ing.

13 “(VIII) Any other indication for
14 use for a designated medical gas or
15 combination of designated medical
16 gases deemed appropriate by the Sec-
17 retary, unless any period of exclusivity
18 under clause (iii) or (iv) of section
19 505(c)(3)(E), clause (iii) or (iv) of
20 section 505(j)(5)(F), or section 527,
21 or the extension of any such period
22 under section 505A, applicable to
23 such indication for use for such gas or
24 combination of gases has not expired.

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

6 “(I) the information required by
7 section 503(b)(4);

8 “(II) a warning statement con-
9 cerning the use of the medical gas as
10 determined by the Secretary by regu-
11 lation; and

12 “(III) appropriate directions and
13 warnings concerning storage and han-
14 dling.

15 “(B) INAPPLICABILITY OF EXCLUSIVITY
16 PROVISIONS.—

17 “(i) NO EXCLUSIVITY FOR A CER-
18 TIFIED MEDICAL GAS.—No designated
19 medical gas deemed under subparagraph
20 (A)(i) to have in effect an approved appli-
21 cation is eligible for any period of exclu-
22 sivity under section 505(c), 505(j), or 527,
23 or the extension of any such period under
24 section 505A, on the basis of such deemed
25 approval.

1 “(ii) EFFECT ON CERTIFICATION.—

2 No period of exclusivity under section
3 505(c), 505(j), or section 527, or the ex-
4 tension of any such period under section
5 505A, with respect to an application for a
6 drug product shall prohibit, limit, or other-
7 wise affect the submission, grant, or effect
8 of a certification under this section, except
9 as provided in subsection (a)(3)(A)(i)(VIII)
10 and section 575(1)(H).

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

12
13 “(A) WITHDRAWAL, SUSPENSION OF AP-
14 PROVAL.—Nothing in this subchapter limits the
15 Secretary’s authority to withdraw or suspend
16 approval of a drug product, including a des-
17 ignated medical gas deemed under this section
18 to have in effect an approved application under
19 section 505 or section 512 of this Act.

20 “(B) REVOCATION OF CERTIFICATION.—
21 The Secretary may revoke the grant of a certifi-
22 cation under paragraph (2) if the Secretary de-
23 termines that the request for certification con-
24 tains any material omission or falsification.

25 “(b) PRESCRIPTION REQUIREMENT.—

1 “(1) IN GENERAL.—A designated medical gas
2 shall be subject to the requirements of section
3 503(b)(1) unless the Secretary exercises the author-
4 ity provided in section 503(b)(3) to remove such
5 medical gas from the requirements of section
6 503(b)(1), the gas is approved for use without a pre-
7 scription pursuant to an application under section
8 505 or 512, or the use in question is authorized pur-
9 suant to another provision of this Act relating to use
10 of medical products in emergencies.

11 “(2) OXYGEN.—

12 “(A) NO PRESCRIPTION REQUIRED FOR
13 CERTAIN USES.—Notwithstanding paragraph
14 (1), oxygen may be provided without a prescrip-
15 tion for the following uses:

16 “(i) For use in the event of depres-
17 surization or other environmental oxygen
18 deficiency.

19 “(ii) For oxygen deficiency or for use
20 in emergency resuscitation, when adminis-
21 tered by properly trained personnel.

22 “(B) LABELING.—For oxygen provided
23 pursuant to subparagraph (A), the require-
24 ments of section 503(b)(4) shall be deemed to
25 have been met if its labeling bears a warning

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

4 **“SEC. 577. INAPPLICABILITY OF DRUG FEES TO DES-**
5 **IGNATED MEDICAL GASES.**

6 “A designated medical gas, alone or in combination
7 with another designated gas or gases (as medically appro-
8 priate) deemed under section 576 to have in effect an ap-
9 proved application shall not be assessed fees under section
10 736(a) on the basis of such deemed approval.”.

11 **SEC. 822. CHANGES TO REGULATIONS.**

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

16 (1) determine whether any changes to the Fed-
17 eral drug regulations are necessary for medical
18 gases; and

19 (2) submit to the Committee on Health, Edu-
20 cation, Labor and Pensions of the Senate and the
21 Committee on Energy and Commerce of the House
22 of Representatives a report regarding any such
23 changes.

24 (b) REGULATIONS.—If the Secretary determines
25 under subsection (a) that changes to the Federal drug reg-

1 ulations are necessary for medical gases, the Secretary
2 shall issue final regulations revising the Federal drug reg-
3 ulations with respect to medical gases not later than 48
4 months after the date of the enactment of this Act.

5 (c) DEFINITIONS.—In this section:

6 (1) The term “Federal drug regulations” means
7 regulations in title 21 of the Code of Federal Regu-
8 lations pertaining to drugs.

9 (2) The term “medical gas” has the meaning
10 given to such term in section 575 of the Federal
11 Food, Drug, and Cosmetic Act, as added by section
12 821 of this Act.

13 (3) The term “Secretary” means the Secretary
14 of Health and Human Services, acting through the
15 Commissioner of Food and Drugs.

16 **SEC. 823. RULES OF CONSTRUCTION.**

17 Nothing in this subtitle and the amendments made
18 by this subtitle applies with respect to—

19 (1) a drug that is approved prior to May 1,
20 2012, pursuant to an application submitted under
21 section 505 or 512 of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355, 360b);

23 (2) any gas listed in subparagraphs (A) through
24 (G) of section 575(1) of the Federal Food, Drug,
25 and Cosmetic Act, as added by section 821 of this

1 Act, or any combination of any such gases, for an
2 indication that—

3 (A) is not included in, or is different from,
4 those specified in subclauses (I) through (VII)
5 of section 576(a)(3)(A)(i) of such Act; and

6 (B) is approved on or after May 1, 2012,
7 pursuant to an application submitted under
8 Section 505 or 512; or

9 (3) any designated medical gas added pursuant
10 to subparagraph (H) of section 575(1) of such Act
11 for an indication that—

12 (A) is not included in, or is different from,
13 those originally added pursuant to subpara-
14 graph (H) of section 575(1) and section
15 576(a)(3)(A)(i)(VIII); and

16 (B) is approved on or after May 1, 2012,
17 pursuant to an application submitted under sec-
18 tion 505 or 512 of such Act.

19 **Subtitle C—Generating Antibiotic** 20 **Incentives Now**

21 **SEC. 831. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

22 (a) IN GENERAL.—The Federal Food, Drug, and
23 Cosmetic Act is amended by inserting after section 505D
24 (21 U.S.C. 355e) the following:

1 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**
2 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

3 “(a) EXTENSION.—If the Secretary approves an ap-
4 plication pursuant to section 505 for a drug that has been
5 determined to be a qualified infectious disease product
6 under subsection (d), then the four- and five-year periods
7 described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of
8 section 505, the three-year periods described in clauses
9 (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and
10 (iv) of subsection (j)(5)(F) of section 505, or the seven
11 year period described in section 527, as applicable, shall
12 be extended by five years.

13 “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
14 extension under subsection (a) of a period shall be in addi-
15 tion to any extension of the period under section 505A
16 with respect to the drug.

17 “(c) LIMITATIONS.—Subsection (a) does not apply to
18 the approval of—

19 “(1) a supplement to an application under sec-
20 tion 505(b) for any qualified infectious disease prod-
21 uct for which an extension described in subsection
22 (a) is in effect or has expired;

23 “(2) a subsequent application filed by the same
24 sponsor or manufacturer of a qualified infectious
25 disease product described in paragraph (1) (or a li-

1 censor, predecessor in interest, or other related enti-
2 ty) for—

3 “(A) a change (not including a modifica-
4 tion to the active moiety of the qualified infec-
5 tious disease product) that results in a new in-
6 dication, route of administration, dosing sched-
7 ule, dosage form, delivery system, delivery de-
8 vice, or strength; or

9 “(B) a modification to the active moiety of
10 the qualified infectious disease product that
11 does not result in a change in safety or effec-
12 tiveness; or

13 “(3) a product that does not meet the definition
14 of a qualified infectious disease product under sub-
15 section (f) based upon its approved uses.

16 “(d) DETERMINATION.—The manufacturer or spon-
17 sor of a drug may request that the Secretary designate
18 a drug as a qualified infectious disease product at any
19 time in the drug development process prior to the submis-
20 sion of an application under section 505(b) for the drug,
21 but not later than 45 days before the submission of such
22 application. The Secretary shall, not later than 30 days
23 after the submission of such request, determine whether
24 the drug is a qualified infectious disease product.

1 “(e) REGULATIONS.—The Secretary shall promulgate
2 regulations for carrying out this section. The Secretary
3 shall promulgate the initial regulations for carrying out
4 this section not later than 12 months after the date of
5 the enactment of this section.

6 “(f) DEFINITIONS.—In this section:

7 “(1) QUALIFIED INFECTIOUS DISEASE PROD-
8 UCT.—The term ‘qualified infectious disease prod-
9 uct’ means an antibacterial or antifungal drug for
10 human use that treats or prevents an infection
11 caused by a qualifying pathogen.

12 “(2) QUALIFYING PATHOGEN.—The term
13 ‘qualifying pathogen’ means—

14 “(A) resistant gram-positive pathogens, in-
15 cluding methicillin-resistant *Staphylococcus*
16 *aureus* (MRSA), vancomycin-resistant *Staphy-*
17 *lococcus aureus* (VISA), and vancomycin-resist-
18 ant enterococcus (VRE);

19 “(B) multidrug resistant gram-negative
20 bacteria, including *Acinetobacter*, *Klebsiella*,
21 *Pseudomonas*, and *E. coli* species;

22 “(C) multi-drug resistant tuberculosis; or

23 “(D) any other infectious pathogen identi-
24 fied for purposes of this section by the Sec-
25 retary.”.

1 (b) APPLICATION.—Section 505E of the Federal
2 Food, Drug, and Cosmetic Act, as added by subsection
3 (a), applies only with respect to a drug that is first ap-
4 proved under section 505(c) of such Act (21 U.S.C.
5 355(c)) on or after the date of the enactment of this Act.

6 **SEC. 832. STUDY ON INCENTIVES FOR QUALIFIED INFEC-**
7 **TIOUS DISEASE BIOLOGICAL PRODUCTS.**

8 (a) IN GENERAL.—The Comptroller General of the
9 United States shall—

10 (1) conduct a study on the need for incentives
11 to encourage research on and development and mar-
12 keting of qualified infectious disease biological prod-
13 ucts; and

14 (2) not later than 1 year after the date of the
15 enactment of this Act, submit a report to the Con-
16 gress on the results of such study, including any rec-
17 ommendations of the Comptroller General on appro-
18 priate incentives for addressing such need.

19 (b) DEFINITIONS.—In this section:

20 (1) The term “biological product” has the
21 meaning given to such term in section 351 of the
22 Public Health Service Act (42 U.S.C. 262).

23 (2) The term “qualified infectious disease bio-
24 logical product” means a biological product for

1 human use that treats or prevents an infection
2 caused by a qualifying pathogen.

3 (3) The term “qualifying pathogen” has the
4 meaning given to such term in section 505E of the
5 Federal Food, Drug, and Cosmetic Act, as added by
6 section 831 of this Act.

7 **SEC. 833. CLINICAL TRIALS.**

8 (a) REVIEW AND REVISION OF GUIDELINES.—

9 (1) IN GENERAL.—Not later than 1 year after
10 the date of the enactment of this Act, and not later
11 than 4 years thereafter, the Secretary shall—

12 (A) review the guidance of the Food and
13 Drug Administration for the conduct of clinical
14 trials with respect to antibacterial and
15 antifungal drugs; and

16 (B) as appropriate, revise such guidance to
17 reflect developments in scientific and medical
18 information and technology and to ensure clar-
19 ity regarding the procedures and requirements
20 for approval of an antibiotic and antifungal
21 drug under chapter V of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 351 et
23 seq.).

24 (2) ISSUES FOR REVIEW.—At a minimum, the
25 review under paragraph (1) shall address the appro-

1 piate animal models of infection, in vitro tech-
2 niques, valid microbiological surrogate markers, the
3 use of noninferiority versus superiority trials, and
4 appropriate delta values for noninferiority trials.

5 (3) RULE OF CONSTRUCTION.—Except to the
6 extent to which the Secretary of Health and Human
7 Services makes revisions under paragraph (1)(B),
8 nothing in this section shall be construed to repeal
9 or otherwise affect the guidance of the Food and
10 Drug Administration.

11 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

12 (1) REQUEST.—The sponsor of a drug intended
13 to be used to treat or prevent a qualifying pathogen
14 may request that the Secretary provide written rec-
15 ommendations for nonclinical and clinical investiga-
16 tions which may be conducted with the drug before
17 it may be approved for such use under section 505
18 of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 355).

20 (2) RECOMMENDATIONS.—If the Secretary has
21 reason to believe that a drug for which a request is
22 made under this subsection is a qualified infectious
23 disease product, the Secretary shall provide the per-
24 son making the request written recommendations for
25 the nonclinical and clinical investigations which the

1 Secretary believes, on the basis of information avail-
2 able to the Secretary at the time of the request,
3 would be necessary for approval under section 505
4 of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 355) of such drug for the use described in
6 paragraph (1).

7 (c) DEFINITIONS.—In this section:

8 (1) The term “drug” has the meaning given to
9 such term in section 201 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 321).

11 (2) The term “qualified infectious disease prod-
12 uct” has the meaning given to such term in section
13 505E of the Federal Food, Drug, and Cosmetic Act,
14 as added by section 831 of this Act.

15 (3) The term “qualifying pathogen” has the
16 meaning given to such term in section 505E of the
17 Federal Food, Drug, and Cosmetic Act, as added by
18 section 831 of this Act.

19 (4) The term “Secretary” means the Secretary
20 of Health and Human Services, acting through the
21 Commissioner of Food and Drugs.

22 **SEC. 834. REASSESSMENT OF QUALIFIED INFECTIOUS DIS-**
23 **EASE PRODUCT INCENTIVES IN 5 YEARS.**

24 Not later than five years after the date of enactment
25 of this Act, the Secretary of Health and Human Services

1 shall, in consultation with the Food and Drug Administra-
2 tion, Centers for Disease Control and Prevention and
3 other appropriate agencies, submit to the Committee on
4 Energy and Commerce of the House of Representatives
5 and the Committee on Health, Education, Labor, and
6 Pensions of the Senate a report that contains the fol-
7 lowing:

8 (1)(A) The number of initial designations of
9 drugs as qualified infectious disease products under
10 section 505E of the Federal Food, Drug, and Cos-
11 metic Act;

12 (B) the number of qualified infectious disease
13 products approved under this program; and

14 (C) whether such products address the need for
15 antibacterial and antifungal drugs to treat serious
16 and life-threatening infections.

17 (2) Recommendations—

18 (A) based on the information in paragraph
19 (1) and any other relevant data, on any changes
20 that should be made to the list of pathogens
21 that are defined as qualifying pathogens under
22 section 505E(f)(2) of the Federal Food, Drug,
23 and Cosmetic Act, as added by section 831; and

24 (B) on whether any additional program
25 (such as the development of public-private col-

1 laborations to advance antibacterial drug inno-
2 vation) or changes to the incentives under this
3 subtitle may be needed to promote the develop-
4 ment of antibacterial drugs.

5 (3) An examination of—

6 (A) the adoption of programs to measure
7 the use of antibacterial drugs in health care set-
8 tings; and

9 (B) the implementation and effectiveness
10 of antimicrobial stewardship protocols across all
11 health care settings.

12 (4) Any recommendations for ways to encour-
13 age further development and establishment of stew-
14 ardship programs.

15 **SEC. 835. GUIDANCE ON PATHOGEN-FOCUSED ANTI-**
16 **BACTERIAL DRUG DEVELOPMENT.**

17 (a) DRAFT GUIDANCE.—Not later than June 30,
18 2013, in order to facilitate the development of anti-
19 bacterial drugs for serious or life-threatening bacterial in-
20 fections, particularly in areas of unmet need, the Secretary
21 of Health and Human Services shall publish draft guid-
22 ance that—

23 (1) specifies how preclinical and clinical data
24 can be utilized to inform an efficient and stream-
25 lined pathogen-focused antibacterial drug develop-

1 ment program that meets the approval standards of
2 the Food and Drug Administration; and

3 (2) provides advice on approaches for the devel-
4 opment of antibacterial drugs that target a more
5 limited spectrum of pathogens.

6 (b) FINAL GUIDANCE.—Not later than December 31,
7 2014, after notice and opportunity for public comment on
8 the draft guidance under subsection (a), the Secretary of
9 Health and Human Services shall publish final guidance
10 consistent with this section.

11 **Subtitle D—Accelerated Approval**

12 **SEC. 841. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS** 13 **OR LIFE-THREATENING DISEASES OR CONDI-** 14 **TIONS.**

15 (a) FINDINGS; SENSE OF CONGRESS.—

16 (1) FINDINGS.—The Congress finds as follows:

17 (A) The Food and Drug Administration
18 (referred to in this subsection as the “FDA”)
19 serves a critical role in helping to assure that
20 new medicines are safe and effective. Regu-
21 latory innovation is 1 element of the Nation’s
22 strategy to address serious and life-threatening
23 diseases or conditions by promoting investment
24 in and development of innovative treatments for
25 unmet medical needs.

1 (B) During the 2 decades following the es-
2 tablishment of the accelerated approval mecha-
3 nism, advances in medical sciences, including
4 genomics, molecular biology, and bioinformatics,
5 have provided an unprecedented understanding
6 of the underlying biological mechanism and
7 pathogenesis of disease. A new generation of
8 modern, targeted medicines is under develop-
9 ment to treat serious and life-threatening dis-
10 eases, some applying drug development strate-
11 gies based on biomarkers or pharmacogenomics,
12 predictive toxicology, clinical trial enrichment
13 techniques, and novel clinical trial designs, such
14 as adaptive clinical trials.

15 (C) As a result of these remarkable sci-
16 entific and medical advances, the FDA should
17 be encouraged to implement more broadly effec-
18 tive processes for the expedited development
19 and review of innovative new medicines in-
20 tended to address unmet medical needs for seri-
21 ous or life-threatening diseases or conditions,
22 including those for rare diseases or conditions,
23 using a broad range of surrogate or clinical
24 endpoints and modern scientific tools earlier in
25 the drug development cycle when appropriate.

1 This may result in fewer, smaller, or shorter
2 clinical trials for the intended patient popu-
3 lation or targeted subpopulation without com-
4 promising or altering the high standards of the
5 FDA for the approval of drugs.

6 (D) Patients benefit from expedited access
7 to safe and effective innovative therapies to
8 treat unmet medical needs for serious or life-
9 threatening diseases or conditions.

10 (E) For these reasons, the statutory au-
11 thority in effect on the day before the date of
12 enactment of this Act governing expedited ap-
13 proval of drugs for serious or life-threatening
14 diseases or conditions should be amended in
15 order to enhance the authority of the FDA to
16 consider appropriate scientific data, methods,
17 and tools, and to expedite development and ac-
18 cess to novel treatments for patients with a
19 broad range of serious or life-threatening dis-
20 eases or conditions.

21 (2) SENSE OF CONGRESS.—It is the sense of
22 the Congress that the FDA should apply the acceler-
23 ated approval and fast track provisions set forth in
24 section 506 of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 356), as amended by this sec-

1 tion, to help expedite the development and avail-
2 ability to patients of treatments for serious or life-
3 threatening diseases or conditions while maintaining
4 safety and effectiveness standards for such treat-
5 ments.

6 (b) EXPEDITED APPROVAL.—Section 506 (21 U.S.C.
7 356) is amended to read as follows:

8 **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**
9 **OR LIFE-THREATENING DISEASES OR CONDI-**
10 **TIONS.**

11 “(a) DESIGNATION OF DRUG AS A FAST TRACK
12 PRODUCT.—

13 “(1) IN GENERAL.—The Secretary shall, at the
14 request of the sponsor of a new drug, facilitate the
15 development and expedite the review of such drug if
16 it is intended, whether alone or in combination with
17 one or more other drugs, for the treatment of a seri-
18 ous or life-threatening disease or condition, and it
19 demonstrates the potential to address unmet medical
20 needs for such a disease or condition. In this section,
21 such a drug is referred to as a ‘fast track product’.

22 “(2) REQUEST FOR DESIGNATION.—The spon-
23 sor of a new drug may request the Secretary to des-
24 ignate the drug as a fast track product. A request
25 for the designation may be made concurrently with,

1 or at any time after, submission of an application
2 for the investigation of the drug under section 505(i)
3 of this Act or section 351(a)(3) of the Public Health
4 Service Act.

5 “(3) DESIGNATION.—Within 60 calendar days
6 after the receipt of a request under paragraph (2),
7 the Secretary shall determine whether the drug that
8 is the subject of the request meets the criteria de-
9 scribed in paragraph (1). If the Secretary finds that
10 the drug meets the criteria, the Secretary shall des-
11 ignate the drug as a fast track product and shall
12 take such actions as are appropriate to expedite the
13 development and review of the application for ap-
14 proval of such product.

15 “(b) ACCELERATED APPROVAL OF A DRUG FOR A
16 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
17 TION, INCLUDING A FAST TRACK PRODUCT.—

18 “(1) IN GENERAL.—The Secretary may approve
19 an application for approval of a product for a seri-
20 ous or life-threatening disease or condition, including
21 a fast track product, under section 505(c) of this
22 Act or section 351(a) of the Public Health Service
23 Act upon making a determination that the product
24 has an effect on—

1 “(A) a surrogate endpoint that is reason-
2 ably likely to predict clinical benefit; or

3 “(B) a clinical endpoint that can be meas-
4 ured earlier than irreversible morbidity or mor-
5 tality, that is reasonably likely to predict an ef-
6 fect on irreversible morbidity or mortality or
7 other clinical benefit,

8 taking into account the severity or rarity of the dis-
9 ease or condition and the availability of alternative
10 treatments. The evidence to support that an end-
11 point is reasonably likely to predict clinical benefit
12 may include epidemiological, pathophysiologic, phar-
13 macologic, therapeutic or other evidence developed
14 using, for example, biomarkers, or other scientific
15 methods or tools.

16 “(2) LIMITATION.—Approval of a product
17 under this subsection may, as determined by the
18 Secretary, be subject to the following require-
19 ments—

20 “(A) that the sponsor conduct appropriate
21 post-approval studies to verify and describe the
22 predicted effect of the product on irreversible
23 morbidity or mortality or other clinical benefit;
24 and

1 “(B) that the sponsor submit copies of all
2 promotional materials related to the product, at
3 least 30 days prior to dissemination of the ma-
4 terials—

5 “(i) during the preapproval review pe-
6 riod; and

7 “(ii) following approval, for a period
8 that the Secretary determines to be appro-
9 priate.

10 “(3) EXPEDITED WITHDRAWAL OF AP-
11 PROVAL.—The Secretary may withdraw approval of
12 a product approved pursuant to this subsection
13 using expedited procedures (as prescribed by the
14 Secretary in regulations, which shall include an op-
15 portunity for an informal hearing) if—

16 “(A) the sponsor fails to conduct any re-
17 quired post-approval study of the product with
18 due diligence;

19 “(B) a study required to verify and de-
20 scribe the predicted effect on irreversible mor-
21 bidity or mortality or other clinical benefit of
22 the product fails to verify and describe such ef-
23 fect or benefit;

1 “(C) other evidence demonstrates that the
2 product is not safe or effective under the condi-
3 tions of use; or

4 “(D) the sponsor disseminates false or
5 misleading promotional materials with respect
6 to the product.

7 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR
8 APPROVAL OF A FAST TRACK PRODUCT.—

9 “(1) IN GENERAL.—If the Secretary deter-
10 mines, after preliminary evaluation of clinical data
11 submitted by the sponsor, that a fast track product
12 may be effective, the Secretary shall evaluate for fil-
13 ing, and may commence review of portions of, an ap-
14 plication for the approval of the product before the
15 sponsor submits a complete application. The Sec-
16 retary shall commence such review only if the appli-
17 cant—

18 “(A) provides a schedule for submission of
19 information necessary to make the application
20 complete; and

21 “(B) pays any fee that may be required
22 under section 736.

23 “(2) EXCEPTION.—Any time period for review
24 of human drug applications that has been agreed to
25 by the Secretary and that has been set forth in goals

1 identified in letters of the Secretary (relating to the
2 use of fees collected under section 736 to expedite
3 the drug development process and the review of
4 human drug applications) shall not apply to an ap-
5 plication submitted under paragraph (1) until the
6 date on which the application is complete.

7 “(d) AWARENESS EFFORTS.—The Secretary shall—
8 “(1) develop and disseminate to physicians, pa-
9 tient organizations, pharmaceutical and bio-
10 technology companies, and other appropriate persons
11 a description of the provisions of this section appli-
12 cable to accelerated approval and fast track prod-
13 ucts; and

14 “(2) establish a program to encourage the de-
15 velopment of surrogate and clinical endpoints, in-
16 cluding biomarkers, and other scientific methods and
17 tools that can assist the Secretary in determining
18 whether the evidence submitted in an application is
19 reasonably likely to predict clinical benefit for seri-
20 ous or life-threatening conditions for which there
21 exist significant unmet medical needs.”.

22 **SEC. 842. GUIDANCE; AMENDED REGULATIONS.**

23 (a) INITIAL GUIDANCE.—Not later than one year
24 after the date of enactment of this Act, the Secretary of
25 Health and Human Services (in this subtitle referred to

1 as the “Secretary”) shall issue draft guidance to imple-
2 ment the amendment made by section 841.

3 (b) FINAL GUIDANCE.—Not later than one year after
4 the issuance of draft guidance under subsection (a), after
5 an opportunity for public comment, the Secretary shall—

6 (1) issue final guidance to implement the
7 amendment made by section 841; and

8 (2) amend the regulations governing accelerated
9 approval in parts 314 and 601 of title 21, Code of
10 Federal Regulations, as necessary to conform such
11 regulations with the amendments made by section
12 841.

13 (c) CONSIDERATIONS.—In developing the guidance
14 under subsections (a) and (b)(1) and the amendments
15 under subsection (b)(2), the Secretary shall consider—

16 (1) issues arising under the accelerated ap-
17 proval and fast track processes under section 506 of
18 the Federal Food, Drug, and Cosmetic Act (as
19 amended by section 841) for drugs designated for a
20 rare disease or condition under section 526 of the
21 Federal, Food, Drug, and Cosmetic Act; and

22 (2) how to incorporate novel approaches to the
23 review of surrogate endpoints based on patho-
24 physiologic and pharmacologic evidence in such guid-
25 ance, especially in instances where the low preva-

1 lence of a disease renders the existence or collection
2 of other types of data unlikely or impractical.

3 (d) NO DELAY IN REVIEW OR APPROVAL.—The
4 issuance (or non-issuance) of guidance or conforming reg-
5 ulations implementing the amendments made by section
6 841 shall not preclude the review of, or action on, a re-
7 quest for designation or an application for approval sub-
8 mitted pursuant to section 506 of the Federal Food, Drug,
9 and Cosmetic Act, as amended by section 841.

10 **SEC. 843. INDEPENDENT REVIEW.**

11 (a) IN GENERAL.—The Secretary may, in conjunc-
12 tion with other planned reviews of the new drug review
13 process, contract with an independent entity with expertise
14 in assessing the quality and efficiency of biopharma-
15 ceutical development and regulatory review programs, to
16 evaluate the Food and Drug Administration’s application
17 of the processes described in section 506 of the Federal
18 Food, Drug, and Cosmetic Act, as amended by section
19 841, and the impact of such processes on the development
20 and timely availability of innovative treatments for pa-
21 tients suffering from serious or life-threatening conditions.

22 (b) CONSULTATION.—Any evaluation under sub-
23 section (a) shall include consultation with regulated indus-
24 tries, patient advocacy and disease research foundations,
25 and relevant academic medical centers.

Subtitle E—Critical Path Reauthorization

SEC. 851. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subsection (f) of section 566 (21 U.S.C. 360bbb–5) is amended to read as follows:

“(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$6,000,000 for each of fiscal years 2013 through 2017.”.

Subtitle F—Miscellaneous

SEC. 861. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking “2012” and inserting “2017”.

SEC. 862. EXTENSION OF PERIOD FOR FIRST APPLICANT TO OBTAIN TENTATIVE APPROVAL WITHOUT FORFEITING 180-DAY EXCLUSIVITY PERIOD.

(a) EXTENSION.—

(1) IN GENERAL.—If a first applicant files an application during the 30-month period ending on the date of enactment of this Act and such application initially contains a certification described in paragraph (2)(A)(vii)(IV) of section 505(j) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(j)), or if a first applicant files an application
3 and the application is amended during such period
4 to first contain such a certification, the phrase “30
5 months” in paragraph (5)(D)(i)(IV) of such section
6 shall, with respect to such application, be read as
7 meaning—

8 (A) during the period beginning on the
9 date of enactment of this Act, and ending on
10 September 30, 2013, “45 months”;

11 (B) during the period beginning on Octo-
12 ber 1, 2013, and ending on September 30,
13 2014, “42 months”;

14 (C) during the period beginning on Octo-
15 ber 1, 2014, and ending on September 30,
16 2015, “39 months”; and

17 (D) during the period beginning on Octo-
18 ber 1, 2015, and ending on September 30,
19 2016, “36 months”.

20 (2) CONFORMING AMENDMENT.—In the case of
21 an application to which an extended period under
22 paragraph (1) applies, the reference to the 30-month
23 period under section 505(q)(1)(G) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(q)(1)(G)) shall be read to be the applicable pe-
2 riod under paragraph (1).

3 (b) PERIOD FOR OBTAINING TENTATIVE APPROVAL
4 OF CERTAIN APPLICATIONS.—If an application is filed on
5 or before the date of enactment of this Act and such appli-
6 cation is amended during the period beginning on the day
7 after the date of enactment of this Act and ending on Sep-
8 tember 30, 2017, to first contain a certification described
9 in paragraph (2)(A)(vii)(IV) of section 505(j) of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)),
11 the date of the filing of such amendment (rather than the
12 date of the filing of such application) shall be treated as
13 the beginning of the 30-month period described in para-
14 graph (5)(D)(i)(IV) of such section 505(j).

15 (c) DEFINITIONS.—For the purposes of this section,
16 the terms “application” and “first applicant” mean appli-
17 cation and first applicant, as such terms are used in sec-
18 tion 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)).

20 **SEC. 863. FINAL AGENCY ACTION RELATING TO PETITIONS**
21 **AND CIVIL ACTIONS.**

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

23 (1) in paragraph (1)—

24 (A) in subparagraph (A), by striking “sub-
25 section (b)(2) or (j)” inserting “subsection

1 (b)(2) or (j) of the Act or 351(k) of the Public
2 Health Service Act”; and

3 (B) in subparagraph (F), by striking “180
4 days” and inserting “150 days”;

5 (2) in paragraph (2)(A)—

6 (A) in the subparagraph heading, by strik-
7 ing “180” and inserting “150”; and

8 (B) in clause (i), by striking “180-day”
9 and inserting “150-day”; and

10 (3) in paragraph (5), by striking “subsection
11 (b)(2) or (j)” inserting “subsection (b)(2) or (j) of
12 the Act or 351(k) of the Public Health Service Act”.

13 **SEC. 864. DEADLINE FOR DETERMINATION ON CERTAIN PE-**
14 **TITIONS.**

15 (a) IN GENERAL.—Section 505 (21 U.S.C. 355) is
16 amended by adding at the end the following:

17 “(w) DEADLINE FOR DETERMINATION ON CERTAIN
18 PETITIONS.—The Secretary shall issue a final, substantive
19 determination on a petition submitted pursuant to sub-
20 section (b) of section 314.161 of title 21, Code of Federal
21 Regulations (or any successor regulations), no later than
22 270 days after the date the petition is submitted.”.

23 (b) APPLICATION.—The amendment made by sub-
24 section (a) shall apply to any petition that is submitted
25 pursuant to subsection (b) of section 314.161 of title 21,

1 Code of Federal Regulations (or any successor regula-
2 tions), on or after the date of enactment of this Act.

3 **SEC. 865. RARE PEDIATRIC DISEASE PRIORITY REVIEW**
4 **VOUCHER INCENTIVE PROGRAM.**

5 Subchapter B of Chapter V (21 U.S.C. 360aa et seq.)
6 is amended by adding at the end the following:

7 **“SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
8 **FOR RARE PEDIATRIC DISEASES.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) PRIORITY REVIEW.—The term ‘priority re-
11 view’, with respect to a human drug application as
12 defined in section 735(1), means review and action
13 by the Secretary on such application not later than
14 6 months after receipt by the Secretary of such ap-
15 plication, as described in the Manual of Policies and
16 Procedures of the Food and Drug Administration
17 and goals identified in the letters described in sec-
18 tion 101(b) of the Prescription Drug User Fee
19 Amendments of 2012.

20 “(2) PRIORITY REVIEW VOUCHER.—The term
21 ‘priority review voucher’ means a voucher issued by
22 the Secretary to the sponsor of a rare pediatric dis-
23 ease product application that entitles the holder of
24 such voucher to priority review of a single human
25 drug application submitted under section 505(b)(1)

1 or section 351(a) of the Public Health Service Act
2 after the date of approval of the rare pediatric dis-
3 ease product application.

4 “(3) RARE PEDIATRIC DISEASE.—The term
5 ‘rare pediatric disease’ means a disease that meets
6 each of the following criteria:

7 “(A) The disease primarily affects individ-
8 uals aged from birth to 18 years, including age
9 groups often called neonates, infants, children,
10 and adolescents.

11 “(B) The disease is a rare disease or con-
12 dition, within the meaning of section 526.

13 “(4) RARE PEDIATRIC DISEASE PRODUCT AP-
14 PPLICATION.—The term ‘rare pediatric disease prod-
15 uct application’ means a human drug application, as
16 defined in section 735(1), that—

17 “(A) is for a drug or biological product—

18 “(i) that is for the prevention or
19 treatment of a rare pediatric disease; and

20 “(ii) that contains no active ingredient
21 (including any ester or salt of the active
22 ingredient) that has been previously ap-
23 proved in any other application under sec-
24 tion 505(b)(1), 505(b)(2), or 505(j) of this

1 Act or section 351(a) or 351(k) of the
2 Public Health Service Act;

3 “(B) is submitted under section 505(b)(1)
4 of this Act or section 351(a) of the Public
5 Health Service Act;

6 “(C) the Secretary deems eligible for pri-
7 ority review;

8 “(D) that relies on clinical data derived
9 from studies examining a pediatric population
10 and dosages of the drug intended for that popu-
11 lation;

12 “(E) that does not seek approval for an
13 adult indication in the original rare pediatric
14 disease product application; and

15 “(F) is approved after the date of the en-
16 actment of the Prescription Drug User Fee
17 Amendments of 2012.

18 “(b) PRIORITY REVIEW VOUCHER.—

19 “(1) IN GENERAL.—The Secretary shall award
20 a priority review voucher to the sponsor of a rare pe-
21 diatric disease product application upon approval by
22 the Secretary of such rare pediatric disease product
23 application.

24 “(2) TRANSFERABILITY.—

1 “(A) IN GENERAL.—The sponsor of a rare
2 pediatric disease product application that re-
3 ceives a priority review voucher under this sec-
4 tion may transfer (including by sale) the enti-
5 tlement to such voucher. There is no limit on
6 the number of times a priority review voucher
7 may be transferred before such voucher is used.

8 “(B) NOTIFICATION OF TRANSFER.—Each
9 person to whom a voucher is transferred shall
10 notify the Secretary of such change in owner-
11 ship of the voucher not later than 30 days after
12 such transfer.

13 “(3) LIMITATION.—A sponsor of a rare pedi-
14 atric disease product application may not receive a
15 priority review voucher under this section if the rare
16 pediatric disease product application was submitted
17 to the Secretary prior to the date that is 90 days
18 after the date of enactment of the Prescription Drug
19 User Fee Amendments of 2012.

20 “(4) NOTIFICATION.—

21 “(A) IN GENERAL.—The sponsor of a
22 human drug application shall notify the Sec-
23 retary not later than 90 days prior to submis-
24 sion of the human drug application that is the
25 subject of a priority review voucher of an intent

1 to submit the human drug application, includ-
2 ing the date on which the sponsor intends to
3 submit the application. Such notification shall
4 be a legally binding commitment to pay for the
5 user fee to be assessed in accordance with this
6 section.

7 “(B) TRANSFER AFTER NOTICE.—The
8 sponsor of a human drug application that pro-
9 vides notification of the intent of such sponsor
10 to use the voucher for the human drug applica-
11 tion under subparagraph (A) may transfer the
12 voucher after such notification is provided, if
13 such sponsor has not yet submitted the human
14 drug application described in the notification.

15 “(5) TERMINATION OF AUTHORITY.—The Sec-
16 retary may not award any priority review vouchers
17 under paragraph (1) after the last day of the 1-year
18 period that begins on the date that the Secretary
19 awards the third rare pediatric disease priority
20 voucher under this section.

21 “(c) PRIORITY REVIEW USER FEE.—

22 “(1) IN GENERAL.—The Secretary shall estab-
23 lish a user fee program under which a sponsor of a
24 human drug application that is the subject of a pri-
25 ority review voucher shall pay to the Secretary a fee

1 determined under paragraph (2). Such fee shall be
2 in addition to any fee required to be submitted by
3 the sponsor under chapter VII.

4 “(2) FEE AMOUNT.—The amount of the pri-
5 ority review user fee shall be determined each fiscal
6 year by the Secretary, based on the difference be-
7 tween—

8 “(A) the average cost incurred by the Food
9 and Drug Administration in the review of a
10 human drug application subject to priority re-
11 view in the previous fiscal year; and

12 “(B) the average cost incurred by the
13 Food and Drug Administration in the review of
14 a human drug application that is not subject to
15 priority review in the previous fiscal year.

16 “(3) ANNUAL FEE SETTING.—The Secretary
17 shall establish, before the beginning of each fiscal
18 year beginning after September 30, 2012, the
19 amount of the priority review user fee for that fiscal
20 year.

21 “(4) PAYMENT.—

22 “(A) IN GENERAL.—The priority review
23 user fee required by this subsection shall be due
24 upon the notification by a sponsor of the intent
25 of such sponsor to use the voucher, as specified

1 in subsection (b)(4)(A). All other user fees as-
2 sociated with the human drug application shall
3 be due as required by the Secretary or under
4 applicable law.

5 “(B) COMPLETE APPLICATION.—An appli-
6 cation described under subparagraph (A) for
7 which the sponsor requests the use of a priority
8 review voucher shall be considered incomplete if
9 the fee required by this subsection and all other
10 applicable user fees are not paid in accordance
11 with the Secretary’s procedures for paying such
12 fees.

13 “(C) NO WAIVERS, EXEMPTIONS, REDUC-
14 TIONS, OR REFUNDS.—The Secretary may not
15 grant a waiver, exemption, reduction, or refund
16 of any fees due and payable under this section.

17 “(5) OFFSETTING COLLECTIONS.—Fees col-
18 lected pursuant to this subsection for any fiscal
19 year—

20 “(A) shall be deposited and credited as off-
21 setting collections to the account providing ap-
22 propriations to the Food and Drug Administra-
23 tion; and

1 “(B) shall not be collected for any fiscal
2 year except to the extent provided in advance in
3 appropriation Acts.

4 “(d) DESIGNATION PROCESS.—

5 “(1) IN GENERAL.—Upon the request of the
6 manufacturer or the sponsor of a new drug, the Sec-
7 retary may designate—

8 “(A) the new drug as a drug for a rare pe-
9 diatric disease; and

10 “(B) the application for the new drug as a
11 rare pediatric disease product application.

12 “(2) REQUEST FOR DESIGNATION.—The re-
13 quest for a designation under paragraph (1), shall
14 be made at the same time a request for designation
15 of orphan disease status under section 526 or fast-
16 track designation under section 506 is made. Re-
17 questing designation under this subsection is not a
18 prerequisite to receiving a priority review voucher
19 under this section.

20 “(3) DETERMINATION BY SECRETARY.—Not
21 later than 60 days after a request is submitted
22 under paragraph (1), the Secretary shall determine
23 whether—

1 “(A) the disease or condition that is the
2 subject of such request is a rare pediatric dis-
3 ease; and

4 “(B) the application for the new drug is a
5 rare pediatric disease product application.

6 “(e) MARKETING OF RARE PEDIATRIC DISEASE
7 PRODUCTS.—

8 “(1) IN GENERAL.—The Secretary shall deem a
9 rare pediatric disease product application incomplete
10 if such application does not contain a description of
11 the plan of the sponsor of such application to mar-
12 ket the product in the United States.

13 “(2) REVOCATION.—The Secretary may revoke
14 any priority review voucher awarded under sub-
15 section (b) if the rare pediatric disease product for
16 which such voucher was awarded is not marketed in
17 the United States within the 365 day period begin-
18 ning on the date of the approval of such drug under
19 section 505 of this Act or section 351 of the Public
20 Health Service Act.

21 “(3) POSTAPPROVAL PRODUCTION REPORT.—
22 The sponsor of an approved rare pediatric disease
23 product shall submit a report to the Secretary not
24 later than 5 years after the approval of the applica-
25 ble rare pediatric disease product application. Such

1 report shall provide the following information, with
2 respect to each of the first 4 years after approval of
3 such product:

4 “(A) The estimated population in the
5 United States suffering from the rare pediatric
6 disease.

7 “(B) The estimated demand in the United
8 States for such rare pediatric disease product.

9 “(C) The actual amount of such rare pedi-
10 atric disease product distributed in the United
11 States.

12 “(f) NOTICE AND REPORT.—

13 “(1) NOTICE OF ISSUANCE OF VOUCHER AND
14 APPROVAL OF PRODUCTS UNDER VOUCHER.—The
15 Secretary shall publish a notice in the Federal Reg-
16 ister and on the Web site of the Food and Drug Ad-
17 ministration not later than 30 days after the occur-
18 rence of each of the following:

19 “(A) The Secretary issues a priority review
20 voucher under this section.

21 “(B) The Secretary approves a drug pur-
22 suant to an application submitted under section
23 505(b) of this Act or section 351(a) of the Pub-
24 lic Health Service Act for which the sponsor of

1 the application used a priority review voucher
2 under this section.

3 “(2) REPORT.—If, after the last day of the 1-
4 year period that begins on the date that the Sec-
5 retary awards the third rare pediatric disease pri-
6 ority voucher under this section, a sponsor of an ap-
7 plication submitted under section 505(b) of this Act
8 or section 351(a) of the Public Health Service Act
9 for a drug uses a priority review voucher under this
10 section for such application, the Secretary shall sub-
11 mit to the Committee on Energy and Commerce of
12 the House of Representatives and the Committee on
13 Health, Education, Labor, and Pensions of the Sen-
14 ate a document—

15 “(A) notifying such Committees of the use
16 of such voucher; and

17 “(B) identifying the drug for which such
18 priority review voucher is used.

19 “(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing
20 in this section precludes a sponsor who seeks a priority
21 review voucher under this section from participating in
22 any other incentive program, including under this Act.

23 “(h) RELATION TO OTHER PROVISIONS.—The provi-
24 sions of this section shall supplement, not supplant, any
25 other provisions of this Act or the Public Health Service

1 Act that encourage the development of drugs for tropical
2 diseases and rare pediatric diseases.

3 “(i) GAO STUDY AND REPORT.—

4 “(1) STUDY.—

5 “(A) IN GENERAL.—Beginning on the date
6 that the Secretary awards the third rare pedi-
7 atric disease priority voucher under this section,
8 the Comptroller General of the United States
9 shall conduct a study of the effectiveness of
10 awarding rare pediatric disease priority vouch-
11 ers under this section in the development of on
12 human drug products that treat or prevent such
13 diseases.

14 “(B) CONTENTS OF STUDY.—In con-
15 ducting the study under subparagraph (A), the
16 Comptroller General shall examine the fol-
17 lowing:

18 “(i) The indications for which each
19 rare disease product for which a priority
20 review voucher was awarded was approved
21 under section 505 or section 351 of the
22 Public Health Service Act.

23 “(ii) Whether, and to what extent, an
24 unmet need related to the treatment or
25 prevention of a rare pediatric disease was

1 met through the approval of such a rare
2 disease product.

3 “(iii) The value of the priority review
4 voucher if transferred.

5 “(iv) Identification of each drug for
6 which a priority review voucher was used.

7 “(v) The length of the period of time
8 between the date on which a priority re-
9 view voucher was awarded and the date on
10 which it was used.

11 “(2) REPORT.—Not later than 1 year after the
12 date under paragraph (1)(A), the Comptroller Gen-
13 eral shall submit to the Committee on Energy and
14 Commerce of the House of Representatives and the
15 Committee on Health, Education, Labor, and Pen-
16 sions of the Senate, a report containing the results
17 of the study under paragraph (1).”.

18 **SEC. 866. COMBATING PRESCRIPTION DRUG ABUSE.**

19 (a) IN GENERAL.—To combat the significant rise in
20 prescription drug abuse and the consequences of such
21 abuse, the Secretary of Health and Human Services (re-
22 ferred to in this section as the “Secretary”), acting
23 through the Commissioner of Food and Drugs (referred
24 to in this section as the “Commissioner”) and in coordina-
25 tion with other Federal agencies, as appropriate, shall re-

1 view current Federal initiatives and identify gaps and op-
2 portunities with respect to ensuring the safe use of pre-
3 scription drugs with the potential for abuse.

4 (b) REPORT.—Not later than 1 year after the date
5 of enactment of this Act, the Secretary shall issue a report
6 to Congress on the findings of the review under subsection
7 (a). Such report shall include recommendations on—

8 (1) how best to leverage and build upon existing
9 Federal and federally funded data sources, such as
10 prescription drug monitoring program data and the
11 sentinel initiative of the Food and Drug Administra-
12 tion under section 505(k)(3) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as
14 it relates to collection of information relevant to ad-
15 verse events, patient safety, and patient outcomes, to
16 create a centralized data clearinghouse and early
17 warning tool;

18 (2) how best to develop and disseminate widely
19 best practices models and suggested standard re-
20 quirements to States for achieving greater interoper-
21 ability and effectiveness of prescription drug moni-
22 toring programs, especially with respect to producing
23 standardized data on adverse events, patient safety,
24 and patient outcomes; and

1 (3) how best to develop provider and patient
2 education tools and a strategy to widely disseminate
3 such tools and assess the efficacy of such tools.

4 (c) **GUIDANCE ON TAMPER-DETERRENT PROD-**
5 **UCTS.**—Not later than 6 months after the date of enact-
6 ment of this Act, the Secretary, acting through the Com-
7 missioner, shall promulgate guidance on the development
8 of tamper-deterrent drug products.

9 **SEC. 867. ASSESSMENT AND MODIFICATION OF REMS.**

10 (a) **ASSESSMENT AND MODIFICATION OF APPROVED**
11 **STRATEGY.**—Section 505–1(g) (21 U.S.C. 355–1(g)) is
12 amended—

13 (1) in paragraph (1), by striking “, and propose
14 a modification to,”;

15 (2) in paragraph (2)—

16 (A) in the matter before subparagraph
17 (A)—

18 (i) by striking “, subject to paragraph
19 (5),”; and

20 (ii) by striking “, and may propose a
21 modification to,”;

22 (B) in subparagraph (C), by striking “new
23 safety or effectiveness information indicates
24 that” and all that follows and inserting the fol-
25 lowing: “an assessment is needed to evaluate

1 whether the approved strategy should be modi-
2 fied to—

3 “(i) ensure the benefits of the drug
4 outweigh the risks of the drug; or

5 “(ii) minimize the burden on the
6 health care delivery system of complying
7 with the strategy.”; and

8 (C) by striking subparagraph (D);

9 (3) in paragraph (3), by striking “for a drug
10 shall include—” and all that follows and inserting
11 the following “for a drug shall include, with respect
12 to each goal included in the strategy, an assessment
13 of the extent to which the approved strategy, includ-
14 ing each element of the strategy, is meeting the goal
15 or whether 1 or more such goals or such elements
16 should be modified.”; and

17 (4) by amending paragraph (4) to read as fol-
18 lows:

19 “(4) MODIFICATION.—

20 “(A) ON INITIATIVE OF RESPONSIBLE
21 PERSON.—After the approval of a risk evalua-
22 tion and mitigation strategy by the Secretary,
23 the responsible person may, at any time, submit
24 to the Secretary a proposal to modify the ap-
25 proved strategy. Such proposal may propose the

1 addition, modification, or removal of any goal
2 or element of the approved strategy and shall
3 include an adequate rationale to support such
4 proposed addition, modification, or removal of
5 any goal or element of the strategy.

6 “(B) ON INITIATIVE OF SECRETARY.—
7 After the approval of a risk evaluation and
8 mitigation strategy by the Secretary, the Sec-
9 retary may, at any time, require a responsible
10 person to submit a proposed modification to the
11 strategy within 120 days or within such reason-
12 able time as the Secretary specifies, if the Sec-
13 retary, in consultation with the offices described
14 in subsection (c)(2), determines that 1 or more
15 goals or elements should be added, modified, or
16 removed from the approved strategy to—

17 “(i) ensure the benefits of the drug
18 outweigh the risks of the drug; or

19 “(ii) minimize the burden on the
20 health care delivery system of complying
21 with the strategy.”.

22 (b) REVIEW OF PROPOSED STRATEGIES; REVIEW OF
23 ASSESSMENTS AND MODIFICATIONS OF APPROVED
24 STRATEGIES.—Section 505–1(h) (21 U.S.C. 355–1(h)) is
25 amended—

1 (1) in the subsection heading by inserting “AND
2 MODIFICATIONS” after “REVIEW OF ASSESS-
3 MENTS”;

4 (2) in paragraph (1)—

5 (A) by inserting “and proposed modifica-
6 tion to” after “under subsection (a) and each
7 assessment of”; and

8 (B) by inserting “, and, if necessary,
9 promptly initiate discussions with the respon-
10 sible person about such proposed strategy, as-
11 sessment, or modification” after “subsection
12 (g)”;

13 (3) by striking paragraph (2);

14 (4) by redesignating paragraphs (3) through
15 (9) as paragraphs (2) through (8), respectively;

16 (5) in paragraph (2), as redesignated by para-
17 graph (4)—

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

20 “(A) IN GENERAL.—

21 “(i) TIMEFRAME.—Unless the dispute
22 resolution process described under para-
23 graph (3) or (4) applies, and, except as
24 provided in clause (ii) or clause (iii) below,
25 the Secretary, in consultation with the of-

1 fices described in subsection (c)(2), shall
2 review and act on the proposed risk evalua-
3 tion and mitigation strategy for a drug or
4 any proposed modification to any required
5 strategy within 180 days of receipt of the
6 proposed strategy or modification.

7 “(ii) MINOR MODIFICATIONS.—The
8 Secretary shall review and act on a pro-
9 posed minor modification, as defined by
10 the Secretary in guidance, within 60 days
11 of receipt of such modification.

12 “(iii) REMS MODIFICATION DUE TO
13 SAFETY LABEL CHANGES.—Not later than
14 60 days after the Secretary receives a pro-
15 posed modification to an approved risk
16 evaluation and mitigation strategy to con-
17 form the strategy to approved safety label
18 changes, including safety labeling changes
19 initiated by the sponsor in accordance with
20 FDA regulatory requirements, or to a safe-
21 ty label change that the Secretary has di-
22 rected the holder of the application to
23 make pursuant to section 505(o)(4), the
24 Secretary shall review and act on such pro-

1 posed modification to the approved strat-
2 egy.

3 “(iv) GUIDANCE.—The Secretary shall
4 establish, through guidance, that respon-
5 sible persons may implement certain modi-
6 fications to an approved risk evaluation
7 and mitigation strategy following notifica-
8 tion to the Secretary.”; and

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

11 “(C) PUBLIC AVAILABILITY.—Upon acting
12 on a proposed risk evaluation and mitigation
13 strategy or proposed modification to a risk eval-
14 uation and mitigation strategy under subpara-
15 graph (A), the Secretary shall make publicly
16 available an action letter describing the actions
17 taken by the Secretary under such subpara-
18 graph (A).”.

19 (6) in paragraph (4), as redesignated by para-
20 graph (4)—

21 (A) in subparagraph (A)(i)—

22 (i) by striking “Not earlier than 15
23 days, and not later than 35 days, after dis-
24 cussions under paragraph (2) have begun,
25 the” and inserting “The”; and

1 (ii) by inserting “, after the sponsor is
2 required to make a submission under sub-
3 section (a)(2) or (g),” before “request in
4 writing”; and

5 (B) in subparagraph (I)—

6 (i) by striking clauses (i) and (ii); and

7 (ii) by striking “if the Secretary—”
8 and inserting “if the Secretary has com-
9 plied with the timing requirements of
10 scheduling review by the Drug Safety
11 Oversight Board, providing a written rec-
12 ommendation, and issuing an action letter
13 under subparagraphs (B), (F), and (G),
14 respectively.”;

15 (7) in paragraph (5), as redesignated by para-
16 graph (4)—

17 (A) in subparagraph (A), by striking “any
18 of subparagraphs (B) through (D)” and insert-
19 ing “subparagraph (B) or (C)”; and

20 (B) in subparagraph (C), by striking
21 “paragraph (4) or (5)” and inserting “para-
22 graph (3) or (4)”; and

23 (8) in paragraph (8), as redesignated by para-
24 graph (4), by striking “paragraphs (7) and (8)” and
25 inserting “paragraphs (6) and (7).”.

1 (c) GUIDANCE.—Not later than 1 year after the date
2 of enactment of this Act, the Secretary of Health and
3 Human Services shall issue guidance that, for purposes
4 of section 505–1(h)(2)(A) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 355–1(h)(2)(A)), describes the
6 types of modifications to approved risk evaluation and
7 mitigation strategies that shall be considered to be minor
8 modifications of such strategies.

9 **SEC. 868. CONSULTATION WITH EXTERNAL EXPERTS ON**
10 **RARE DISEASES, TARGETED THERAPIES, AND**
11 **GENETIC TARGETING OF TREATMENTS.**

12 Subchapter E of chapter V (21 U.S.C. 360bbb et
13 seq.), as amended by section 811(b), is further amended
14 by adding at the end the following:

15 **“SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON**
16 **RARE DISEASES, TARGETED THERAPIES, AND**
17 **GENETIC TARGETING OF TREATMENTS.**

18 “(a) IN GENERAL.—For the purpose of promoting
19 the efficiency of and informing the review by the Food
20 and Drug Administration of new drugs and biological
21 products for rare diseases and drugs and biological prod-
22 ucts that are genetically targeted, the following shall
23 apply:

24 “(1) CONSULTATION WITH STAKEHOLDERS.—
25 Consistent with sections X.C and IX.E.4 of the

1 PDUFA Reauthorization Performance Goals and
2 Procedures Fiscal Years 2013 through 2017, as ref-
3 erenced in the letters described in section 101(b) of
4 the Prescription Drug User Fee Amendments of
5 2012, the Secretary shall ensure that opportunities
6 exist, at a time the Secretary determines appro-
7 priate, for consultations with stakeholders on the
8 topics described in subsection (b).

9 “(2) CONSULTATION WITH EXTERNAL EX-
10 PERTS.—

11 “(A) IN GENERAL.—The Secretary shall
12 develop and maintain a list of external experts
13 who, because of their special expertise, are
14 qualified to provide advice on rare disease
15 issues, including topics described in subsection
16 (c). The Secretary may, when appropriate to
17 address a specific regulatory question, consult
18 such external experts on issues related to the
19 review of new drugs and biological products for
20 rare diseases and drugs and biological products
21 that are genetically targeted, including the top-
22 ics described in subsection (b), when such con-
23 sultation is necessary because the Secretary
24 lacks the specific scientific, medical, or tech-
25 nical expertise necessary for the performance of

1 the Secretary's regulatory responsibilities and
2 the necessary expertise can be provided by the
3 external experts.

4 “(B) EXTERNAL EXPERTS.—For purposes
5 of subparagraph (A), external experts are indi-
6 viduals who possess scientific or medical train-
7 ing that the Secretary lacks with respect to one
8 or more rare diseases.

9 “(b) TOPICS FOR CONSULTATION.—Topics for con-
10 sultation pursuant to this section may include—

11 “(1) rare diseases;

12 “(2) the severity of rare diseases;

13 “(3) the unmet medical need associated with
14 rare diseases;

15 “(4) the willingness and ability of individuals
16 with a rare disease to participate in clinical trials;

17 “(5) an assessment of the benefits and risks of
18 therapies to treat rare diseases;

19 “(6) the general design of clinical trials for rare
20 disease populations and subpopulations; and

21 “(7) the demographics and the clinical descrip-
22 tion of patient populations.

23 “(c) CLASSIFICATION AS SPECIAL GOVERNMENT EM-
24 PLOYEES.—The external experts who are consulted under
25 this section may be considered special government employ-

1 ees, as defined under section 202 of title 18, United States
2 Code.

3 “(d) PROTECTION OF CONFIDENTIAL INFORMATION
4 AND TRADE SECRETS.—

5 “(1) RULE OF CONSTRUCTION.—Nothing in
6 this section shall be construed to alter the protec-
7 tions offered by laws, regulations, and policies gov-
8 erning disclosure of confidential commercial or trade
9 secret information, and any other information ex-
10 empt from disclosure pursuant to section 552(b) of
11 title 5, United States Code, as such provisions would
12 be applied to consultation with individuals and orga-
13 nizations prior to the date of enactment of this sec-
14 tion.

15 “(2) CONSENT REQUIRED FOR DISCLOSURE.—
16 The Secretary shall not disclose confidential com-
17 mercial or trade secret information to an expert con-
18 sulted under this section without the written consent
19 of the sponsor unless the expert is a special govern-
20 ment employee (as defined under section 202 of title
21 18, United States Code) or the disclosure is other-
22 wise authorized by law.

23 “(e) OTHER CONSULTATION.—Nothing in this sec-
24 tion shall be construed to limit the ability of the Secretary

1 to consult with individuals and organizations as authorized
2 prior to the date of enactment of this section.

3 “(f) NO RIGHT OR OBLIGATION.—

4 “(1) NO RIGHT TO CONSULTATION.—Nothing
5 in this section shall be construed to create a legal
6 right for a consultation on any matter or require the
7 Secretary to meet with any particular expert or
8 stakeholder.

9 “(2) NO ALTERING OF GOALS.—Nothing in this
10 section shall be construed to alter agreed upon goals
11 and procedures identified in the letters described in
12 section 101(b) of the Prescription Drug User Fee
13 Amendments of 2012.

14 “(3) NO CHANGE TO NUMBER OF REVIEW CY-
15 CLES.—Nothing in this section is intended to in-
16 crease the number of review cycles as in effect before
17 the date of enactment of this section.

18 “(g) NO DELAY IN PRODUCT REVIEW.—Prior to a
19 consultation with an external expert, as described in this
20 section, relating to an investigational new drug application
21 under section 505(i), a new drug application under section
22 505(b), or a biologics license application under section 351
23 of the Public Health Service Act, the Director of the Cen-
24 ter for Drug Evaluation and Research or the Director of
25 the Center for Biologics Evaluation and Research (or ap-

1 appropriate Division Director), as appropriate, shall deter-
2 mine that—

3 “(1) such consultation will—

4 “(A) facilitate the Secretary’s ability to
5 complete the Secretary’s review;

6 “(B) address outstanding deficiencies in
7 the application; and

8 “(C) increase the likelihood of an approval
9 decision in the current review cycle; or

10 “(2) the sponsor authorized such consultation.”.

11 **SEC. 869. BREAKTHROUGH THERAPIES.**

12 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as
13 amended by section 841, is further amended—

14 (1) by redesignating subsection (d) as sub-
15 section (e);

16 (2) by redesignating subsections (a) through (c)
17 as subsections (b) through (d), respectively;

18 (3) by inserting before subsection (b), as so re-
19 designated, the following:

20 “(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH
21 THERAPY.—

22 “(1) IN GENERAL.—The Secretary shall, at the
23 request of the sponsor of a drug, expedite the devel-
24 opment and review of such drug if the drug is in-
25 tended, alone or in combination with 1 or more other

1 drugs, to treat a serious or life-threatening disease
2 or condition and preliminary clinical evidence indi-
3 cates that the drug may demonstrate substantial im-
4 provement over existing therapies on 1 or more clini-
5 cally significant endpoints, such as substantial treat-
6 ment effects observed early in clinical development.
7 In this section, such a drug is referred to as a
8 ‘breakthrough therapy’.

9 “(2) REQUEST FOR DESIGNATION.—The spon-
10 sor of a drug may request the Secretary to designate
11 the drug as a breakthrough therapy. A request for
12 the designation may be made concurrently with, or
13 at any time after, the submission of an application
14 for the investigation of the drug under section 505(i)
15 or section 351(a)(3) of the Public Health Service
16 Act.

17 “(3) DESIGNATION.—

18 “(A) IN GENERAL.—Not later than 60 cal-
19 endar days after the receipt of a request under
20 paragraph (2), the Secretary shall determine
21 whether the drug that is the subject of the re-
22 quest meets the criteria described in paragraph
23 (1). If the Secretary finds that the drug meets
24 the criteria, the Secretary shall designate the
25 drug as a breakthrough therapy and shall take

1 such actions as are appropriate to expedite the
2 development and review of the application for
3 approval of such drug.

4 “(B) ACTIONS.—The actions to expedite
5 the development and review of an application
6 under subparagraph (A) may include, as appropriate—
7

8 “(i) holding meetings with the sponsor
9 and the review team throughout the development of the drug;
10

11 “(ii) providing timely advice to, and
12 interactive communication with, the sponsor regarding the development of the drug
13 to ensure that the development program to
14 gather the non-clinical and clinical data
15 necessary for approval is as efficient as
16 practicable;
17

18 “(iii) involving senior managers and
19 experienced review staff, as appropriate, in
20 a collaborative, cross-disciplinary review;

21 “(iv) assigning a cross-disciplinary
22 project lead for the Food and Drug Administration review team to facilitate an
23 efficient review of the development program and to serve as a scientific liaison be-
24
25

1 tween the review team and the sponsor;
2 and

3 “(v) taking steps to ensure that the
4 design of the clinical trials is as efficient as
5 practicable, when scientifically appropriate,
6 such as by minimizing the number of pa-
7 tients exposed to a potentially less effica-
8 cious treatment.”;

9 (4) in subsection (e)(1), as so redesignated, by
10 striking “applicable to accelerated approval” and in-
11 serting “applicable to breakthrough therapies, accel-
12 erated approval,”; and

13 (5) by adding at the end the following:

14 “(f) REPORT.—Beginning in fiscal year 2013, the
15 Secretary shall annually prepare and submit to the Com-
16 mittee on Health, Education, Labor, and Pensions of the
17 Senate and the Committee on Energy and Commerce of
18 the House of Representatives, and make publicly available,
19 with respect to this section for the previous fiscal year—

20 “(1) the number of drugs for which a sponsor
21 requested designation as a breakthrough therapy;

22 “(2) the number of products designated as a
23 breakthrough therapy; and

1 “(3) for each product designated as a break-
2 through therapy, a summary of the actions taken
3 under subsection (a)(3).”.

4 (b) GUIDANCE; AMENDED REGULATIONS.—

5 (1) IN GENERAL.—

6 (A) GUIDANCE.—Not later than 18
7 months after the date of enactment of this Act,
8 the Secretary of Health and Human Services
9 (referred to in this section as the “Secretary”)
10 shall issue draft guidance on implementing the
11 requirements with respect to breakthrough
12 therapies, as set forth in section 506(a) of the
13 Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 356(a)), as amended by this section.
15 The Secretary shall issue final guidance not
16 later than 1 year after the close of the comment
17 period for the draft guidance.

18 (B) AMENDED REGULATIONS.—

19 (i) IN GENERAL.—If the Secretary de-
20 termines that it is necessary to amend the
21 regulations under title 21, Code of Federal
22 Regulations in order to implement the
23 amendments made by this section to sec-
24 tion 506(a) of the Federal Food, Drug,
25 and Cosmetic Act, the Secretary shall

1 amend such regulations not later than 2
2 years after the date of enactment of this
3 Act.

4 (ii) PROCEDURE.—In amending regu-
5 lations under clause (i), the Secretary
6 shall—

7 (I) issue a notice of proposed
8 rulemaking that includes the proposed
9 regulation;

10 (II) provide a period of not less
11 than 60 days for comments on the
12 proposed regulation; and

13 (III) publish the final regulation
14 not less than 30 days before the effec-
15 tive date of the regulation.

16 (iii) RESTRICTIONS.—Notwithstanding
17 any other provision of law, the Secretary
18 shall promulgate regulations implementing
19 the amendments made by section only as
20 described in clause (ii).

21 (2) REQUIREMENTS.—Guidance issued under
22 this section shall—

23 (A) specify the process and criteria by
24 which the Secretary makes a designation under

1 section 506(a)(3) of the Federal Food, Drug,
2 and Cosmetic Act; and

3 (B) specify the actions the Secretary shall
4 take to expedite the development and review of
5 a breakthrough therapy pursuant to such des-
6 ignation under such section 506(a)(3), includ-
7 ing updating good review management practices
8 to reflect breakthrough therapies.

9 (c) INDEPENDENT REVIEW.—Not later than 3 years
10 after the date of enactment of this Act, the Comptroller
11 General of the United States, in consultation with appro-
12 priate experts, shall assess the manner by which the Food
13 and Drug Administration has applied the processes de-
14 scribed in section 506(a) of the Federal Food, Drug, and
15 Cosmetic Act, as amended by this section, and the impact
16 of such processes on the development and timely avail-
17 ability of innovative treatments for patients affected by se-
18 rious or life-threatening conditions. Such assessment shall
19 be made publicly available upon completion.

20 (d) CONFORMING AMENDMENTS.—Section 506B(e)
21 (21 U.S.C. 356b) is amended by striking “section
22 506(b)(2)(A)” each place such term appears and inserting
23 “section 506(c)(2)(A)”.

1 **SEC. 870. GRANTS AND CONTRACTS FOR THE DEVELOP-**
2 **MENT OF ORPHAN DRUGS.**

3 (a) QUALIFIED TESTING DEFINITION.—Section
4 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.
5 360ee(b)(1)(A)(ii)) is amended by striking “after the date
6 such drug is designated under section 526 of such Act
7 and”.

8 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
9 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is
10 amended to read as follows:

11 “(c) AUTHORIZATION OF APPROPRIATIONS.—For
12 grants and contracts under subsection (a), there is author-
13 ized to be appropriated \$30,000,000 for each of fiscal
14 years 2013 through 2017.”.

15 **TITLE IX—DRUG SHORTAGES**

16 **SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF MAN-**
17 **UFACTURING OF CERTAIN DRUGS.**

18 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)
19 is amended to read as follows:

20 **“SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF**
21 **MANUFACTURING OF CERTAIN DRUGS.**

22 “(a) IN GENERAL.—A manufacturer of a drug sub-
23 ject to section 503(b)(1)—

24 “(1) that is—

25 “(A) life-supporting;

26 “(B) life-sustaining; or

1 “(C) intended for use in the prevention or
2 treatment of a debilitating disease or condition;
3 and

4 “(2) that is not a radio pharmaceutical drug
5 product, a product derived from human plasma pro-
6 tein and their recombinant analogs, or any other
7 product as designated by the Secretary,
8 shall notify the Secretary of a discontinuance of the manu-
9 facture of the drug, or an interruption of the manufacture
10 of the drug that is likely to lead to a meaningful disruption
11 in the manufacturer’s supply of the drug, and the reason
12 for such discontinuance or interruption, in accordance
13 with subsection (b).

14 “(b) TIMING.—A notice required by subsection (a)
15 shall be submitted to the Secretary—

16 “(1) at least 6 months prior to the date of the
17 discontinuance or interruption; or

18 “(2) if compliance with paragraph (1) is not
19 possible, as soon as practicable.

20 “(c) DISTRIBUTION.—To the maximum extent prac-
21 ticable, the Secretary shall distribute information on the
22 discontinuation or interruption of the manufacture of the
23 drugs described in subsection (a) to appropriate organiza-
24 tions, including physician, health provider, and patient or-
25 ganizations, as described in section 506D.

1 “(d) CONFIDENTIALITY.—Nothing in this section
2 shall be construed as authorizing the Secretary to disclose
3 any information that is a trade secret or confidential infor-
4 mation subject to section 552(b)(4) of title 5, United
5 States Code, or section 1905 of title 18, United States
6 Code.

7 “(e) COORDINATION WITH ATTORNEY GENERAL.—
8 Not later than 30 days after the receipt of a notification
9 described in subsection (a), the Secretary shall—

10 “(1) determine whether the notification pertains
11 to a controlled substance subject to a production
12 quota under section 306 of the Controlled Sub-
13 stances Act; and

14 “(2) if necessary, as determined by the Sec-
15 retary—

16 “(A) notify the Attorney General that the
17 Secretary has received such a notification;

18 “(B) request that the Attorney General in-
19 crease the aggregate and individual production
20 quotas under section 306 of the Controlled Sub-
21 stances Act applicable to such controlled sub-
22 stance and any ingredient therein to a level the
23 Secretary deems necessary to address a short-
24 age of a controlled substance based on the best
25 available market data; and

1 “(C) if the Attorney General determines
2 that the level requested is not necessary to ad-
3 dress a shortage of a controlled substance, the
4 Attorney General shall provide to the Secretary
5 a written response detailing the basis for the
6 Attorney General’s determination.

7 The Secretary shall make the written response pro-
8 vided under subparagraph (C) available to the public
9 on the Web site of the Food and Drug Administra-
10 tion.

11 “(f) FAILURE TO MEET REQUIREMENTS.—If a per-
12 son fails to submit information required under subsection
13 (a) in accordance with subsection (b)—

14 “(1) the Secretary shall issue a letter to such
15 person informing such person of such failure;

16 “(2) not later than 30 calendar days after the
17 issuance of a letter under paragraph (1), the person
18 who receives such letter shall submit to the Sec-
19 retary a written response to such letter setting forth
20 the basis for noncompliance and providing informa-
21 tion required under subsection (a); and

22 “(3) not later than 45 calendar days after the
23 issuance of a letter under paragraph (1), the Sec-
24 retary shall make such letter and any response to
25 such letter under paragraph (2) available to the pub-

1 lic on the Web site of the Food and Drug Adminis-
2 tration, with appropriate redactions made to protect
3 information described in subsection (d), except that,
4 if the Secretary determines that the letter under
5 paragraph (1) was issued in error or, after review of
6 such response, the person had a reasonable basis for
7 not notifying as required under subsection (a), the
8 requirements of this paragraph shall not apply.”.

9 (b) REGULATIONS.—

10 (1) IN GENERAL.—Not later than 18 months
11 after the date of the enactment of this Act, the Sec-
12 retary of Health and Human Services, after issuing
13 a notice of proposed rule and holding a public hear-
14 ing, shall promulgate final regulations that imple-
15 ment the amendment made by subsection (a).

16 (2) CONTENTS.—Such regulations shall, for
17 purposes of section 506C of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 356c)—

19 (A) define the terms “life-supporting”,
20 “life-sustaining”, and “intended for use in the
21 prevention or treatment of a debilitating disease
22 or condition”; and

23 (B) define the term “interruption of the
24 manufacture of the drug that is likely to lead
25 to a meaningful disruption in the manufactur-

1 er’s supply of the drug” to mean a change in
2 production that is highly likely to lead to more
3 than a negligible reduction in the supply of the
4 drug and affects the ability of the manufacturer
5 to meet demand for such drug, but not to in-
6 clude a change in production due to matters
7 such as routine maintenance or insignificant
8 changes in manufacturing so long as the manu-
9 facturer expects to resume operations in a short
10 period of time.

11 **SEC. 902. DRUG SHORTAGE LIST.**

12 Title V (21 U.S.C. 351 et seq.) is amended by insert-
13 ing after section 506C the following new section:

14 **“SEC. 506D. DRUG SHORTAGE LIST.**

15 “(a) ESTABLISHMENT.—The Secretary shall main-
16 tain an up-to-date list of drugs that are determined by
17 the Secretary to be in shortage in the United States.

18 “(b) CONTENTS.—For each drug on such list, the
19 Secretary shall include the following information:

20 “(1) The name of the drug in shortage.

21 “(2) The name of each manufacturer of such
22 drug.

23 “(3) The reason for the shortage, as determined
24 by the Secretary, selecting from the following cat-
25 egories:

1 “(A) Requirements related to complying
2 with good manufacturing practices.

3 “(B) Regulatory delay.

4 “(C) Shortage of an active ingredient.

5 “(D) Shortage of an inactive ingredient
6 component.

7 “(E) Discontinuation of the manufacture
8 of the drug.

9 “(F) Delay in shipping of the drug.

10 “(G) Demand increase for the drug.

11 “(4) The estimated duration of the shortage as
12 determined by the Secretary.

13 “(c) PUBLIC AVAILABILITY.—

14 “(1) IN GENERAL.—Subject to paragraphs (2)
15 and (3), the Secretary shall make the information in
16 such list publicly available.

17 “(2) TRADE SECRETS AND CONFIDENTIAL IN-
18 FORMATION.—Nothing in this section alters or
19 amends section 1905 of title 18, United States Code,
20 or section 552(b)(4) of title 5 of such Code.

21 “(3) PUBLIC HEALTH EXCEPTION.—The Sec-
22 retary may choose not to make information collected
23 under this section publicly available under paragraph
24 (1) if the Secretary determines that disclosure of
25 such information would adversely affect the public

1 health (such as by increasing the possibility of
2 hoarding or other disruption of the availability of
3 drug products to patients).”.

4 **SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

5 Section 306 of the Controlled Substances Act (21
6 U.S.C. 826) is amended by adding at the end the fol-
7 lowing:

8 “(h)(1) Not later than 30 days after the receipt of
9 a request described in paragraph (2), the Attorney Gen-
10 eral shall—

11 “(A) complete review of such request; and

12 “(B)(i) as necessary to address a shortage of a
13 controlled substance, increase the aggregate and in-
14 dividual production quotas under this section appli-
15 cable to such controlled substance and any ingre-
16 dient therein to the level requested; or

17 “(ii) if the Attorney General determines that
18 the level requested is not necessary to address a
19 shortage of a controlled substance, the Attorney
20 General shall provide a written response detailing
21 the basis for the Attorney General’s determination.
22 The Secretary shall make the written response pro-
23 vided under subparagraph (B)(ii) available to the
24 public on the Web site of the Food and Drug Ad-
25 ministration.

1 “(2) A request is described in this paragraph if—

2 “(A) the request pertains to a controlled sub-
3 stance on the list of drugs in shortage maintained
4 under section 506D of the Federal Food, Drug, and
5 Cosmetic Act;

6 “(B) the request is submitted by the manufac-
7 turer of the controlled substance; and

8 “(C) the controlled substance is in schedule
9 II.”.

10 **SEC. 904. EXPEDITED REVIEW OF MAJOR MANUFACTURING**
11 **CHANGES FOR POTENTIAL AND VERIFIED**
12 **SHORTAGES OF DRUGS THAT ARE LIFE-SUP-**
13 **PORTING, LIFE-SUSTAINING, OR INTENDED**
14 **FOR USE IN THE PREVENTION OF A DEBILI-**
15 **TATING DISEASE OR CONDITION.**

16 Subsection (c) of section 506A (21 U.S.C. 356a) is
17 amended by adding at the end the following new para-
18 graph:

19 “(3) CHANGES ADDRESSING A DRUG SHORT-
20 AGE.—

21 “(A) CERTIFICATION.—

22 “(i) DESCRIPTION.—A certification is
23 described in this subparagraph if the man-
24 ufacturer, having notified the Secretary of
25 an interruption or discontinuance of a drug

1 in accordance with Section 506C, certifies
2 (in such certification) that the major man-
3 ufacturing change for which approval is
4 being sought may prevent or alleviate a
5 discontinuance or interruption of such
6 drug.

7 “(ii) BAD FAITH EXCEPTION.—Sub-
8 paragraphs (B) and (C) do not apply in
9 the case of a certification which the Sec-
10 retary determines to be made in bad faith.

11 “(B) EXPEDITED REVIEW.—If a certifi-
12 cation described in subparagraph (A) is sub-
13 mitted in connection with a supplemental appli-
14 cation for a major manufacturing change, the
15 Secretary shall—

16 “(i) expedite any technical review or
17 inspection necessary for consideration of
18 the supplemental application;

19 “(ii) provide any technical assistance
20 necessary to facilitate approval of the sup-
21 plemental application; and

22 “(iii) not later than 60 days after re-
23 ceipt of the certification, complete review
24 of the supplemental application.”.

1 **SEC. 905. STUDY ON DRUG SHORTAGES.**

2 (a) STUDY.—The Comptroller General of the United
3 States shall conduct a study to examine the cause of drug
4 shortages and formulate recommendations on how to pre-
5 vent or alleviate such shortages.

6 (b) CONSIDERATION.—In conducting the study under
7 this section, the Comptroller General shall consider the
8 following questions:

9 (1) What are the dominant characteristics of
10 drugs that have gone into actual shortage over the
11 preceding three years?

12 (2) Are there systemic high-risk factors (such
13 as drug pricing structure, including Federal reim-
14 bursements, or the number of manufacturers pro-
15 ducing a drug product) that have led to the con-
16 centration of drug shortages in certain drug prod-
17 ucts that have made such products vulnerable to
18 drug shortages?

19 (3) Is there a reason why drug shortages have
20 occurred primarily in the sterile injectable market
21 and in certain therapeutic areas?

22 (4) How have regulations, guidance documents,
23 regulatory practices, and other actions of Federal
24 departments and agencies (including the effective-
25 ness of interagency and intraagency coordination,

1 communication, strategic planning, and decision-
2 making) affected drug shortages?

3 (5) How does hoarding affect drug shortages?

4 (6) How would incentives alleviate or prevent
5 drug shortages?

6 (7) How are healthcare providers, including
7 hospitals and physicians responding to drug short-
8 ages, to what extent are such providers able to ad-
9 just care effectively to compensate for such short-
10 ages, and what impediments exist that hinder pro-
11 vider ability to adjust to such shortages?

12 (c) CONSULTATION WITH STAKEHOLDERS.—In con-
13 ducting the study under this section, the Comptroller Gen-
14 eral shall consult with relevant stakeholders, including
15 physicians, pharmacists, hospitals, patients, drug manu-
16 facturers, and other health providers.

17 (d) REPORT.—Note later than 18 months after the
18 date of the enactment of this Act, the Comptroller General
19 shall submit a report to the Committee on Energy and
20 Commerce of the House of Representatives and the Com-
21 mittee on Health, Education, Labor, and Pensions of the
22 Senate on the results of the study under this section.

23 **SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.**

24 Not later than 18 months after the date of the enact-
25 ment of this Act, and annually thereafter, the Secretary

1 of Health and Human Services shall submit to the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives and the Committee on Health, Education,
4 Labor, and Pensions of the Senate a report on drug short-
5 ages that—

6 (1) describes the communication between the
7 field investigators of the Food and Drug Administra-
8 tion and the staff of the Center for Drug Evaluation
9 and Research's Office of Compliance and Drug
10 Shortage Program, including the Food and Drug
11 Administration's procedures for enabling and ensur-
12 ing such communication;

13 (2) describes the Food and Drug Administra-
14 tion's efforts to expedite the review of new manufac-
15 turing sites, new suppliers, and specification changes
16 to prevent or alleviate a drug shortage;

17 (3) describes the coordination between the Food
18 and Drug Administration and the Drug Enforce-
19 ment Administration on efforts to prevent or allevi-
20 ate drug shortages;

21 (4) identifies the number of, and describes the
22 instances in which the Food and Drug Administra-
23 tion exercised regulatory flexibility and discretion to
24 prevent or alleviate a drug shortage;

1 (5) identifies the number of instances in which
2 the Food and Drug Administration asked firms to
3 increase production to prevent or alleviate a short-
4 age;

5 (6) identifies the number of notifications sub-
6 mitted to the Secretary under section 506C of the
7 Federal Food, Drug, and Cosmetic Act, as amended
8 by section 901 of this Act, including the percentage
9 of such notifications for a drug that is a sterile
10 injectable;

11 (7) describes the Food and Drug Administra-
12 tion's implementation of section 506D of the Fed-
13 eral Food, Drug, and Cosmetic Act (relating to a
14 drug shortage list), as added by section 902 of this
15 Act, and identifies—

16 (A) the name of each drug on the list
17 under such section 506D at any point during
18 the period covered by the report;

19 (B) the name of each manufacturer of
20 each such drug;

21 (C) the reason for the shortage of each
22 such drug; and

23 (D) the anticipated or, if known, actual
24 duration of the shortage of each such drug;

1 (8) identifies whether, and how, the Food and
2 Drug Administration expedited the review of regu-
3 latory submissions to prevent or alleviate shortages,
4 including how the Administration utilized the au-
5 thority in section 506A(c)(3) of the Federal Food,
6 Drug, and Cosmetic Act, as added by section 904 of
7 this Act;

8 (9) identifies the number of certifications sub-
9 mitted under such section 506A(c)(3) and, for each
10 such certification, whether the Food and Drug Ad-
11 ministration completed expedited review within 60
12 days as required by subparagraph (B) of such sec-
13 tion 506A(c)(3);

14 (10) describes the Secretary's public engage-
15 ment on drug shortages with stakeholders, including
16 physicians, pharmacists, patients, hospitals, drug
17 manufacturers, and other health providers; and

18 (11) contains the Secretary's plan for address-
19 ing drug shortages in the upcoming year, including
20 with respect to the issues described in paragraphs
21 (1) through (10).

22 **SEC. 907. ATTORNEY GENERAL REPORT ON DRUG SHORT-**
23 **AGES.**

24 Not later than 6 months after the date of the enact-
25 ment of this Act, and annually thereafter, the Attorney

1 General shall submit to the Committee on Energy and
2 Commerce of the House of Representatives and the Com-
3 mittee on the Judiciary of the Senate a report on drug
4 shortages that—

5 (1) identifies the number of requests received
6 under section 306(h) of the Controlled Substances
7 Act (as added by section 903 of this Act), the aver-
8 age review time for such requests, the number of re-
9 quests granted and denied under such section, and,
10 for each of the requests denied under such section,
11 the basis for such denial;

12 (2) describes the coordination between the Drug
13 Enforcement Administration and Food and Drug
14 Administration on efforts to prevent or alleviate
15 drug shortages; and

16 (3) identifies drugs containing a controlled sub-
17 stance subject to section 306 of the Controlled Sub-
18 stances Act when such a drug is determined by the
19 Secretary of Health and Human Services to be in
20 shortage.

21 **SEC. 908. HOSPITAL REPACKAGING OF DRUGS IN SHORT-**
22 **AGE.**

23 Chapter V (21 U.S.C. 351 et seq.), as amended by
24 section 902 of this Act, is further amended by inserting
25 after section 506D the following:

1 **“SEC. 506E. HOSPITAL REPACKAGING OF DRUGS IN SHORT-**
2 **AGE.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) DRUG.—The term ‘drug’ excludes any con-
5 trolled substance (as such term is defined in section
6 102 of the Controlled Substances Act).

7 “(2) HEALTH SYSTEM.—The term ‘health sys-
8 tem’ means a collection of hospitals that are owned
9 and operated by the same entity and that share ac-
10 cess to databases with drug order information for
11 their patients.

12 “(3) REPACKAGE.—For the purposes of this
13 section only, the term ‘repackage’, with respect to a
14 drug, means to divide the volume of a drug into
15 smaller amounts in order to—

16 “(A) extend the supply of a drug in re-
17 sponse to the placement of the drug on a drug
18 shortage list described in subsection (b); and

19 “(B) facilitate access to the drug by hos-
20 pitals within the same health system.

21 “(b) EXCLUSION FROM REGISTRATION.—Notwith-
22 standing any other provision of this Act, a hospital shall
23 not be considered an establishment for which registration
24 is required under section 510 solely because it repackages
25 a drug and transfers it to another hospital within the same

1 health system in accordance with the conditions in sub-
2 section (c)—

3 “(1) during any period in which the drug is list-
4 ed on the Drug Shortage List of the Food and Drug
5 Administration; or

6 “(2) during the 60-day period following any pe-
7 riod described in paragraph (1).

8 “(c) CONDITIONS.—Subsection (b) shall only apply to
9 a hospital, with respect to the repackaging of a drug for
10 transfers to another hospital within the same health sys-
11 tem, if the following conditions are met:

12 “(1) DRUG FOR INTRASYSTEM USE ONLY.—In
13 no case may a drug that has been repackaged in ac-
14 cordance with this section be sold or otherwise dis-
15 tributed by the health system or a hospital within
16 the system to an entity or individual that is not a
17 hospital within such health system.

18 “(2) COMPLIANCE WITH STATE RULES.—Re-
19 packaging of a drug under this section shall be done
20 in compliance with applicable State requirements in
21 which the health system is located.

22 “(d) TERMINATION.—This section shall not apply on
23 or after the date on which the Secretary issues final guid-
24 ance that clarifies the policy of the Food and Drug Admin-
25 istration regarding hospital pharmacies repackaging and

- 1 safely transferring repackaged drugs to other hospitals
- 2 within the same health system during a drug shortage.”.