

[DISCUSSION DRAFT]112TH CONGRESS
2^D SESSION**H. R.** _____

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

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “_____ Act of
5 2012”.

1 SEC. 2. TABLE OF CONTENTS.**2** 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—FEES RELATING TO DEVICES

- Sec. 201. **[to be supplied]**.

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 of the Food and Drug Administration 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. Reauthorization of Best Pharmaceuticals for Children Act and Pediatric Research Equity Act.
- Sec. 502. Government Accountability Office report.
- Sec. 503. Internal Committee for Review of Pediatric Plans, Assessments, Deferrals, Deferral Extensions, and Waivers.
- Sec. 504. Staff of Office of Pediatric Therapeutics.
- Sec. 505. Continuation of operation of Pediatric Advisory Committee.
- Sec. 506. Pediatric Subcommittee of the Oncologic Drugs Advisory Committee.

TITLE VI—FOOD AND DRUG ADMINISTRATION ADMINISTRATIVE REFORMS

- Sec. 601. FDA's mission.
- Sec. 602. Public participation in issuance of FDA guidance documents.
- Sec. 603. Conflicts of interest.
- Sec. 604. Electronic submission of applications.
- Sec. 605. Cosmetics **【to be supplied】**.

TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

- Sec. 701. Tracking and review of applications for investigational device exemptions.
- Sec. 702. Other rules relating to investigational device exemptions.
- Sec. 703. Clarification of least burdensome standard.
- Sec. 704. Agency documentation and review of significant decisions.
- Sec. 705. Transparency in clearance process.
- Sec. 706. No 510(k) report required for certain modifications.

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 Medical Device Regulators Forum.

Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

- Sec. 741. Persons accredited to review reports under section 510(k) and make recommendations for initial classification.
- Sec. 742. Persons accredited to conduct inspections.

Subtitle G—Humanitarian Device Reform

- Sec. 751. Expanded access to humanitarian use devices.

TITLE VIII—DRUG REGULATORY IMPROVEMENTS

Subtitle A—Pharmaceutical Supply Chain

- Sec. 801. **【to be supplied】**.

Subtitle B—Medical Gas Safety

- Sec. 811. Regulation of medical gases.
- Sec. 812. Fees relating to medical gas regulation.
- Sec. 813. Miscellaneous provisions.

Subtitle C—Generating Antibiotic Incentives Now

- Sec. 821. Extension of exclusivity period for drugs.

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

14 “(8) The term ‘adjustment factor’ applicable to
15 a fiscal year is the Consumer Price Index for all
16 urban consumers (Washington–Baltimore, DC–MD–
17 VA–WV; Not Seasonally Adjusted; All items) of the
18 preceding fiscal year divided by such Index for Octo-
19 ber 1996.”.

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

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

22 (1) in subsection (a)—

23 (A) in the matter preceding paragraph (1),
24 by striking “fiscal year 2008” and inserting
25 “fiscal year 2013”;

1 (B) in paragraph (1)(E), by striking “sub-
2 section (d)” and inserting “subsection (d) or
3 (e)”;

4 (C) in the matter following clause (ii) in
5 paragraph (2)(A), by striking “payable on or
6 before October 1 of each year” and inserting
7 “due on the later of the first business day on
8 or after October 1 of such fiscal year or the
9 first business day after the enactment of an ap-
10 propriations Act providing for the collection and
11 obligation of fees for such fiscal year under this
12 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)”;

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)—

11 (I) by striking “fiscal years 2008
12 through 2012” and inserting “fiscal
13 years 2013 through 2017”; and

14 (II) by striking “subsections (c),
15 (d), (f), and (g)” and inserting “sub-
16 sections (c), (d), (e), (g), and (h)”;

17 (ii) in subparagraph (A), by striking
18 “\$392,783,000; and” and inserting
19 “\$693,099,000;”; and

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

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

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

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

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

11 “(A) INFLATION ADJUSTMENT.—The infla-
12 tion adjustment for fiscal year 2013 shall be
13 the sum of—

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

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

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

1 “(i) \$652,709,000 plus the amount of
2 the inflation adjustment calculated under
3 subparagraph (A); multiplied by

4 “(ii) the amount (if any) by which a
5 percentage workload adjustment for fiscal
6 year 2013, as determined using the meth-
7 odology described in subsection (c)(2)(A),
8 would exceed the percentage workload ad-
9 justment (as so determined) for fiscal year
10 2012, if both such adjustment percentages
11 were calculated using the 5-year base pe-
12 riod consisting of fiscal years 2003
13 through 2007.

14 “(C) LIMITATION.—Under no cir-
15 cumstances shall the adjustment under sub-
16 paragraph (B) result in fee revenues for fiscal
17 year 2013 that are less than the sum of the
18 amount under paragraph (1)(A) and the
19 amount under paragraph (1)(B).”;

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

22 “(c) ADJUSTMENTS.—

23 “(1) INFLATION ADJUSTMENT.—For fiscal year
24 2014 and subsequent fiscal years, the revenues es-
25 tablished in subsection (b) shall be adjusted by the

1 Secretary by notice, published in the Federal Reg-
2 ister, for a fiscal year by the amount equal to the
3 sum of—

4 “(A) one;

5 “(B) the average annual change in the
6 cost, per full-time equivalent position of the
7 Food and Drug Administration, of all personnel
8 compensation and benefits paid with respect to
9 such positions for the first 3 years of the pre-
10 ceeding 4 fiscal years, multiplied by the propor-
11 tion of personnel compensation and benefits
12 costs to total costs of the process for the review
13 of human drug applications (as defined in sec-
14 tion 735(6)) for the first 3 years of the pre-
15 ceeding 4 fiscal years, and

16 “(C) the average annual change that oc-
17 curred in the Consumer Price Index for urban
18 consumers (Washington-Baltimore, DC–MD–
19 VA–WV; Not Seasonally Adjusted; All items;
20 Annual Index) for the first 3 years of the pre-
21 ceeding 4 years of available data multiplied by
22 the proportion of all costs other than personnel
23 compensation and benefits costs to total costs
24 of the process for the review of human drug ap-

1 plications (as defined in section 735(6)) for the
2 first 3 years of the preceding 4 fiscal years.

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

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

16 “(A) The adjustment shall be determined
17 by the Secretary based on a weighted average
18 of the change in the total number of human
19 drug applications (adjusted for changes in re-
20 view activities, as described in the notice that
21 the Secretary is required to publish in the Fed-
22 eral Register under this subparagraph), efficacy
23 supplements, and manufacturing supplements
24 submitted to the Secretary, and the change in
25 the total number of active commercial investiga-

1 tional new drug applications (adjusted for
2 changes in review activities, as so described)
3 during the most recent 12-month period for
4 which data on such submissions is available.
5 The Secretary shall publish in the Federal Reg-
6 ister the fee revenues and fees resulting from
7 the adjustment and the supporting methodolo-
8 gies.

9 “(B) Under no circumstances shall the ad-
10 justment result in fee revenues for a fiscal year
11 that are less than the sum of the amount under
12 subsection (b)(1)(A) and the amount under
13 subsection (b)(1)(B), as adjusted for inflation
14 under paragraph (1).

15 “(C) The Secretary shall contract with an
16 independent accounting or consulting firm to
17 periodically review the adequacy of the adjust-
18 ment and publish the results of those reviews.
19 The first review shall be conducted and pub-
20 lished by the end of fiscal year 2013 (to exam-
21 ine the performance of the adjustment since fis-
22 cal year 2009), and the second review shall be
23 conducted and published by the end of fiscal
24 year 2015 (to examine the continued perform-
25 ance of the adjustment). The reports shall

1 evaluate whether the adjustment reasonably
2 represents actual changes in workload volume
3 and complexity and present options to dis-
4 continue, retain, or modify any elements of the
5 adjustment. The reports shall be published for
6 public comment. After review of the reports and
7 receipt of public comments, the Secretary shall,
8 if warranted, adopt appropriate changes to the
9 methodology. If the Secretary adopts changes to
10 the methodology based on the first report, the
11 changes shall be effective for the first fiscal
12 year for which fees are set after the Secretary
13 adopts such changes and each subsequent fiscal
14 year.

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

1 nual notice establishing fee revenues and fees for fis-
2 cal year 2017. If the Secretary has carryover bal-
3 ances for such process in excess of 3 months of such
4 operating reserves, the adjustment under this sub-
5 paragraph shall not be made.

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

14 “(5) LIMIT.—The total amount of fees charged,
15 as adjusted under this subsection, for a fiscal year
16 may not exceed the total costs for such fiscal year
17 for the resources allocated for the process for the re-
18 view of human drug applications.”;

19 (4) in subsection (d)(4)(A), by striking “DEFI-
20 NITION” and inserting “SMALL BUSINESS DE-
21 FINED”;

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

24 (6) by inserting after subsection (d) the fol-
25 lowing new subsection:

1 “(e) FEE WAIVER FOR CERTAIN DRUGS.—The Sec-
2 retary shall grant a waiver from or reduction of one or
3 more fees established under subsection (a)(1) with respect
4 to a human drug application or supplement if the Sec-
5 retary finds that—

6 “(1) such waiver or reduction is necessary to
7 prevent or alleviate a verified or potential drug
8 shortage; and

9 “(2) the application or supplement is for a drug
10 described in section 506C(a).”;

11 (7) in subsection (g)—

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

15 (B) in paragraph (2)—

16 (i) in subparagraph (A)(i), by striking
17 “shall be retained” and inserting “subject
18 to subparagraph (C), shall be retained”;
19 and

20 (ii) by adding at the end the following
21 new subparagraph:

22 “(C) PROVISION FOR EARLY PAYMENTS.—
23 Payment of fees authorized under this section
24 for a fiscal year, prior to the due date for such
25 fees, may be accepted by the Secretary in ac-

1 cordance with authority provided in advance in
2 a prior year appropriations Act.”;

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

6 (D) in paragraph (4)—

7 (i) by striking “fiscal years 2008
8 through 2010” and inserting “fiscal years
9 2013 through 2015”;

10 (ii) by striking “fiscal year 2011” and
11 inserting “fiscal year 2016”;

12 (iii) by striking “fiscal years 2008
13 though 2011” and inserting “fiscal years
14 2013 through 2016”; and

15 (iv) by striking “fiscal year 2012”
16 and inserting “fiscal year 2017”; and

17 (8) in subsection (j), as redesignated, by strik-
18 ing “subsection (d)” and inserting “subsection (d)
19 or (e)”.

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

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

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

24 “(a) PERFORMANCE REPORT.—

1 “(1) IN GENERAL.—Beginning with fiscal year
2 2013, not later than 120 days after the end of each
3 fiscal year for which fees are collected under this
4 part, the Secretary shall prepare and submit to the
5 Committee on Energy and Commerce of the House
6 of Representatives and the Committee on Health,
7 Education, Labor, and Pensions of the Senate a re-
8 port concerning—

9 “(A) the progress of the Food and Drug
10 Administration in achieving the goals identified
11 in the letters described in section 101(b) of the
12 Prescription Drug User Fee Amendments of
13 2012 during such fiscal year and the future
14 plans of the Food and Drug Administration for
15 meeting the goals; and

16 “(B) the progress of each review division
17 within the Center for Drug Evaluation and Re-
18 search and the Center for Biologics Evaluation
19 and Research in achieving the goals, and each
20 such division’s future plans for meeting the
21 goals, including—

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

1 Act filed per fiscal year by each review di-
2 vision;

3 “(ii) the percentage of such applica-
4 tions approved by each review division;

5 “(iii) the total number of review cycles
6 per such approval and the average and me-
7 dian review cycles per such application by
8 each review division;

9 “(iv) the average and median review
10 times per such application by each review
11 division;

12 “(v) the percentage of applications
13 that are considered pursuant to accelerated
14 approval by each review division;

15 “(vi) the percentage of such applica-
16 tions that are approved based on one clin-
17 ical study by each review division; and

18 “(vii) the number of full-time equiva-
19 lent positions and overall budget assigned
20 to each review division.

21 “(2) INCLUSION.—The report under this sub-
22 section for a fiscal year shall include information on
23 all previous cohorts for which the Secretary has not
24 given a complete response on all human drug appli-
25 cations and supplements in the cohort.”.

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

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

5 **SEC. 105. SUNSET DATES.**

6 (a) AUTHORIZATION.—The amendments made by
7 sections 102 and 103 cease to be effective October 1,
8 2017.

9 (b) REPORTING REQUIREMENTS.—The amendments
10 made by section 104 cease to be effective January 31,
11 2018.

12 **SEC. 106. EFFECTIVE DATE.**

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

20 **SEC. 107. SAVINGS CLAUSE.**

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

1 before the date of the enactment of this title, shall con-
2 tinue to be in effect with respect to human drug applica-
3 tions and supplements (as defined in such part as of such
4 day) that on or after October 1, 2007, but before October
5 1, 2012, were accepted by the Food and Drug Administra-
6 tion for filing with respect to assessing and collecting any
7 fee required by such part for a fiscal year prior to fiscal
8 year 2012.

9 **TITLE II—FEES RELATING TO**
10 **DEVICES**

11 **SEC. 201. [TO BE SUPPLIED].**

12 **TITLE III—FEES RELATING TO**
13 **GENERIC DRUGS**

14 **SEC. 301. SHORT TITLE.**

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

17 (b) **FINDING.**—The Congress finds that the fees au-
18 thorized by the amendments made in this title will be dedi-
19 cated to human generic drug activities, as set forth in the
20 goals identified for purposes of part 7 of subchapter C
21 of chapter VII of the Federal Food, Drug, and Cosmetic
22 Act, in the letters from the Secretary of Health and
23 Human Services to the Chairman of the Committee on
24 Health, Education, Labor, and Pensions of the Senate and
25 the Chairman of the Committee on Energy and Commerce

1 of the House of Representatives, as set forth in the Con-
2 gressional Record.

3 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
4 **NERIC DRUG FEES.**

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

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

8 **“SEC. 744A. DEFINITIONS.**

9 “For purposes of this part:

10 “(1) The term ‘abbreviated new drug applica-
11 tion’—

12 “(A) means an application submitted
13 under section 505(j), an abbreviated application
14 submitted under section 507 (as in effect on the
15 day before the date of enactment of the Food
16 and Drug Administration Modernization Act of
17 1997), or an abbreviated new drug application
18 submitted pursuant to regulations in effect
19 prior to the implementation of the Drug Price
20 Competition and Patent Term Restoration Act
21 of 1984; and

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

24 “(2) The term ‘active pharmaceutical ingre-
25 dient’ means—

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

4 “(i) to be used as a component of a
5 drug; and

6 “(ii) to furnish pharmacological activ-
7 ity or other direct effect in the diagnosis,
8 cure, mitigation, treatment, or prevention
9 of disease, or to affect the structure or any
10 function of the human body; or

11 “(B) a substance intended for final crys-
12 tallization, purification, or salt formation, or
13 any combination of those activities, to become a
14 substance or mixture described in subparagraph
15 (A).

16 “(3) The term ‘adjustment factor’ means a fac-
17 tor applicable to a fiscal year that is the Consumer
18 Price Index for all urban consumers (all items;
19 United States city average) for October of the pre-
20 ceding fiscal year divided by such Index for October
21 2011.

22 “(4) 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 “(5)(A) The term ‘facility’—

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

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

10 “(II) at one geographic location or ad-
11 dress engaged in manufacturing or proc-
12 essing an active pharmaceutical ingredient
13 or a finished dosage form; and

14 “(ii) does not include a business or other
15 entity whose only manufacturing or processing
16 activities are one or more of the following: re-
17 packaging, relabeling, or testing.

18 “(B) For purposes of subparagraph (A), sepa-
19 rate buildings within close proximity are considered
20 to be at one geographic location or address if the ac-
21 tivities in them are—

22 “(i) closely related to the same business
23 enterprise;

24 “(ii) under the supervision of the same
25 local management; and

1 “(iii) capable of being inspected by the
2 Food and Drug Administration during a single
3 inspection.

4 “(C) If a business or other entity would meet
5 the definition of a facility under this paragraph but
6 for being under multiple management, the business
7 or other entity is deemed to constitute multiple fa-
8 cilities, one per management entity, for purposes of
9 this paragraph.

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

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

14 “(B) a drug product in a form in which re-
15 constitution is necessary prior to administration
16 to a patient, such as oral suspensions or
17 lyophilized powders; or

18 “(C) any combination of an active pharma-
19 ceutical ingredient with another component of a
20 drug product for purposes of production of a
21 drug product described in subparagraph (A) or
22 (B).

23 “(7) The term ‘generic drug submission’ means
24 an abbreviated new drug application, an amendment
25 to an abbreviated new drug application, or a prior

1 approval supplement to an abbreviated new drug ap-
2 plication.

3 “(8) The term ‘human generic drug activities’
4 means the following activities of the Secretary asso-
5 ciated with generic drugs and inspection of facilities
6 associated with generic drugs:

7 “(A) The activities necessary for the re-
8 view of generic drug submissions, including re-
9 view of drug master files referenced in such
10 submissions.

11 “(B) The issuance of—

12 “(i) approval letters which approve
13 abbreviated new drug applications or sup-
14 plements to such applications; or

15 “(ii) complete response letters which
16 set forth in detail the specific deficiencies
17 in such applications and, where appro-
18 priate, the actions necessary to place such
19 applications in condition for approval.

20 “(C) The issuance of letters related to
21 Type II active pharmaceutical drug master files
22 which—

23 “(i) set forth in detail the specific de-
24 ficiencies in such submissions, and where

1 appropriate, the actions necessary to re-
2 solve those deficiencies; or

3 “(ii) document that no deficiencies
4 need to be addressed.

5 “(D) Inspections related to generic drugs.

6 “(E) Monitoring of research conducted in
7 connection with the review of generic drug sub-
8 missions and drug master files.

9 “(F) Postmarket safety activities with re-
10 spect to drugs approved under abbreviated new
11 drug applications or supplements, including the
12 following activities:

13 “(i) Collecting, developing, and re-
14 viewing safety information on approved
15 drugs, including adverse event reports.

16 “(ii) Developing and using improved
17 adverse-event data-collection systems, in-
18 cluding information technology systems.

19 “(iii) Developing and using improved
20 analytical tools to assess potential safety
21 problems, including access to external data
22 bases.

23 “(iv) Implementing and enforcing sec-
24 tion 505(o) (relating to postapproval stud-
25 ies and clinical trials and labeling changes)

1 and section 505(p) (relating to risk evalua-
2 tion and mitigation strategies) insofar as
3 those activities relate to abbreviated new
4 drug applications.

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

8 “(G) Regulatory science activities related
9 to generic drugs.

10 “(9) The term ‘positron emission tomography
11 drug’ has the meaning given to the term ‘com-
12 pounded positron emission tomography drug’ in sec-
13 tion 201(ii), except that paragraph (1)(B) of such
14 section shall not apply.

15 “(10) The term ‘prior approval supplement’
16 means a request to the Secretary to approve a
17 change in the drug substance, drug product, produc-
18 tion process, quality controls, equipment, or facilities
19 covered by an approved abbreviated new drug appli-
20 cation when that change has a substantial potential
21 to have an adverse effect on the identity, strength,
22 quality, purity, or potency of the drug product as
23 these factors may relate to the safety or effective-
24 ness of the drug product.

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

3 “(A) officers and employees of the Food
4 and Drug Administration, contractors of the
5 Food and Drug Administration, advisory com-
6 mittees, and costs related to such officers and
7 employees and to contracts with such contrac-
8 tors;

9 “(B) management of information, and the
10 acquisition, maintenance, and repair of com-
11 puter resources;

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

17 “(D) collecting fees under subsection (a)
18 and accounting for resources allocated for the
19 review of abbreviated new drug applications and
20 supplements and inspection related to generic
21 drugs.

22 “(12) The term ‘Type II active pharmaceutical
23 ingredient drug master file’ means a submission of
24 information to the Secretary by a person that in-
25 tends to authorize the Food and Drug Administra-

1 tion to reference the information to support approval
2 of a generic drug submission without the submitter
3 having to disclose the information to the generic
4 drug submission applicant.

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

7 “(a) TYPES OF FEES.—Beginning in fiscal year
8 2013, the Secretary shall assess and collect fees in accord-
9 ance with this section as follows:

10 “(1) ONE-TIME BACKLOG FEE FOR ABBRE-
11 VIATED NEW DRUG APPLICATIONS PENDING ON OC-
12 TOBER 1, 2012.—

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

20 “(B) METHOD OF FEE AMOUNT CALCULA-
21 TION.—The amount of each one-time backlog
22 fee shall be calculated by dividing \$50,000,000
23 by the total number of abbreviated new drug
24 applications pending on October 1, 2012, that

1 have not received a tentative approval as of that
2 date.

3 “(C) NOTICE.—Not later than October 31,
4 2012, the Secretary shall cause to be published
5 in the Federal Register a notice announcing the
6 amount of the fee required by subparagraph
7 (A).

8 “(D) FEE DUE DATE.—The fee required
9 by subparagraph (A) shall be due no later than
10 30 calendar days after the date of the publica-
11 tion of the notice specified in subparagraph (C).

12 “(2) DRUG MASTER FILE FEE.—

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

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

1 file is subsequently referenced in generic drug
2 submissions.

3 “(C) 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 drug master file fee for fiscal year
9 2013.

10 “(ii) FISCAL YEAR 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 drug master file fee established by
16 this paragraph for such fiscal year.

17 “(D) AVAILABILITY FOR REFERENCE.—

18 “(i) IN GENERAL.—Subject to sub-
19 section (g)(2)(C), for a generic drug sub-
20 mission to reference a Type II active phar-
21 maceutical ingredient drug master file, the
22 drug master file must be deemed available
23 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 abbrevi-
23 ated 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) FREE 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 when
24 it arrives in the appropriate electronic portal of the
25 Food and Drug Administration or, if in paper form,

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

3 “(b) FEE REVENUE AMOUNTS.—

4 “(1) IN GENERAL.—

5 “(A) FISCAL YEAR 2013.—For fiscal year
6 2013, fees under subsection (a) except as pro-
7 vided in subsection (o) (relating to waivers)
8 shall be established to generate a total esti-
9 mated revenue amount under such subsection of
10 \$299,000,000. Of that amount—

11 “(i) \$50,000,000 shall be generated
12 by the one-time backlog fee for generic
13 drug applications pending on October 1,
14 2012, established in subsection (a)(1); and

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

18 “(B) FISCAL YEARS 2014 THROUGH 2017.—

19 For each of the fiscal years 2014 through 2017,
20 fees under paragraphs (2) through (4) of sub-
21 section (a) shall be established to generate a
22 total estimated revenue amount under such sub-
23 section that is equal to \$299,000,000, as ad-
24 justed pursuant to subsection (c).

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

8 “(A) 6 percent shall be derived from fees
9 under subsection (a)(2) (relating to drug mas-
10 ter files).

11 “(B) 24 percent shall be derived from fees
12 under subsection (a)(3) (relating to abbreviated
13 new drug applications and supplements). The
14 amount of a fee for a prior approval supplement
15 shall be half the amount of the fee for an ab-
16 breviated new drug application.

17 “(C) 56 percent shall be derived from fees
18 under subsection (a)(4)(A)(i) (relating to ge-
19 neric drug facilities). The amount of the fee for
20 a facility located outside the United States and
21 its territories and possessions shall be not less
22 than \$15,000 and not more than \$30,000 high-
23 er than the amount of the fee for a facility lo-
24 cated in the United States and its territories
25 and possessions, as determined by the Secretary

1 on the basis of data concerning the difference
2 in cost between inspections of facilities located
3 in the United States, including its territories
4 and possessions, and those located outside of
5 the United States and its territories and posses-
6 sions.

7 “(D) 14 percent shall be derived from fees
8 under subsection (a)(4)(A)(ii) (relating to active
9 pharmaceutical ingredient facilities). The
10 amount of the fee for a facility located outside
11 the United States and its territories and posses-
12 sions shall be not less than \$15,000 and not
13 more than \$30,000 higher than the amount of
14 the fee for a facility located in the United
15 States, including its territories and possessions,
16 as determined by the Secretary on the basis of
17 data concerning the difference in cost between
18 inspections of facilities located in the United
19 States and its territories and possessions and
20 those located outside of the United States and
21 its territories and possessions.

22 “(c) ADJUSTMENTS.—

23 “(1) INFLATION ADJUSTMENT.—For fiscal year
24 2014 and subsequent fiscal years, the revenues es-
25 tablished in subsection (b) shall be adjusted by the

1 Secretary by notice, published in the Federal Reg-
2 ister, for a fiscal year, by an amount equal to the
3 sum of—

4 “(A) one;

5 “(B) the average annual change in the
6 cost, per full-time equivalent position of the
7 Food and Drug Administration, of all personnel
8 compensation and benefits paid with respect to
9 such positions for the first 3 years of the pre-
10 ceeding 4 fiscal years multiplied by the propor-
11 tion of personnel compensation and benefits
12 costs to total costs of human generic drug ac-
13 tivities for the first 3 years of the preceding 4
14 fiscal years; and

15 “(C) the average annual change that oc-
16 curred in the Consumer Price Index for urban
17 consumers (Washington-Baltimore, DC–MD–
18 VA–WV; Not Seasonally Adjusted; All items;
19 Annual Index) for the first 3 years of the pre-
20 ceeding 4 years of available data multiplied by
21 the proportion of all costs other than personnel
22 compensation and benefits costs to total costs
23 of human generic drug activities for the first 3
24 years of the preceding 4 fiscal years.

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

5 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
6 year 2017, the Secretary may, in addition to adjust-
7 ments under paragraph (1), further increase the fee
8 revenues and fees established in subsection (b) if
9 such an adjustment is necessary to provide for not
10 more than 3 months of operating reserves of carry-
11 over user fees for human generic drug activities for
12 the first 3 months of fiscal year 2018. Such fees
13 may only be used in fiscal year 2018. If such an ad-
14 justment is necessary, the rationale for the amount
15 of the increase shall be contained in the annual no-
16 tice establishing fee revenues and fees for fiscal year
17 2017. If the Secretary has carryover balances for
18 such activities in excess of 3 months of such oper-
19 ating reserves, the adjustment under this subpara-
20 graph shall not be made.

21 “(d) ANNUAL FEE SETTING.—

22 “(1) FISCAL YEAR 2013.—For fiscal year
23 2013—

24 “(A) the Secretary shall establish, by Octo-
25 ber 31, 2012, the one-time generic drug backlog

1 fee for generic drug applications pending on Oc-
2 tober 1, 2012, the drug master file fee, the ab-
3 breviated new drug application fee, and the
4 prior approval supplement fee under subsection
5 (a), based on the revenue amounts established
6 under subsection (b); and

7 “(B) the Secretary shall establish, not
8 later than 45 days after the date to comply
9 with the requirement for identification of facili-
10 ties in subsection (f)(2), the generic drug facil-
11 ity fee and active pharmaceutical ingredient fa-
12 cility fee under subsection (a) based on the rev-
13 enue amounts established under subsection (b).

14 “(2) FISCAL YEARS 2014 THROUGH 2017.—Not
15 more than 60 days before the first day of each of
16 fiscal years 2014 through 2017, the Secretary shall
17 establish the drug master file fee, the abbreviated
18 new drug application fee, the prior approval supple-
19 ment fee, the generic drug facility fee, and the active
20 pharmaceutical ingredient facility fee under sub-
21 section (a) for such fiscal year, based on the revenue
22 amounts established under subsection (b) and the
23 adjustments provided under subsection (c).

24 “(3) FEE FOR ACTIVE PHARMACEUTICAL IN-
25 GREDIENT INFORMATION NOT INCLUDED BY REF-

1 ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-
2 GREDIENT DRUG MASTER FILE.—In establishing the
3 fees under paragraphs (1) and (2), the amount of
4 the fee under subsection (a)(3)(F) shall be deter-
5 mined by multiplying—

6 “(A) the sum of—

7 “(i) the total number of such active
8 pharmaceutical ingredients in such submis-
9 sion; and

10 “(ii) for each such ingredient that is
11 manufactured at more than one such facil-
12 ity, the total number of such additional fa-
13 cilities; and

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

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

21 “(f) IDENTIFICATION OF FACILITIES.—

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

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

9 “(2) REQUIRED SUBMISSION OF FACILITY
10 IDENTIFICATION.—Each person that owns a facility
11 described in subsection (a)(4)(A) or a site or organi-
12 zation required to be identified by paragraph (4)
13 shall submit to the Secretary the information re-
14 quired under this subsection each year. Such infor-
15 mation shall—

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

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

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

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

4 “(B) whether the facility manufactures ac-
5 tive pharmaceutical ingredients or finished dos-
6 age forms, or both;

7 “(C) whether or not the facility is located
8 within the United States and its territories and
9 possessions;

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

13 “(E) whether the facility manufactures
14 drugs that are not generic drugs.

15 “(4) CERTAIN SITES AND ORGANIZATIONS.—

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

21 “(B) SITES AND ORGANIZATIONS.—A site
22 or organization is described in this subpara-
23 graph if it is identified in a generic drug sub-
24 mission and is—

1 “(i) a site in which a bioanalytical
2 study is conducted;

3 “(ii) a clinical research organization;

4 “(iii) a contract analytical testing site;

5 or

6 “(iv) a contract repackager site.

7 “(C) NOTICE.—The Secretary may, by no-
8 tice published in the Federal Register, specify
9 the means and format for submission of the in-
10 formation under subparagraph (A) and may
11 specify, as necessary for purposes of this sec-
12 tion, any additional information to be sub-
13 mitted.

14 “(D) INSPECTION AUTHORITY.—The Sec-
15 retary’s inspection authority under section
16 704(a)(1) shall extend to all such sites and or-
17 ganizations.

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

19 “(1) GENERIC DRUG BACKLOG FEE.—Failure
20 to pay the fee under subsection (a)(1) shall result in
21 the Secretary placing the person that owns the ab-
22 breviated new drug application subject to that fee on
23 an arrears list, such that no new abbreviated new
24 drug applications or supplement submitted on or
25 after October 1, 2012, from that person, or any af-

1 filiate of that person, will be received within the
2 meaning of section 505(j)(5)(A) until such out-
3 standing fee is paid.

4 “(2) DRUG MASTER FILE FEE.—

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

12 “(B)(i) Any generic drug submission sub-
13 mitted on or after October 1, 2012, that ref-
14 erences, by a letter of authorization, a Type II
15 active pharmaceutical ingredient drug master
16 file that has not been deemed available for ref-
17 erence shall not be received within the meaning
18 of section 505(j)(5)(A) unless the condition
19 specified in clause (ii) is met.

20 “(ii) The condition specified in this clause
21 is that the fee established under subsection
22 (a)(2) has been paid within 20 calendar days of
23 the Secretary providing the notification to the
24 sponsor of the abbreviated new drug application
25 or supplement of the failure of the owner of the

1 Type II active pharmaceutical ingredient drug
2 master file to pay the drug master file fee as
3 specified in subparagraph (C).

4 “(C)(i) If an abbreviated new drug applica-
5 tion or supplement to an abbreviated new drug
6 application references a Type II active pharmaceuti-
7 cal ingredient drug master file for which a
8 fee under subsection (a)(2)(A) has not been
9 paid by the applicable date under subsection
10 (a)(2)(E), the Secretary shall notify the sponsor
11 of the abbreviated new drug application or sup-
12 plement of the failure of the owner of the Type
13 II active pharmaceutical ingredient drug master
14 file to pay the applicable fee.

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

21 “(3) ABBREVIATED NEW DRUG APPLICATION
22 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—
23 Failure to pay a fee under subparagraph (A) or (F)
24 of subsection (a)(3) within 20 calendar days of the
25 applicable due date under subparagraph (C) of such

1 subsection shall result in the abbreviated new drug
2 application or the prior approval supplement to an
3 abbreviated new drug application not being received
4 within the meaning of section 505(j)(5)(A) until
5 such outstanding fee is paid.

6 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
7 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

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

13 “(i) The Secretary shall place the fa-
14 cility on a publicly available arrears list,
15 such that no new abbreviated new drug ap-
16 plication or supplement submitted on or
17 after October 1, 2012, from the person
18 that is responsible for paying such fee, or
19 any affiliate of that person, will be received
20 within the meaning of section 505(j)(5)(A).

21 “(ii) Any new generic drug submission
22 submitted on or after October 1, 2012,
23 that references such a facility shall not be
24 received, within the meaning of section
25 505(j)(5)(A) if the outstanding facility fee

1 is not paid within 20 calendar days of the
2 Secretary providing the notification to the
3 sponsor of the failure of the owner of the
4 facility to pay the facility fee under sub-
5 section (a)(4)(C).

6 “(iii) All drugs or active pharma-
7 ceutical ingredients manufactured in such
8 a facility or containing an ingredient man-
9 ufactured in such a facility shall be deemed
10 misbranded under section 502(aa).

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

16 “(C) NONRECEIVAL FOR NONPAYMENT.—

17 “(i) NOTICE.—If an abbreviated new
18 drug application or supplement to an ab-
19 breviated new drug application submitted
20 on or after October 1, 2012, references a
21 facility for which a facility fee has not been
22 paid by the applicable date under sub-
23 section (a)(4)(C), the Secretary shall notify
24 the sponsor of the generic drug submission

1 of the failure of the owner of the facility
2 to pay the facility fee.

3 “(ii) NONRECEIVAL.—If the facility
4 fee is not paid within 20 calendar days of
5 the Secretary providing the notification
6 under clause (i), the abbreviated new drug
7 application or supplement to an abbrevi-
8 ated new drug application shall not be re-
9 ceived within the meaning of section
10 505(j)(5)(A).

11 “(h) LIMITATIONS.—

12 “(1) IN GENERAL.—Fees under subsection (a)
13 shall be refunded for a fiscal year beginning after
14 fiscal year 2012, unless appropriations for salaries
15 and expenses of the Food and Drug Administration
16 for such fiscal year (excluding the amount of fees
17 appropriated for such fiscal year) are equal to or
18 greater than the amount of appropriations for the
19 salaries and expenses of the Food and Drug Admin-
20 istration for the fiscal year 2009 (excluding the
21 amount of fees appropriated for such fiscal year)
22 multiplied by the adjustment factor (as defined in
23 section 744A) applicable to the fiscal year involved.

24 “(2) AUTHORITY.—If the Secretary does not
25 assess fees under subsection (a) during any portion

1 of a fiscal year and if at a later date in such fiscal
2 year the Secretary may assess such fees, the Sec-
3 retary may assess and collect such fees, without any
4 modification in the rate, for Type II active pharma-
5 ceutical ingredient drug master files, abbreviated
6 new drug applications and prior approval supple-
7 ments, and generic drug facilities and active phar-
8 maceutical ingredient facilities at any time in such
9 fiscal year notwithstanding the provisions of sub-
10 section (a) relating to the date fees are to be paid.

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

12 “(1) IN GENERAL.—Fees authorized under sub-
13 section (a) shall be collected and available for obliga-
14 tion only to the extent and in the amount provided
15 in advance in appropriations Acts, subject to para-
16 graph (2). Such fees are authorized to remain avail-
17 able until expended. Such sums as may be necessary
18 may be transferred from the Food and Drug Admin-
19 istration salaries and expenses appropriation account
20 without fiscal year limitation to such appropriation
21 account for salaries and expenses with such fiscal
22 year limitation. The sums transferred shall be avail-
23 able solely for human generic drug activities.

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

1 “(A) IN GENERAL.—The fees authorized
2 by this section—

3 “(i) subject to subparagraphs (C) and
4 (D), shall be collected and available in each
5 fiscal year in an amount not to exceed the
6 amount specified in appropriation Acts, or
7 otherwise made available for obligation for
8 such fiscal year; and

9 “(ii) shall be available for a fiscal year
10 beginning after fiscal year 2012 to defray
11 the costs of human generic drug activities
12 (including such costs for an additional
13 number of full-time equivalent positions in
14 the Department of Health and Human
15 Services to be engaged in such activities),
16 only if the Secretary allocates for such
17 purpose an amount for such fiscal year
18 (excluding amounts from fees collected
19 under this section) no less than
20 \$97,000,000 multiplied by the adjustment
21 factor defined in subsection (p)(3) applica-
22 ble to the fiscal year involved.

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

1 costs funded by appropriations and allocated for
2 human generic activities are not more than 10
3 percent below the level specified in such sub-
4 paragraph.

5 “(C) FEE COLLECTION DURING FIRST
6 PROGRAM YEAR.—Until the date of enactment
7 of an Act making appropriations through Sep-
8 tember 30, 2013 for the salaries and expenses
9 account of the Food and Drug Administration,
10 fees authorized by this section for fiscal year
11 2013, may be collected and shall be credited to
12 such account and remain available until ex-
13 pended.

14 “(D) PROVISION FOR EARLY PAYMENTS IN
15 SUBSEQUENT YEARS.—Payment of fees author-
16 ized under this section for a fiscal year (after
17 fiscal year 2013), prior to the due date for such
18 fees, may be accepted by the Secretary in ac-
19 cordance with authority provided in advance in
20 a prior year appropriations Act.

21 “(3) AUTHORIZATION OF APPROPRIATIONS.—
22 For each of the fiscal years 2013 through 2017,
23 there is authorized to be appropriated for fees under
24 this section an amount equivalent to the total rev-
25 enue amount determined under subsection (b) for

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

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

10 “(k) CONSTRUCTION.—This section may not be con-
11 strued to require that the number of full-time equivalent
12 positions in the Department of Health and Human Serv-
13 ices, for officers, employees, and advisory committees not
14 engaged in human generic drug activities, be reduced to
15 offset the number of officers, employees, and advisory
16 committees so engaged.

17 “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

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

1 “(2) IDENTIFICATION REQUIREMENT.—Facili-
2 ties that produce positron emission tomography
3 drugs or active pharmaceutical ingredients of such
4 drugs are required to be identified pursuant to sub-
5 section (f).

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

11 “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—
12 An abbreviated new drug application that is not consid-
13 ered to be received within the meaning of section
14 505(j)(5)(A) because of failure to pay an applicable fee
15 under this provision within the time period specified in
16 subsection (g) shall be deemed not to have been ‘substan-
17 tially complete’ on the date of its submission within the
18 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbre-
19 viated new drug application that is not substantially com-
20 plete on the date of its submission solely because of failure
21 to pay an applicable fee under the preceding sentence shall
22 be deemed substantially complete and received within the
23 meaning of section 505(j)(5)(A) as of the date such appli-
24 cable fee is received.

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

6 “(1) such waiver or reduction is necessary to
7 prevent or alleviate a verified or potential drug
8 shortage; and

9 “(2) the application or supplement is for a drug
10 described in section 506C(a).”.

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

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

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

17 “(a) PERFORMANCE REPORT.—Beginning with fiscal
18 year 2013, not later than 120 days after the end of each
19 fiscal year for which fees are collected under this part,
20 the Secretary shall prepare and submit to the Committee
21 on Energy and Commerce of the House of Representatives
22 and the Committee on Health, Education, Labor, and
23 Pensions of the Senate a report concerning the progress
24 of the Food and Drug Administration in achieving the
25 goals identified in the letters described in section 301(b)

1 of the Generic Drug User Fee Amendments of 2012 dur-
2 ing such fiscal year and the future plans of the Food and
3 Drug Administration for meeting the goals.

4 “(b) FISCAL REPORT.—Beginning with fiscal year
5 2013, not later than 120 days after the end of each fiscal
6 year for which fees are collected under this part, the Sec-
7 retary shall prepare and submit to the Committee on En-
8 ergy and Commerce of the House of Representatives and
9 the Committee on Health, Education, Labor, and Pen-
10 sions of the Senate a report on the implementation of the
11 authority for such fees during such fiscal year and the
12 use, by the Food and Drug Administration, of the fees
13 collected for such fiscal year.

14 “(c) PUBLIC AVAILABILITY.—The Secretary shall
15 make the reports required under subsections (a) and (b)
16 available to the public on the Internet Web site of the
17 Food and Drug Administration.

18 “(d) REAUTHORIZATION.—

19 “(1) CONSULTATION.—In developing rec-
20 ommendations to present to the Congress with re-
21 spect to the goals, and plans for meeting the goals,
22 for human generic drug activities for the first 5 fis-
23 cal years after fiscal year 2017, and for the reau-
24 thorization of this part for such fiscal years, the Sec-
25 retary shall consult with—

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

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

5 “(C) scientific and academic experts;

6 “(D) health care professionals;

7 “(E) representatives of patient and con-
8 sumer advocacy groups; and

9 “(F) the generic drug industry.

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

13 “(A) publish a notice in the Federal Reg-
14 ister requesting public input on the reauthoriza-
15 tion;

16 “(B) hold a public meeting at which the
17 public may present its views on the reauthoriza-
18 tion, including specific suggestions for changes
19 to the goals referred to in subsection (a);

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

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

1 “(3) PERIODIC CONSULTATION.—Not less fre-
2 quently than once every month during negotiations
3 with the generic drug industry, the Secretary shall
4 hold discussions with representatives of patient and
5 consumer advocacy groups to continue discussions of
6 their views on the reauthorization and their sugges-
7 tions for changes to this part as expressed under
8 paragraph (2).

9 “(4) PUBLIC REVIEW OF RECOMMENDA-
10 TIONS.—After negotiations with the generic drug in-
11 dustry, the Secretary shall—

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

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

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

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

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

1 “(5) 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 (4), 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 “(6) MINUTES OF NEGOTIATION MEETINGS.—

9 “(A) PUBLIC AVAILABILITY.—Before pre-
10 senting the recommendations developed under
11 paragraphs (1) through (5) to the Congress, the
12 Secretary shall make publicly available, on the
13 Internet Web site of the Food and Drug Ad-
14 ministration, minutes of all negotiation meet-
15 ings conducted under this subsection between
16 the Food and Drug Administration and the ge-
17 neric drug industry.

18 “(B) CONTENT.—The minutes described
19 under subparagraph (A) shall summarize any
20 substantive proposal made by any party to the
21 negotiations as well as significant controversies
22 or differences of opinion during the negotiations
23 and their resolution.”.

1 **SEC. 304. SUNSET DATES.**

2 (a) AUTHORIZATION.—The amendments made by
3 section 302 cease to be effective October 1, 2017.

4 (b) REPORTING REQUIREMENTS.—The amendments
5 made by section 303 cease to be effective January 31,
6 2018.

7 **SEC. 305. EFFECTIVE DATE.**

8 The amendments made by this title shall take effect
9 on October 1, 2012, or the date of the enactment of this
10 title, whichever is later, except that fees under section 302
11 shall be assessed for all human generic drug submissions
12 and Type II active pharmaceutical drug master files re-
13 ceived on or after October 1, 2012, regardless of the date
14 of enactment of this title.

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

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

18 “(aa) If it is a drug, or an active pharmaceutical in-
19 gredient, and it was manufactured, prepared, propagated,
20 compounded, or processed in a facility for which fees have
21 not been paid as required by section 744A(a)(4) or for
22 which identifying information required by section 744B(f)
23 has not been submitted, or it contains an active pharma-
24 ceutical ingredient that was manufactured, prepared,
25 propagated, compounded, or processed in such a facility.”.

1 **SEC. 307. STREAMLINED HIRING AUTHORITY OF THE FOOD**
2 **AND DRUG ADMINISTRATION TO SUPPORT**
3 **ACTIVITIES RELATED TO HUMAN GENERIC**
4 **DRUGS.**

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

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

9 “(a) **IN GENERAL.**—In addition to any other per-
10 sonnel authorities under other provisions of law, the Sec-
11 retary may, without regard to the provisions of title 5,
12 United States Code, governing appointments in the com-
13 petitive service, appoint employees to positions in the Food
14 and Drug Administration to perform, administer, or sup-
15 port activities described in subsection (b), if the Secretary
16 determines that such appointments are needed to achieve
17 the objectives specified in subsection (c).

18 “(b) **ACTIVITIES DESCRIBED.**—The activities de-
19 scribed in this subsection are activities under this Act re-
20 lated to human generic drug activities (as defined in sec-
21 tion 744A).

22 “(c) **OBJECTIVES SPECIFIED.**—The objectives speci-
23 fied in this subsection are the performance goals with re-
24 spect to section 744A (regarding assessment and use of
25 human generic drug fees), as set forth in the letters de-

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

3 “(d) INTERNAL CONTROLS.—The Secretary shall in-
4 stitute appropriate internal controls for appointments
5 under this section.

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

9 **TITLE IV—FEES RELATING TO**
10 **BIOSIMILAR BIOLOGICAL**
11 **PRODUCTS**

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

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

15 (b) FINDING.—The Congress finds that the fees au-
16 thorized by the amendments made in this title will be dedi-
17 cated to expediting the process for the review of biosimilar
18 biological product applications, including postmarket safe-
19 ty activities, as set forth in the goals identified for pur-
20 poses of part 8 of subchapter C of chapter VII of the Fed-
21 eral Food, Drug, and Cosmetic Act, in the letters from
22 the Secretary of Health and Human Services to the Chair-
23 man of the Committee on Health, Education, Labor, and
24 Pensions of the Senate and the Chairman of the Com-

1 mittee on Energy and Commerce of the House of Rep-
2 resentatives, as set forth in the Congressional Record

3 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
4 **PRODUCTS.**

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

8 **“PART 8—FEES RELATING TO BIOSIMILAR**
9 **BIOLOGICAL PRODUCTS**

10 **“SEC. 744G. DEFINITIONS.**

11 “For purposes of this part:

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

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

21 “(A) one business entity controls, or has
22 the power to control, the other business entity;
23 or

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

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

4 “(4)(A) Subject to subparagraph (B), the term
5 ‘biosimilar biological product application’ means an
6 application for licensure of a biological product
7 under section 351(k) of the Public Health Service
8 Act.

9 “(B) Such term does not include—

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

11 “(ii) an application filed under section
12 351(k) of the Public Health Service Act that
13 cites as the reference product a bovine blood
14 product for topical application licensed before
15 September 1, 1992, or a large volume paren-
16 teral drug product approved before such date;

17 “(iii) an application filed under section
18 351(k) of the Public Health Service Act with
19 respect to—

20 “(I) whole blood or a blood component
21 for transfusion;

22 “(II) an allergenic extract product;

23 “(III) an in vitro diagnostic biological
24 product; or

1 “(IV) a biological product for further
2 manufacturing use only; or

3 “(iv) an application for licensure under
4 section 351(k) of the Public Health Service Act
5 that is submitted by a State or Federal Govern-
6 ment entity for a product that is not distributed
7 commercially.

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

14 “(6) The term ‘biosimilar biological product de-
15 velopment program’ means the program under this
16 part for expediting the process for the review of sub-
17 missions in connection with biosimilar biological
18 product development.

19 “(7)(A) The term ‘biosimilar biological product
20 establishment’ means a foreign or domestic place of
21 business—

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

1 “(ii) at which one or more biosimilar bio-
2 logical products are manufactured in final dos-
3 age form.

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

6 “(8) The term ‘biosimilar initial advisory meet-
7 ing’—

8 “(A) means a meeting, if requested, that is
9 limited to—

10 “(i) a general discussion regarding
11 whether licensure under section 351(k) of
12 the Public Health Service Act may be fea-
13 sible for a particular product; and

14 “(ii) if so, general advice on the ex-
15 pected content of the development pro-
16 gram; and

17 “(B) does not include any meeting that in-
18 volves substantive review of summary data or
19 full study reports.

20 “(9) The term ‘costs of resources allocated for
21 the process for the review of biosimilar biological
22 product applications’ means the expenses in connec-
23 tion with the process for the review of biosimilar bio-
24 logical product applications for—

1 “(A) officers and employees of the Food
2 and Drug Administration, contractors of the
3 Food and Drug Administration, advisory com-
4 mittees, and costs related to such officers em-
5 ployees and committees and to contracts with
6 such contractors;

7 “(B) management of information, and the
8 acquisition, maintenance, and repair of com-
9 puter resources;

10 “(C) leasing, maintenance, renovation, and
11 repair of facilities and acquisition, maintenance,
12 and repair of fixtures, furniture, scientific
13 equipment, and other necessary materials and
14 supplies; and

15 “(D) collecting fees under section 744H
16 and accounting for resources allocated for the
17 review of submissions in connection with bio-
18 similar biological product development, bio-
19 similar biological product applications, and sup-
20 plements.

21 “(10) The term ‘final dosage form’ means, with
22 respect to a biosimilar biological product, a finished
23 dosage form which is approved for administration to
24 a patient without substantial further manufacturing
25 (such as lyophilized products before reconstitution).

1 “(11) The term ‘financial hold’—

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

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

15 “(12) The term ‘person’ includes an affiliate of
16 such person.

17 “(13) The term ‘process for the review of bio-
18 similar biological product applications’ means the
19 following activities of the Secretary with respect to
20 the review of submissions in connection with bio-
21 similar biological product development, biosimilar bi-
22 ological product applications, and supplements:

23 “(A) The activities necessary for the re-
24 view of submissions in connection with bio-
25 similar biological product development, bio-

1 similar biological product applications, and sup-
2 plements.

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

11 “(C) The inspection of biosimilar biological
12 product establishments and other facilities un-
13 dertaken as part of the Secretary’s review of
14 pending biosimilar biological product applica-
15 tions and supplements.

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

19 “(E) Monitoring of research conducted in
20 connection with the review of biosimilar biologi-
21 cal product applications.

22 “(F) Postmarket safety activities with re-
23 spect to biologics approved under biosimilar bio-
24 logical product applications or supplements, in-
25 cluding the following activities:

1 “(i) Collecting, developing, and re-
2 viewing safety information on biosimilar bi-
3 ological products, including adverse-event
4 reports.

5 “(ii) Developing and using improved
6 adverse-event data-collection systems, in-
7 cluding information technology systems.

8 “(iii) Developing and using improved
9 analytical tools to assess potential safety
10 problems, including access to external data
11 bases.

12 “(iv) Implementing and enforcing sec-
13 tion 505(o) (relating to postapproval stud-
14 ies and clinical trials and labeling changes)
15 and section 505(p) (relating to risk evalua-
16 tion and mitigation strategies).

17 “(v) Carrying out section 505(k)(5)
18 (relating to adverse-event reports and
19 postmarket safety activities).

20 “(14) The term ‘supplement’ means a request
21 to the Secretary to approve a change in a biosimilar
22 biological product application which has been ap-
23 proved, including a supplement requesting that the
24 Secretary determine that the biosimilar biological
25 product meets the standards for interchangeability

1 described in section 351(k)(4) of the Public Health
2 Service Act.

3 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
4 **BIOLOGICAL PRODUCT FEES.**

5 “(a) TYPES OF FEES.—Beginning in fiscal year
6 2013, the Secretary shall assess and collect fees in accord-
7 ance with this section as follows:

8 “(1) BIOSIMILAR DEVELOPMENT PROGRAM
9 FEES.—

10 “(A) INITIAL BIOSIMILAR BIOLOGICAL
11 PRODUCT DEVELOPMENT FEE.—

12 “(i) IN GENERAL.—Each person that
13 submits to the Secretary a meeting request
14 described under clause (ii) or a clinical
15 protocol for an investigational new drug
16 protocol described under clause (iii) shall
17 pay for the product named in the meeting
18 request or the investigational new drug ap-
19 plication the initial biosimilar biological
20 product development fee established under
21 subsection (b)(1)(A).

22 “(ii) MEETING REQUEST.—The meet-
23 ing request defined in this clause is a re-
24 quest for a biosimilar biological product
25 development meeting for a product.

1 “(iii) CLINICAL PROTOCOL FOR IND.—
2 A clinical protocol for an investigational
3 new drug protocol described in this clause
4 is a clinical protocol consistent with the
5 provisions of section 505(i), including any
6 regulations promulgated under section
7 505(i), (referred to in this section as ‘in-
8 vestigational new drug application’) de-
9 scribing an investigation that the Secretary
10 determines is intended to support a bio-
11 similar biological product application for a
12 product.

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

16 “(I) Not later than 5 days after
17 the Secretary grants a request for a
18 biosimilar biological product develop-
19 ment meeting.

20 “(II) The date of submission of
21 an investigational new drug applica-
22 tion describing an investigation that
23 the Secretary determines is intended
24 to support a biosimilar biological
25 product application.

1 “(v) TRANSITION RULE.—Each per-
2 son that has submitted an investigational
3 new drug application prior to the date of
4 enactment of the Biosimilars User Fee Act
5 of 2012 shall pay the initial biosimilar bio-
6 logical product development fee by the ear-
7 lier of the following:

8 “(I) Not later than 60 days after
9 the date of the enactment of the
10 Biosimilars User Fee Act of 2012, if
11 the Secretary determines that the in-
12 vestigational new drug application de-
13 scribes an investigation that is in-
14 tended to support a biosimilar biologi-
15 cal product application.

16 “(II) Not later than 5 days after
17 the Secretary grants a request for a
18 biosimilar biological product develop-
19 ment meeting.

20 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
21 PRODUCT DEVELOPMENT FEE.—

22 “(i) IN GENERAL.—A person that
23 pays an initial biosimilar biological product
24 development fee for a product shall pay for
25 such product, beginning in the fiscal year

1 following the fiscal year in which the initial
2 biosimilar biological product development
3 fee was paid, an annual fee established
4 under subsection (b)(1)(B) for biosimilar
5 biological product development (referred to
6 in this section as ‘annual biosimilar bio-
7 logical product development fee’).

8 “(ii) DUE DATE.—The annual bio-
9 similar biological product development pro-
10 gram fee for each fiscal year will be due on
11 the later of—

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

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

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

23 “(I) submitted a marketing appli-
24 cation for the biological product that
25 was accepted for filing; or

1 “(II) discontinued participation
2 in the biosimilar biological product de-
3 velopment program for the product
4 under subparagraph (C).

5 “(C) DISCONTINUATION OF FEE OBLIGA-
6 TION.—A person may discontinue participation
7 in the biosimilar biological product development
8 program for a product effective October 1 of a
9 fiscal year by, not later than August 1 of the
10 preceding fiscal year—

11 “(i) if no investigational new drug ap-
12 plication concerning the product has been
13 submitted, submitting to the Secretary a
14 written declaration that the person has no
15 present intention of further developing the
16 product as a biosimilar biological product;
17 or

18 “(ii) if an investigational new drug
19 application concerning the product has
20 been submitted, by withdrawing the inves-
21 tigational new drug application in accord-
22 ance with part 312 of title 21, Code of
23 Federal Regulations (or any successor reg-
24 ulations).

25 “(D) REACTIVATION FEE.—

1 “(i) IN GENERAL.—A person that has
2 discontinued participation in the biosimilar
3 biological product development program for
4 a product under subparagraph (C) shall
5 pay a fee (referred to in this section as ‘re-
6 activation fee’) by the earlier of the fol-
7 lowing:

8 “(I) Not later than 5 days after
9 the Secretary grants a request for a
10 biosimilar biological product develop-
11 ment meeting for the product (after
12 the date on which such participation
13 was discontinued).

14 “(II) Upon the date of submis-
15 sion (after the date on which such
16 participation was discontinued) of an
17 investigational new drug application
18 describing an investigation that the
19 Secretary determines is intended to
20 support a biosimilar biological product
21 application for that product.

22 “(ii) APPLICATION OF ANNUAL
23 FEE.—A person that pays a reactivation
24 fee for a product shall pay for such prod-
25 uct, beginning in the next fiscal year, the

1 annual biosimilar biological product devel-
2 opment fee under subparagraph (B).

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

5 “(i) NO BIOSIMILAR BIOLOGICAL
6 PRODUCT DEVELOPMENT MEETINGS.—If a
7 person has failed to pay an initial or an-
8 nual biosimilar biological product develop-
9 ment fee as required under subparagraph
10 (A) or (B), or a reactivation fee as re-
11 quired under subparagraph (D), the Sec-
12 retary shall not provide a biosimilar bio-
13 logical product development meeting relat-
14 ing to the product for which fees are owed.

15 “(ii) NO RECEIPT OF INVESTIGA-
16 TIONAL NEW DRUG APPLICATIONS.—Ex-
17 cept in extraordinary circumstances, the
18 Secretary shall not consider an investiga-
19 tional new drug application to have been
20 received under section 505(i)(2) if—

21 “(I) the Secretary determines
22 that the investigation is intended to
23 support a biosimilar biological product
24 application; and

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

8 “(iii) FINANCIAL HOLD.—Notwith-
9 standing section 505(i)(2), except in ex-
10 traordinary circumstances, the Secretary
11 shall prohibit the sponsor of a clinical in-
12 vestigation from continuing the investiga-
13 tion if—

14 “(I) the Secretary determines
15 that the investigation is intended to
16 support a biosimilar biological product
17 application; and

18 “(II) the sponsor has failed to
19 pay an initial or annual biosimilar bio-
20 logical product development fee for
21 the product as required under sub-
22 paragraph (A) or (B), or a reactiva-
23 tion fee for the product as required
24 under subparagraph (D).

1 “(iv) NO ACCEPTANCE OF BIOSIMILAR
2 BIOLOGICAL PRODUCT APPLICATIONS OR
3 SUPPLEMENTS.—If a person has failed to
4 pay an initial or annual biosimilar biological
5 product development fee as required
6 under subparagraph (A) or (B), or a reac-
7 tivation fee as required under subpara-
8 graph (D), any biosimilar biological prod-
9 uct application or supplement submitted by
10 that person shall be considered incomplete
11 and shall not be accepted for filing by the
12 Secretary until all such fees owed by such
13 person have been paid.

14 “(F) LIMITS REGARDING BIOSIMILAR DE-
15 VELOPMENT PROGRAM FEES.—

16 “(i) NO REFUNDS.—The Secretary
17 shall not refund any initial or annual bio-
18 similar biological product development fee
19 paid under subparagraph (A) or (B), or
20 any reactivation fee paid under subpara-
21 graph (D).

22 “(ii) NO WAIVERS, EXEMPTIONS, OR
23 REDUCTIONS.—The Secretary shall not
24 grant a waiver, exemption, or reduction of
25 any initial or annual biosimilar biological

1 product development fee due or payable
2 under subparagraph (A) or (B), or any re-
3 activation fee due or payable under sub-
4 paragraph (D).

5 “(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
6 CATION AND SUPPLEMENT FEE.—

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

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

13 “(I) the amount of the fee estab-
14 lished under subsection (b)(1)(D) for
15 a biosimilar biological product applica-
16 tion; minus

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

22 “(ii) A fee for a biosimilar biological
23 product application for which clinical data
24 (other than comparative bioavailability

1 studies) with respect to safety or effective-
2 ness are not required, that is equal to—

3 “(I) half of the amount of the fee
4 established under subsection (b)(1)(D)
5 for a biosimilar biological product ap-
6 plication; minus

7 “(II) the cumulative amount of
8 fees paid, if any, under subparagraphs
9 (A), (B), and (D) of paragraph (1)
10 for that product.

11 “(iii) A fee for a supplement for which
12 clinical data (other than comparative bio-
13 availability studies) with respect to safety
14 or effectiveness are required, that is equal
15 to half of the amount of the fee established
16 under subsection (b)(1)(D) for a biosimilar
17 biological product application.

18 “(B) REDUCTION IN FEES.—Notwith-
19 standing section 404 of the Biosimilars User
20 Fee Act of 2012, any person who pays a fee
21 under subparagraph (A), (B), or (D) of para-
22 graph (1) for a product before October 1, 2017,
23 but submits a biosimilar biological product ap-
24 plication for that product after such date, shall
25 be entitled to the reduction of any biosimilar bi-

1 ological product application fees that may be
2 assessed at the time when such biosimilar bio-
3 logical product application is submitted, by the
4 cumulative amount of fees paid under subpara-
5 graphs (A), (B), and (D) of paragraph (1) for
6 that product.

7 “(C) PAYMENT DUE DATE.—Any fee re-
8 quired by subparagraph (A) shall be due upon
9 submission of the application or supplement for
10 which such fee applies.

11 “(D) EXCEPTION FOR PREVIOUSLY FILED
12 APPLICATION OR SUPPLEMENT.—If a biosimilar
13 biological product application or supplement
14 was submitted by a person that paid the fee for
15 such application or supplement, was accepted
16 for filing, and was not approved or was with-
17 drawn (without a waiver), the submission of a
18 biosimilar biological product application or a
19 supplement for the same product by the same
20 person (or the person’s licensee, assignee, or
21 successor) shall not be subject to a fee under
22 subparagraph (A).

23 “(E) REFUND OF APPLICATION FEE IF AP-
24 PLICATION REFUSED FOR FILING OR WITH-
25 DRAWN BEFORE FILING.—The Secretary shall

1 refund 75 percent of the fee paid under this
2 paragraph for any application or supplement
3 which is refused for filing or withdrawn without
4 a waiver before filing.

5 “(F) FEES FOR APPLICATIONS PRE-
6 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
7 BEFORE FILING.—A biosimilar biological prod-
8 uct application or supplement that was sub-
9 mitted but was refused for filing, or was with-
10 drawn before being accepted or refused for fil-
11 ing, shall be subject to the full fee under sub-
12 paragraph (A) upon being resubmitted or filed
13 over protest, unless the fee is waived under sub-
14 section (c).

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

17 “(A) IN GENERAL.—Except as provided in
18 subparagraph (E)(ii), each person that is
19 named as the applicant in a biosimilar biologi-
20 cal product application shall be assessed an an-
21 nual fee established under subsection (b)(1)(E)
22 for each biosimilar biological product establish-
23 ment that is listed in the approved biosimilar
24 biological product application as an establish-

1 ment that manufactures the biosimilar biological
2 product named in such application.

3 “(B) ASSESSMENT IN FISCAL YEARS.—The
4 establishment fee shall be assessed in each fis-
5 cal year for which the biosimilar biological prod-
6 uct named in the application is assessed a fee
7 under paragraph (4) unless the biosimilar bio-
8 logical product establishment listed in the appli-
9 cation does not engage in the manufacture of
10 the biosimilar biological product during such
11 fiscal year.

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

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

16 “(ii) the first business day after the
17 enactment of an appropriations Act pro-
18 viding for the collection and obligation of
19 fees for such fiscal year under this section.

20 “(D) APPLICATION TO ESTABLISHMENT.—

21 “(i) Each biosimilar biological product
22 establishment shall be assessed only one
23 fee per biosimilar biological product estab-
24 lishment, notwithstanding the number of
25 biosimilar biological products manufac-

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

3 “(ii) In the event an establishment is
4 listed in a biosimilar biological product ap-
5 plication by more than one applicant, the
6 establishment fee for the fiscal year shall
7 be divided equally and assessed among the
8 applicants whose biosimilar biological prod-
9 ucts are manufactured by the establish-
10 ment during the fiscal year and assessed
11 biosimilar biological product fees under
12 paragraph (4).

13 “(E) EXCEPTION FOR NEW PRODUCTS.—
14 If, during the fiscal year, an applicant initiates
15 or causes to be initiated the manufacture of a
16 biosimilar biological product at an establish-
17 ment listed in its biosimilar biological product
18 application—

19 “(i) that did not manufacture the bio-
20 similar biological product in the previous
21 fiscal year; and

22 “(ii) for which the full biosimilar bio-
23 logical product establishment fee has been
24 assessed in the fiscal year at a time before

1 manufacture of the biosimilar biological
2 product was begun,
3 the applicant shall not be assessed a share of
4 the biosimilar biological product establishment
5 fee for the fiscal year in which the manufacture
6 of the product began.

7 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

8 “(A) IN GENERAL.—Each person who is
9 named as the applicant in a biosimilar biologi-
10 cal product application shall pay for each such
11 biosimilar biological product the annual fee es-
12 tablished under subsection (b)(1)(F).

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

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

18 “(ii) the first business day after the
19 enactment of an appropriations Act pro-
20 viding for the collection and obligation of
21 fees for such year under this section.

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

1 “(b) FEE SETTING AND AMOUNTS.—

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

8 “(A) INITIAL BIOSIMILAR BIOLOGICAL
9 PRODUCT DEVELOPMENT FEE.—The initial bio-
10 similar biological product development fee under
11 subsection (a)(1)(A) for a fiscal year shall be
12 equal to 10 percent of the amount established
13 under section 736(c)(5) for a human drug ap-
14 plication described in section 736(a)(1)(A)(i)
15 for that fiscal year.

16 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
17 PRODUCT DEVELOPMENT FEE.—The annual
18 biosimilar biological product development fee
19 under subsection (a)(1)(B) for a fiscal year
20 shall be equal to 10 percent of the amount es-
21 tablished under section 736(c)(5) for a human
22 drug application described in section
23 736(a)(1)(A)(i) for that fiscal year.

24 “(C) REACTIVATION FEE.—The reactiva-
25 tion fee under subsection (a)(1)(D) for a fiscal

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

5 “(D) BIOSIMILAR BIOLOGICAL PRODUCT
6 APPLICATION FEE.—The biosimilar biological
7 product application fee under subsection (a)(2)
8 for a fiscal year shall be equal to the amount
9 established under section 736(c)(5) for a
10 human drug application described in section
11 736(a)(1)(A)(i) for that fiscal year.

12 “(E) BIOSIMILAR BIOLOGICAL PRODUCT
13 ESTABLISHMENT FEE.—The biosimilar biologi-
14 cal product establishment fee under subsection
15 (a)(3) for a fiscal year shall be equal to the
16 amount established under section 736(c)(5) for
17 a prescription drug establishment for that fiscal
18 year.

19 “(F) BIOSIMILAR BIOLOGICAL PRODUCT
20 FEE.—The biosimilar biological product fee
21 under subsection (a)(4) for a fiscal year shall be
22 equal to the amount established under section
23 736(c)(5) for a prescription drug product for
24 that fiscal year.

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

6 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-
7 NESS.—

8 “(1) WAIVER OF APPLICATION FEE.—The Sec-
9 retary shall grant to a person who is named in a bio-
10 similar biological product application a waiver from
11 the application fee assessed to that person under
12 subsection (a)(2)(A) for the first biosimilar biologi-
13 cal product application that a small business or its
14 affiliate submits to the Secretary for review. After a
15 small business or its affiliate is granted such a waiv-
16 er, the small business or its affiliate shall pay—

17 “(A) application fees for all subsequent
18 biosimilar biological product applications sub-
19 mitted to the Secretary for review in the same
20 manner as an entity that is not a small busi-
21 ness; and

22 “(B) all supplement fees for all supple-
23 ments to biosimilar biological product applica-
24 tions submitted to the Secretary for review in

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

3 “(2) CONSIDERATIONS.—In determining wheth-
4 er to grant a waiver of a fee under paragraph (1),
5 the Secretary shall consider only the circumstances
6 and assets of the applicant involved and any affiliate
7 of the applicant.

8 “(3) SMALL BUSINESS DEFINED.—In this sub-
9 section, the term ‘small business’ means an entity
10 that has fewer than 500 employees, including em-
11 ployees of affiliates, and does not have a drug prod-
12 uct that has been approved under a human drug ap-
13 plication (as defined in section 735) or a biosimilar
14 biological product application (as defined in section
15 744G(4)) and introduced or delivered for introduc-
16 tion into interstate commerce.

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

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

24 “(1) IN GENERAL.—Subject to paragraph (2),
25 fees authorized under subsection (a) shall be col-

1 lected and available for obligation only to the extent
2 and in the amount provided in advance in appropria-
3 tions Acts. Such fees are authorized to remain avail-
4 able until expended. Such sums as may be necessary
5 may be transferred from the Food and Drug Admin-
6 istration salaries and expenses appropriation account
7 without fiscal year limitation to such appropriation
8 account for salaries and expenses with such fiscal
9 year limitation. The sums transferred shall be avail-
10 able solely for the process for the review of bio-
11 similar biological product applications.

12 “(2) COLLECTIONS AND APPROPRIATION
13 ACTS.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graphs (C) and (D), the fees authorized by this
16 section shall be collected and available in each
17 fiscal year in an amount not to exceed the
18 amount specified in appropriation Acts, or oth-
19 erwise made available for obligation for such
20 fiscal year.

21 “(B) USE OF FEES AND LIMITATION.—
22 The fees authorized by this section shall be
23 available for a fiscal year beginning after fiscal
24 year 2012 to defray the costs of the process for
25 the review of biosimilar biological product appli-

1 cations (including such costs for an additional
2 number of full-time equivalent positions in the
3 Department of Health and Human Services to
4 be engaged in such process), only if the Sec-
5 retary allocates for such purpose an amount for
6 such fiscal year (excluding amounts from fees
7 collected under this section) no less than
8 \$20,000,000, multiplied by the adjustment fac-
9 tor applicable to the fiscal year involved.

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

19 “(D) PROVISION FOR EARLY PAYMENTS IN
20 SUBSEQUENT YEARS.—Payment of fees author-
21 ized under this section for a fiscal year (after
22 fiscal year 2013), prior to the due date for such
23 fees, may be accepted by the Secretary in ac-
24 cordance with authority provided in advance in
25 a prior year appropriations Act.

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—

2 For each of fiscal years 2013 through 2017, there
3 is authorized to be appropriated for fees under this
4 section an amount equivalent to the total amount of
5 fees assessed for such fiscal year under this section.

6 “(f) COLLECTION OF UNPAID FEES.—In any case
7 where the Secretary does not receive payment of a fee as-
8 sessed under subsection (a) within 30 days after it is due,
9 such fee shall be treated as a claim of the United States
10 Government subject to subchapter II of chapter 37 of title
11 31, United States Code.

12 “(g) WRITTEN REQUESTS FOR WAIVERS AND RE-
13 FUNDS.—To qualify for consideration for a waiver under
14 subsection (c), or for a refund of any fee collected in ac-
15 cordance with subsection (a)(2)(A), a person shall submit
16 to the Secretary a written request for such waiver or re-
17 fund not later than 180 days after such fee is due.

18 “(h) CONSTRUCTION.—This section may not be con-
19 strued to require that the number of full-time equivalent
20 positions in the Department of Health and Human Serv-
21 ices, for officers, employers, and advisory committees not
22 engaged in the process of the review of biosimilar biologi-
23 cal product applications, be reduced to offset the number
24 of officers, employees, and advisory committees so en-
25 gaged.”.

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

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

5 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**
6 **MENTS.**

7 “(a) PERFORMANCE REPORT.—Beginning with fiscal
8 year 2013, not later than 120 days after the end of each
9 fiscal year for which fees are collected under this part,
10 the Secretary shall prepare and submit to the Committee
11 on Energy and Commerce of the House of Representatives
12 and the Committee on Health, Education, Labor, and
13 Pensions of the Senate a report concerning the progress
14 of the Food and Drug Administration in achieving the
15 goals identified in the letters described in section 401(b)
16 of the Biosimilar User Fee Act of 2012 during such fiscal
17 year and the future plans of the Food and Drug Adminis-
18 tration for meeting such goals. The report for a fiscal year
19 shall include information on all previous cohorts for which
20 the Secretary has not given a complete response on all
21 biosimilar biological product applications and supplements
22 in the cohort.

23 “(b) FISCAL REPORT.—Not later than 120 days after
24 the end of fiscal year 2013 and each subsequent fiscal year
25 for which fees are collected under this part, the Secretary
26 shall prepare and submit to the Committee on Energy and

1 Commerce of the House of Representatives and the Com-
2 mittee on Health, Education, Labor, and Pensions of the
3 Senate a report on the implementation of the authority
4 for such fees during such fiscal year and the use, by the
5 Food and Drug Administration, of the fees collected for
6 such fiscal year.

7 “(c) PUBLIC AVAILABILITY.—The Secretary shall
8 make the reports required under subsections (a) and (b)
9 available to the public on the Internet Web site of the
10 Food and Drug Administration.

11 “(d) STUDY.—

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

17 “(2) INTERIM RESULTS.—Not later than June
18 1, 2015, the Secretary shall publish, for public com-
19 ment, interim results of the study described under
20 paragraph (1).

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

25 “(e) REAUTHORIZATION.—

1 “(1) CONSULTATION.—In developing rec-
2 ommendations to present to the Congress with re-
3 spect to the goals described in subsection (a), and
4 plans for meeting the goals, for the process for the
5 review of biosimilar biological product applications
6 for the first 5 fiscal years after fiscal year 2017, and
7 for the reauthorization of this part for such fiscal
8 years, the Secretary shall consult with—

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

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

13 “(C) scientific and academic experts;

14 “(D) health care professionals;

15 “(E) representatives of patient and con-
16 sumer advocacy groups; and

17 “(F) the regulated industry.

18 “(2) PUBLIC REVIEW OF RECOMMENDA-
19 TIONS.—After negotiations with the regulated indus-
20 try, the Secretary shall—

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

24 “(B) publish such recommendations in the
25 Federal Register;

1 “(C) provide for a period of 30 days for
2 the public to provide written comments on such
3 recommendations;

4 “(D) hold a meeting at which the public
5 may present its views on such recommenda-
6 tions; and

7 “(E) after consideration of such public
8 views and comments, revise such recommenda-
9 tions as necessary.

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

17 **SEC. 404. SUNSET DATES.**

18 (a) AUTHORIZATION.—The amendment made by sec-
19 tion 402 shall cease to be effective October 1, 2017.

20 (b) REPORTING REQUIREMENTS.—The amendment
21 made by section 403 shall cease to be effective January
22 31, 2018.

1 **SEC. 405. EFFECTIVE DATE.**

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

5 (1) October 1, 2012; or

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

7 (b) EXCEPTION.—Fees under part 8 of subchapter
8 C of chapter VII of the Federal Food, Drug, and Cosmetic
9 Act, as added by this title, shall be assessed for all bio-
10 similar biological product applications received on or after
11 October 1, 2012, regardless of the date of the enactment
12 of this title.

13 **SEC. 406. SAVINGS CLAUSE.**

14 Notwithstanding section 106 of the Prescription
15 Drug User Fee Amendments of 2007 (21 U.S.C. 379g
16 note), and notwithstanding the amendments made by this
17 title, part 2 of subchapter C of chapter VII of the Federal
18 Food, Drug, and Cosmetic Act, as in effect on the day
19 before the date of the enactment of this title, shall con-
20 tinue to be in effect with respect to human drug applica-
21 tions and supplements (as defined in such part as of such
22 day) that were accepted by the Food and Drug Adminis-
23 tration for filing on or after October 1, 2007, but before
24 October 1, 2012, with respect to assessing and collecting
25 any fee required by such part for a fiscal year prior to
26 fiscal year 2013.

1 **SEC. 407. CONFORMING AMENDMENT.**

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

4 **TITLE V—REAUTHORIZATION OF**
5 **BEST PHARMACEUTICALS**
6 **FOR CHILDREN ACT AND PE-**
7 **DIATRIC RESEARCH EQUITY**
8 **ACT**

9 **SEC. 501. REAUTHORIZATION OF BEST PHARMACEUTICALS**
10 **FOR CHILDREN ACT AND PEDIATRIC RE-**
11 **SEARCH EQUITY ACT.**

12 (a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—
13 Section 505A of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 355a) is amended—

15 (1) in subsection (d)(1)(A), by adding at the
16 end the following: “If a request under this subpara-
17 graph does not request studies in neonates, such re-
18 quest shall include a statement describing the ra-
19 tionale for not requesting studies in neonates.”;

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

22 (3) in subsection (l)—

23 (A) in paragraph (1)—

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

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

3 (B) in paragraph (2)—

4 (i) in the paragraph heading, by strik-
5 ing “YEARS” and inserting “PERIODS”;
6 and

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

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

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

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

20 (4) in subsection (n)—

21 (A) in the subsection heading, by striking
22 “COMPLETED” and inserting “SUBMITTED”;

23 (B) in paragraph (1)—

24 (i) in the text preceding subparagraph

25 (A), by striking “have not been completed”

1 and inserting “have not been submitted by
2 the date specified in the written request
3 issued”; and

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

6 “(A) For a drug for which there remains
7 any listed patent or exclusivity protection, make
8 a determination regarding whether an assess-
9 ment shall be required to be submitted under
10 section 505B(b).

11 “(B) For a drug that has no remaining
12 listed patents or exclusivity protection, the Sec-
13 retary shall refer the drug for inclusion on the
14 list established under section 409I of the Public
15 Health Service Act for the conduct of studies.”;

16 (5) in subsection (o)(2), by amending subpara-
17 graph (B) to read as follows:

18 “(B) a statement of any appropriate pedi-
19 atric contraindications, warnings, precautions,
20 or other information that the Secretary con-
21 siders necessary to assure safe use.”; and

22 (6) by striking subsection (q) (relating to a sun-
23 set).

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

1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355c) is amended—

3 (1) in subsection (a)—

4 (A) in paragraph (1)—

5 (i) in the matter before subparagraph
6 (A), by inserting “for a drug” after “(or
7 supplement to an application)”;

8 (ii) in subparagraph (A), by striking
9 “for a” and inserting “, including, with re-
10 spect to a drug, an application for a”;

11 (iii) in subparagraph (B), by striking
12 “for a” and inserting “, including, with re-
13 spect to a drug, an application for a”; and
14 (B) in paragraph (3)—

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

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

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

23 “(i) the Secretary finds that the cri-
24 teria specified in subelause (II) or (III) of

1 subparagraph (A)(i) continue to be met;
2 and

3 “(ii) the applicant submits the mate-
4 rials required under subparagraph
5 (A)(ii).”;

6 (iii) in subparagraph (C), as redesign-
7 nated, by amending clause (ii) to read as
8 follows:

9 “(ii) PUBLIC AVAILABILITY.—Not
10 later than 60 days after the submission to
11 the Secretary of the information submitted
12 through the annual review under clause (i),
13 the Secretary shall make available to the
14 public in an easily accessible manner, in-
15 cluding through the Web site of the Food
16 and Drug Administration—

17 “(I) such information;

18 “(II) the name of the applicant
19 for the product subject to the assess-
20 ment;

21 “(III) the date on which the
22 product was approved; and

23 “(IV) the date of each deferral or
24 deferral extension under this para-
25 graph for the product.”;

1 (C) in paragraph (4)(C)—

2 (i) in the first sentence, by inserting

3 “partial” before “waiver is granted”; and

4 (ii) in the second sentence, by striking

5 “either a full or partial waiver” and insert-

6 ing “a partial waiver”;

7 (2) in subsection (g)—

8 (A) in paragraph (1)(A), by striking “after

9 the date of the submission of the application or

10 supplement” and inserting “after the date of

11 the submission of an application or supplement

12 that receives a priority review or 300 days after

13 the date of the submission of an application or

14 supplement that receives a standard review”;

15 and

16 (B) in paragraph (2), by striking “the

17 label of such product” and inserting “the label-

18 ing of such product”;

19 (3) in subsection (h)(1)—

20 (A) by inserting “an application (or sup-

21 plement to an application) that contains” after

22 “date of submission of”; and

23 (B) by inserting “if the application (or

24 supplement) receives a priority review, or not

25 later than 300 days after the date of submis-

1 sion of an application (or supplement to an ap-
2 plication) that contains a pediatric assessment
3 under this section, if the application (or supple-
4 ment) receives a standard review,” after “under
5 this section,”;

6 (4) in subsection (i)—

7 (A) in paragraph (1)—

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

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

13 (B) in paragraph (2)—

14 (i) in the paragraph heading, by strik-
15 ing “YEARS” and inserting “PERIODS”;
16 and

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

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

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

23 “(3) PRESERVATION OF AUTHORITY.—Nothing
24 in this subsection shall prohibit the Office of Pedi-
25 atric Therapeutics from providing for the review of

1 adverse event reports by the Pediatric Advisory
2 Committee prior to the 18-month period referred to
3 in paragraph (1), if such review is necessary to en-
4 sure safe use of a drug in a pediatric population.”;

5 (5) by striking subsection (m) (relating to inte-
6 gration with other pediatric studies); and

7 (6) by redesignating subsection (n) as sub-
8 section (m).

9 (c) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS
10 IN PHSA.—Section 351(m)(1) of the Public Health Serv-
11 ice Act (42 U.S.C. 262(m)(1)) is amended by striking “(f),
12 (i), (j), (k), (l), (p), and (q)” and inserting “(f), (h), (i),
13 (j), (k), (l), and (p)”.

14 (d) APPLICATION; TRANSITION RULE.—

15 (1) APPLICATION.—Notwithstanding any provi-
16 sion of section 505A and 505B of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355a, 355c)
18 stating that a provision applies beginning on the
19 date of the enactment of the Best Pharmaceuticals
20 for Children Act of 2007 or the date of the enact-
21 ment of the Pediatric Research Equity Act of 2007,
22 any amendment made by this Act to such a provi-
23 sion applies beginning on the date of the enactment
24 of this Act.

1 (2) TRANSITIONAL RULE FOR ADVERSE EVENT
2 REPORTING.—With respect to a drug for which a la-
3 beling change described under section 505A(l)(1) or
4 505B(i)(1) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved
6 or made, respectively, during the one-year period
7 that ends on the day before the date of enactment
8 of this Act, the Secretary shall apply section 505A(l)
9 and section 505B(i), as applicable, to such drug, as
10 such sections were in effect on such day.

11 **SEC. 502. GOVERNMENT ACCOUNTABILITY OFFICE RE-**
12 **PORT.**

13 (a) IN GENERAL.— Not later than January 1, 2016,
14 and the end of each subsequent 5-year period, the Comp-
15 troller General of the United States, in consultation with
16 the Secretary of Health and Human Services, shall submit
17 to the Congress a report that evaluates the effectiveness
18 of sections 505A and 505B of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355a, 355c) and section
20 409I of the Public Health Service Act (42 U.S.C. 284m)
21 in ensuring that medicines used by children are tested in
22 pediatric populations and properly labeled for use in chil-
23 dren.

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

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

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

10 (3) the number and importance of drugs and
11 biological products for children that are not being
12 tested for their use in pediatric populations, notwith-
13 standing the existence of such programs;

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

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

20 (A) the date labeling changes are made;

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

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

25 (i) the disputes;

1 (ii) the recommendations of the Pedi-
2 atric Advisory Committee; and

3 (iii) the outcomes of such process;

4 (6) any recommendations for modifications to
5 the programs established under sections 505A and
6 505B of the Federal Food, Drug, and Cosmetic Act
7 and section 409I of the Public Health Service Act
8 that the Secretary determines to be appropriate, in-
9 cluding a detailed rationale for each recommenda-
10 tion;

11 (7)(A) the efforts made by the Secretary to in-
12 crease the number of studies conducted in the
13 neonate population (including efforts made to en-
14 courage the conduct of appropriate studies in neo-
15 nates by companies with products that have suffi-
16 cient safety and other information to make the con-
17 duct of the studies ethical and safe); and

18 (B) the results of such efforts; and

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

1 (B) any recommendations for modifications to
2 the programs under such sections that would lead to
3 new and better therapies for children with cancer,
4 including a detailed rationale for each recommenda-
5 tion.

6 **SEC. 503. INTERNAL COMMITTEE FOR REVIEW OF PEDI-**
7 **ATRIC PLANS, ASSESSMENTS, DEFERRALS,**
8 **DEFERRAL EXTENSIONS, AND WAIVERS.**

9 Section 505C of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 355d) is amended—

11 (1) in the section heading, by inserting “**DE-**
12 **FERRAL EXTENSIONS,**” after “**DEFERRALS,**”;
13 and

14 (2) by inserting “neonatology” after “pediatric
15 ethics”.

16 **SEC. 504. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.**

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

19 (1) in paragraph (1), by striking “and” at the
20 end;

21 (2) by redesignating paragraph (2) as para-
22 graph (4);

23 (3) by inserting after paragraph (1) the fol-
24 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**

6 **SEC. 601. FDA’S MISSION.**

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

8 (1) in paragraph (2), by striking “with respect
9 to such products” and inserting “with respect to
10 regulated products”;

11 (2) in paragraph (4), by striking “(1) through
12 (3)” and inserting “(1) through (4)”;

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

15 (4) by inserting after paragraph (1) the fol-
16 lowing:

17 “(2) establish a regulatory system that—

18 “(A) advances medical innovation by incor-
19 porating modern scientific tools, standards, and
20 approaches to ensure the predictable, con-
21 sistent, efficient, and reasonable review, clear-
22 ance, approval, and licensing (as appropriate)
23 of innovative products, including drugs, devices,
24 and biological products;

1 “(B) protects the public health and enables
2 patients to access novel products while pro-
3 moting economic growth, innovation, competi-
4 tiveness, and job creation among the industries
5 regulated by this Act;

6 “(C) is based on the best available science;

7 “(D) allows for public participation and an
8 open exchange of ideas;

9 “(E) promotes predictability, allows flexi-
10 bility, and reduces uncertainty;

11 “(F) identifies and uses the most innova-
12 tive and least burdensome tools for achieving
13 regulatory ends;

14 “(G) ensures that regulations are acces-
15 sible, consistent, transparent, written in plain
16 language, and easy to understand;

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

19 “(I) incorporates a patient-focused benefit-
20 risk framework that accounts for varying de-
21 grees of risk tolerance, including for people liv-
22 ing with a life-impacting chronic disease or dis-
23 ability;”.

1 **SEC. 602. PUBLIC PARTICIPATION IN ISSUANCE OF FDA**
2 **GUIDANCE DOCUMENTS.**

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

5 “(C) For any guidance document that sets
6 forth initial interpretations of a statute or regu-
7 lation, sets forth changes in interpretation or
8 policy that are of more than a minor nature, in-
9 cludes complex scientific issues, or covers highly
10 controversial issues—

11 “(i) the Secretary shall—

12 “(I) at least 3 months before
13 issuance of a draft of such guidance
14 document, publish notice in the Fed-
15 eral Register of the Secretary’s intent
16 to prepare such guidance document;
17 and

18 “(II) during preparation and be-
19 fore issuance of the draft of such
20 guidance document, meet with inter-
21 ested stakeholders and solicit public
22 comment;

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

1 practicable, unnecessary, or contrary to the
2 public interest—

3 “(I) the Secretary shall publish
4 such finding and a brief statement of
5 the reasons for such finding in the
6 Federal Register;

7 “(II) clause (i) shall not apply
8 with respect to such guidance docu-
9 ment; and

10 “(III) during a 3-month period
11 beginning not later than the date of
12 issuance of the draft of such guidance
13 document, the Secretary shall meet
14 with interested stakeholders and so-
15 licit public comment;

16 “(iii) upon issuance of a draft guid-
17 ance document under clause (i) or (ii), the
18 Secretary shall—

19 “(I) designate the draft as pro-
20 posed or final; and

21 “(II) not later than 12 months
22 after the date of issuance of a pro-
23 posed draft guidance document, issue
24 a final draft of such guidance docu-

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

3 “(iv) if the Secretary issues a pro-
4 posed draft guidance document and fails to
5 finalize the draft by the deadline deter-
6 mined under clause (iii)(II), the Secretary
7 shall, beginning on the date of such dead-
8 line, treat the proposed draft as null and
9 void; and

10 “(v) not less than every 5 years after
11 the issuance of a final guidance document
12 in accordance with clause (iii), the Sec-
13 retary shall—

14 “(I) conduct a retrospective anal-
15 ysis of such guidance document to en-
16 sure it is not outmoded, ineffective,
17 insufficient, or excessively burden-
18 some; and

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

23 “(D) A notice to industry guidance letter,
24 a notice to industry advisory letter, and any
25 similar notice that sets forth initial interpreta-

1 tions of a statute or regulation, sets forth
2 changes in interpretation or policy that are of
3 more than a minor nature, includes complex sci-
4 entific issues, or covers highly controversial
5 issues shall be treated as a guidance document
6 for purposes of subparagraph (C).”.

7 **SEC. 603. CONFLICTS OF INTEREST.**

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

10 **SEC. 604. ELECTRONIC SUBMISSION OF APPLICATIONS.**

11 Subchapter D of chapter VII (21 U.S.C. 379k et
12 seq.) is amended by inserting after section 745 the fol-
13 lowing:

14 **“SEC. 745A. ELECTRONIC SUBMISSION OF APPLICATIONS.**

15 “(a) IN GENERAL.—Beginning no earlier than 24
16 months after the issuance of a final guidance issued after
17 public notice and opportunity for comment, submissions
18 under subsection (b), (i), or (j) of section 505 of this Act
19 or subsection (a) or (k) of section 351 of the Public Health
20 Service Act shall be submitted in such electronic format
21 as specified by the Secretary in such guidance.

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

1 mission, and set forth criteria for waivers of and exemp-
2 tions from the requirements of this section.

3 “(c) EXCEPTION.—This section shall not apply to
4 submissions described in section 561.”.

5 **SEC. 605. COSMETICS [TO BE SUPPLIED].**

6 *[Language to be inserted.]*

7 **TITLE VII—MEDICAL DEVICE**
8 **REGULATORY IMPROVEMENTS**

9 **Subtitle A—Premarket**
10 **Predictability**

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

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

15 “(8)(A) Upon the submission of an application for
16 an exemption for a device under this subsection, the sub-
17 mission of a request to classify a device under section 513,
18 or the submission of a report for a device under section
19 510(k), whichever occurs first, the Secretary shall assign
20 a tracking number to the device.

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

24 “(i) Submission or approval of an application
25 for an exemption under this subsection.

1 “(ii) Submission of a request to classify the de-
2 vice under section 513.

3 “(iii) Submission or clearance of a report under
4 section 510(k).

5 “(iv) Any meeting or meeting request, including
6 in anticipation of the submission of such an applica-
7 tion or report.

8 “(v) Submission or approval of an application
9 under section 515(c).

10 “(vi) Any formal or informal request by the
11 Secretary for additional information.

12 “(vii) Any deficiency letter.

13 “(viii) Any response by the applicant to a re-
14 quest described in clause (v) or a deficiency letter.

15 “(ix) Any written submission by the applicant
16 to the Food and Drug Administration.

17 “(x) Any other matter, as determined appro-
18 priate by the Secretary.

19 “(9) Upon the submission of an application for an
20 exemption under this subsection for a device, the Sec-
21 retary shall assign, to review the application, a reviewer
22 with prior review experience with that type of device or
23 technology or other relevant expertise.”.

1 **SEC. 702. OTHER RULES RELATING TO INVESTIGATIONAL**
2 **DEVICE EXEMPTIONS.**

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

5 (1) in paragraph (2)(A), by adding at the end
6 the following: “Procedures and conditions pursuant
7 to the preceding sentence shall require the Sec-
8 retary, in determining whether to grant such an ex-
9 emption, to evaluate whether the investigational
10 study of such a device can be conducted ethically
11 and with reasonable risk.”;

12 (2) in paragraph (2)(B)(ii), by striking “evalu-
13 ate the safety and effectiveness of the device” and
14 inserting “evaluate whether the investigational study
15 is being conducted ethically and with reasonable
16 risk”;

17 (3) in paragraph (4)(B), by adding at the end
18 the following: “The Secretary may not disapprove an
19 application because the investigation does not or
20 may not meet any requirement, including a data re-
21 quirement, relating to the approval or clearance of
22 a device because the Secretary believes that a dif-
23 ferent clinical testing design or plan could produce
24 data more relevant to an approval or clearance deci-
25 sion.”;

1 (4) in paragraph (7)(A), by striking “(7)(A) In
2 the case” and all that follows through the end of
3 paragraph (7)(A) and inserting the following:

4 “(7)(A)(i) In the case of a person intending to inves-
5 tigate the safety or effectiveness of a class II or a class
6 III device, the Secretary shall ensure that the person has
7 an opportunity, prior to submitting an application to the
8 Secretary, to submit to the Secretary, for review, an inves-
9 tigational plan (including a clinical protocol). If the appli-
10 cant submits a written request for a meeting with the Sec-
11 retary regarding such review, the Secretary shall, not later
12 than 30 days after receiving the request, meet with the
13 applicant for the purpose of reaching agreement regarding
14 the investigational plan (including a clinical protocol). The
15 written request shall include a detailed description of the
16 device, a detailed description of the proposed conditions
17 of use of the device, information (if available) regarding
18 the expected performance of the device, and a proposed
19 plan (including a clinical protocol) for determining—

20 “(I) whether there is a reasonable assur-
21 ance of safety and effectiveness; or

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

1 “(ii) In the case where the Secretary fails to meet
2 the applicant not later than 30 days after receiving a re-
3 quest for a meeting as described under clause (i), the pro-
4 posed plan submitted in such request shall be deemed to
5 be the agreement reached between the Secretary and the
6 applicant under subparagraph (B) and such agreement
7 shall not be subject to change except as provided in sub-
8 paragraph (B).”; and

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

12 **SEC. 703. CLARIFICATION OF LEAST BURDENSOME STAND-**
13 **ARD.**

14 (a) **PREMARKET APPROVAL.**—Section 513(a)(3)(D)
15 (21 U.S.C. 360e(a)(3)(D)) is amended—

16 (1) by redesignating clause (iii) as clause (iv);
17 and

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

19 “(iii) In carrying out clause (ii), the
20 Secretary—

21 “(I) shall not request information
22 unrelated or irrelevant to a dem-
23 onstration of reasonable assurance of
24 device effectiveness;

1 “(II) shall consider alternative
2 approaches to evaluating device effec-
3 tiveness in order to reduce the time,
4 effort, and cost of reaching proper
5 resolution of the issue;

6 “(III) shall use all reasonable
7 mechanisms to lessen review times
8 and render regulatory decisions;

9 “(IV) shall consider whether pre-
10 clinical data, such as well-designed
11 bench and animal testing, can meet
12 the statutory threshold for approval;
13 and

14 “(V) if clinical data are needed,
15 shall consider alternatives to random-
16 ized, controlled clinical trials and the
17 use of surrogate endpoints.”.

18 (b) SUBSTANTIAL EQUIVALENCE DETERMINA-
19 TION.—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is
20 amended—

21 (1) by striking “(D) Whenever” and inserting
22 “(D)(i) Whenever”; and

23 (2) by adding at the end the following:

1 “(ii) For purposes of clause (i), the term ‘information
2 that is necessary to making substantial equivalence deter-
3 minations’ means information that—

4 “(I) constitutes threshold evidence supporting a
5 determination of substantial equivalence between a
6 new device and the predicate device to which the
7 premarket notification submitter claims substantial
8 equivalence; and

9 “(II) is relevant and directly related to the sub-
10 stantial equivalence determination.

11 “(iii) Any request for additional information under
12 clause (i) shall be a complete request for all of the addi-
13 tional information that the Secretary determines would be
14 necessary to support a determination of substantial
15 equivalence.

16 “(iv) The Secretary shall use all reasonable means
17 to employ mechanisms to increase the efficiency of pre-
18 market notification reviews and thereby reduce the time
19 necessary to render appropriate classification determina-
20 tions of substantial equivalence.”.

21 **SEC. 704. AGENCY DOCUMENTATION AND REVIEW OF SIG-**
22 **NIFICANT DECISIONS.**

23 Chapter V is amended by inserting after section 517
24 (21 U.S.C. 360g) the following:

1 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**
2 **SIGNIFICANT DECISIONS REGARDING DE-**
3 **VICES.**

4 “(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-
5 CANT DECISIONS.—

6 “(1) IN GENERAL.—The Secretary shall com-
7 pletely document the scientific and regulatory ration-
8 ale for any significant decision of the Center for De-
9 vices and Radiological Health regarding submission
10 or review of a report under section 510(k), an appli-
11 cation under section 515, or an application for an
12 exemption under section 520(g), including docu-
13 mentation of significant controversies or differences
14 of opinion and the resolution of such controversies
15 or differences of opinion.

16 “(2) PROVISION OF DOCUMENTATION.—Upon
17 request, the Secretary shall furnish such complete
18 documentation to the person who is seeking to sub-
19 mit, or who has submitted, such report or applica-
20 tion.

21 “(b) APPEAL RIGHTS AND PROCEDURES.—

22 “(1) APPEAL TO CENTER DIRECTOR.—Any per-
23 son may, within 30 days after a significant decision
24 described in subsection (a)(1), appeal such decision
25 to the Director of the Center for Devices and Radio-

1 logical Health (in this subsection referred to as the
2 ‘Center Director’).

3 “(2) PETITION; PROCEDURES.—The Center Di-
4 rector—

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

9 “(B) subject to paragraph (6), may pro-
10 vide for such procedures as may be necessary
11 with respect to such an appeal.

12 “(3) RESOLUTION BY CENTER DIRECTOR.—

13 “(A) MEETING.—The Center Director
14 shall provide, upon the request of any person
15 bringing an appeal under paragraph (1), for at
16 least one meeting, to be held within 45 days
17 after the filing of the appeal, to discuss the sig-
18 nificant decision involved, the appeal of such
19 decision, and possible resolutions of the appeal.

20 “(B) FINAL DECISION.—The Center Direc-
21 tor shall issue a final written decision resolving
22 any appeal under paragraph (1), including the
23 grounds for such decision, not later than 90
24 days after the filing of the appeal.

25 “(4) APPEAL TO COMMISSIONER.—

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

3 “(i) within 30 days after receiving any
4 decision of the Center Director resolving
5 the appeal, may appeal such decision to
6 the Commissioner; or

7 “(ii) if the Center Director has not
8 made a decision resolving the appeal under
9 paragraph (1) within 90 days after the fil-
10 ing of such appeal, may file directly with
11 the Commissioner an appeal of the signifi-
12 cant decision subject to such appeal under
13 paragraph (1).

14 “(B) FINAL DECISION.—The Commis-
15 sioner shall issue a final written decision resolv-
16 ing any appeal under subparagraph (A), includ-
17 ing the grounds for such decision, not later
18 than 30 days after the filing of such appeal
19 under subparagraph (A).

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

23 “(A) the number of appeals under para-
24 graph (1) and the disposition of those appeals;

1 “(B) for each appeal under paragraph (1),
2 the number of days taken to reach a final deci-
3 sion under paragraph (3)(B);

4 “(C) the number of appeals to the Com-
5 missioner under paragraph (4)(A), including
6 the number of such appeals under paragraph
7 (4)(A)(ii), and the disposition of those appeals;
8 and

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

13 “(6) AUTHORITY OF SECRETARY TO ESTABLISH
14 APPEAL PROCEDURES AND TIMELINES.—

15 “(A) ESTABLISHMENT.—Subject to sub-
16 paragraph (B), the Secretary may, by regula-
17 tion or guidance, establish appeal procedures or
18 timelines applicable to appeals under paragraph
19 (1) or (4).

20 “(B) LIMITATION.—No procedure or
21 timeline established under subparagraph (A)
22 may alter any requirement or extend or delay
23 any timeline specified in any of paragraphs (1)
24 through (5).”.

1 **SEC. 705. TRANSPARENCY IN CLEARANCE PROCESS.**

2 (a) PUBLICATION OF DETAILED DECISION SUM-
3 MARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended
4 by adding at the end the following:

5 “(5) Subject to subsection (c) and section 301(j), the
6 Secretary shall regularly publish detailed decision sum-
7 maries for each clearance of a device under section
8 510(k).”.

9 (b) APPLICATION.—The requirement of section
10 520(h)(5) of the Federal Food, Drug, and Cosmetic Act,
11 as added by subsection (a), applies only with respect to
12 clearance of a device occurring after the date of the enact-
13 ment of this Act.

14 **SEC. 706. NO 510(K) REPORT REQUIRED FOR CERTAIN**
15 **MODIFICATIONS.**

16 (a) IN GENERAL.—Section 510(n) (21 U.S.C.
17 360(n)) is amended—

18 (1) by striking “(n) The Secretary” and insert-
19 ing “(n)(1) The Secretary”; and

20 (2) by adding at the end the following:

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

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

26 “(B) such modification—

1 “(i) does not significantly affect the safety
2 or effectiveness of the device; and

3 “(ii) is implemented by the manufacturer
4 of the device.”.

5 (b) REGULATIONS.—Not later than 1 year after the
6 date of the enactment of this Act, the Secretary shall pro-
7 mulgate a final regulation to implement section 510(n)(2)
8 of the Federal Food, Drug, and Cosmetic Act, as added
9 by subsection (a), including to define the phrase “signifi-
10 cantly affect the safety or effectiveness of the device” in
11 subparagraph (B)(i) of such section.

12 **Subtitle B—Patients Come First**

13 **SEC. 711. ESTABLISHMENT OF SCHEDULE AND PROMULGA- 14 TION OF REGULATION.**

15 (a) ESTABLISHMENT OF SCHEDULE.—Not later than
16 90 days after the date of enactment of this Act, the Sec-
17 retary of Health and Human Services shall establish the
18 schedule referred to in section 515(i)(3) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

20 (b) REGULATION.—Not later than one year after the
21 date that the schedule is established under such section
22 515(i)(3) (as required by subsection (a)) the Secretary
23 shall issue a final regulation under section 515(b) of such
24 Act for each device that the Secretary requires to remain

1 in class III through a determination under section
2 515(i)(2) of such Act.

3 **SEC. 712. PROGRAM TO IMPROVE THE DEVICE RECALL SYS-**
4 **TEM.**

5 Chapter V is amended by inserting after section 518
6 (21 U.S.C. 360h) the following:

7 **“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**
8 **SYSTEM.**

9 “(a) IN GENERAL.—The Secretary shall—

10 “(1) establish a program to routinely and sys-
11 tematically assess information relating to device re-
12 calls and use such information to proactively identify
13 strategies for mitigating health risks presented by
14 defective or unsafe devices;

15 “(2) clarify procedures for conducting device re-
16 call audit checks to improve the ability of investiga-
17 tors to perform those checks in a consistent manner;

18 “(3) develop detailed criteria for assessing
19 whether a person performing a device recall has per-
20 formed an effective correction or action plan for the
21 recall; and

22 “(4) document the basis for each termination
23 by the Food and Drug Administration of a device re-
24 call.

1 “(b) ASSESSMENT CONTENT.—The program estab-
2 lished under subsection (a)(1) shall, at a minimum, iden-
3 tify—

4 “(1) trends in the number and types of device
5 recalls;

6 “(2) devices that are most frequently the sub-
7 ject of a recall; and

8 “(3) underlying causes of device recalls.

9 “(c) DEFINITION.—In this section, the term ‘recall’
10 means—

11 “(1) the removal from the market of a device
12 pursuant to an order of the Secretary under sub-
13 section (b) or (e) of section 518; or

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

18 **Subtitle C—Novel Device**

19 **Regulatory Relief**

20 **SEC. 721. MODIFICATION OF DE NOVO APPLICATION PROC-**
21 **ESS.**

22 (a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.
23 360c(f)(2)) is amended—

24 (1) by inserting “(i)” after “(2)(A)”;

1 (2) by striking “under the criteria set forth”
2 and all that follows and inserting a period; and

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

5 “(ii) In lieu of submitting a report under
6 section 510(k) and submitting a request for
7 classification under clause (i) for a device, if a
8 person determines there is no legally marketed
9 device upon which to base a determination of
10 substantial equivalence (as defined in sub-
11 section (i)), a person may submit a request
12 under this clause for the Secretary to classify
13 the device.

14 “(iii) Upon receipt of a request under
15 clause (i) or (ii), the Secretary shall classify the
16 device subject to the request under the criteria
17 set forth in subparagraphs (A) through (C) of
18 subsection (a)(1).

19 “(iv) Notwithstanding clause (iii), the Sec-
20 retary may decline to undertake a classification
21 of a device pursuant to a request under clause
22 (ii) if the Secretary identifies a legally marketed
23 device that would permit a substantial equiva-
24 lence determination under paragraph (1) for
25 the device.

1 “(v) A person submitting a request under
2 clause (i) or (ii) may, in the request, rec-
3 ommend to the Secretary a classification for the
4 device. Any such request shall describe the de-
5 vice and provide detailed information and rea-
6 sons for the recommended classification.”.

7 (b) CONFORMING AMENDMENTS.—Section 513(f) of
8 such Act (21 U.S.C. 360c(f)) is amended in paragraph
9 (1)—

10 (1) in subparagraph (A), by striking “, or” at
11 the end and inserting a semicolon;

12 (2) in subparagraph (B), by striking the period
13 and inserting “; or”; and

14 (3) by inserting after subparagraph (B) the fol-
15 lowing:

16 “(C) the device is classified pursuant to a
17 request submitted under paragraph (2).”.

18 **Subtitle D—Keeping America Com-**
19 **petitive Through Harmonization**

20 **SEC. 731. HARMONIZATION OF DEVICE PREMARKET RE-**
21 **VIEW, INSPECTION, AND LABELING SYMBOLS;**
22 **REPORT.**

23 (a) IN GENERAL.—Paragraph (4) of section 803(c)
24 (21 U.S.C. 383(c)) is amended to read as follows:

1 “(4) With respect to devices, the Secretary shall, to
2 the maximum extent practicable, enter into agreements
3 with those countries identified in clauses (i) and (ii) of
4 section 802(b)(1)(A) regarding methods and approaches
5 to harmonizing regulatory requirements for inspections
6 and common international labeling symbols.”.

7 (b) REPORT.—Not later than 3 years after the date
8 of enactment of this Act, the Secretary of Health and
9 Human Services shall submit to the Committee on Health,
10 Education, Labor, and Pensions of the Senate and the
11 Committee on Energy and Commerce of the House of
12 Representatives, a report listing the agreements entered
13 into under section 803(c)(4) of the Federal Food, Drug,
14 and Cosmetic Act (as amended by subsection (a)) and
15 itemizing the methods and approaches that have been har-
16 monized pursuant to such section.

17 **SEC. 732. PARTICIPATION IN INTERNATIONAL MEDICAL DE-**
18 **VICE REGULATORS FORUM.**

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

21 (1) by striking “(3)” and inserting “(3)(A)”;

22 and

23 (2) by adding at the end the following:

1 “(B) In carrying out subparagraph (A), the Secretary
2 shall participate in the International Medical Device Regu-
3 lators Forum and shall—

4 “(i) provide guidance to the Forum on strate-
5 gies, policies, directions, membership, and other ac-
6 tivities of the Forum;

7 “(ii) ensure that the representatives of the
8 United States on the Forum are made up of an
9 equal representation of international regulators and
10 representatives from the device industry that are
11 subject to regulation

12 “(iii) in providing guidance under clause (i), so-
13 licit, review, and consider comments from industry,
14 academia, health care professionals, and patient
15 groups; and

16 “(iv) inform the public of the Secretary’s activi-
17 ties within the Forum and share with the public any
18 documentation relating to the Forum’s strategies,
19 policies, and other activities, including releasing the
20 minutes that record Forum meetings and describing
21 Forum activities.”.

1 **Subtitle E—FDA Renewing Effi-**
2 **ciency From Outside Reviewer**
3 **Management**

4 **SEC. 741. PERSONS ACCREDITED TO REVIEW REPORTS**
5 **UNDER SECTION 510(k) AND MAKE REC-**
6 **COMMENDATIONS FOR INITIAL CLASSIFICA-**
7 **TION.**

8 (a) TIME PERIOD FOR REVIEW OF RECOMMENDA-
9 TIONS OF ACCREDITED PERSONS.—Section 523(a) (21
10 U.S.C. 360m(a)) is amended—

11 (1) in paragraph (1), by striking “reviewing re-
12 ports” and inserting “reviewing, and making rec-
13 ommendations to the Secretary regarding, reports”;
14 and

15 (2) in paragraph (2), by amending subpara-
16 graph (B) to read as follows:

17 “(B) TIME PERIOD FOR REVIEW.—Not
18 later than 30 days after the date on which the
19 Secretary is notified under subparagraph (A) by
20 an accredited person with respect to a rec-
21 ommendation regarding a report submitted
22 under section 510(k) or an initial classification
23 of a device, the Secretary shall make a deter-
24 mination with respect to the recommendation.
25 If the Secretary fails to make such a determina-

1 tion by the end of such 30-day period, the rec-
2 ommendation is deemed to be accepted by the
3 Secretary.”.

4 (b) ACCESS TO DEVICE INFORMATION.—Section
5 523(a)(2) (21 U.S.C. 360m(a)(2)), as amended by sub-
6 section (a)(2), is amended by adding at the end the fol-
7 lowing:

8 “(D) ACCESS TO DEVICE INFORMATION.—
9 Subject to section 301(j), for the purpose of
10 providing accredited persons with additional in-
11 formation to review reports submitted under
12 section 510(k) and make recommendations re-
13 garding the initial classification of devices, the
14 Secretary shall regularly publish—

15 “(i) detailed decision summaries for
16 each clearance of a device under section
17 510(k), classification of a device under sec-
18 tion 513, approval of an application for a
19 device under section 515, or grant of an
20 exemption for a device under section
21 520(m), occurring after the date of the en-
22 actment of this subparagraph; and

23 “(ii) total product life cycles informa-
24 tion for devices.”.

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

4 “(3) CERTAIN DEVICES.—

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

9 “(i) may not be used to perform a re-
10 view of a class III device; and

11 “(ii) may be used to perform a review
12 of a class II device which is intended to be
13 permanently implantable or life sustaining
14 or supporting only if a notification is sub-
15 mitted under subparagraph (B).

16 “(B) NOTIFICATION OF INTENT TO PER-
17 FORM A REVIEW.—Before performing a review
18 of a report submitted under section 510(k) for
19 a class II device which is intended to be perma-
20 nently implantable or life sustaining or sup-
21 porting, an accredited person shall submit to
22 the Secretary a notification of the person’s in-
23 tent to perform the review. If the Secretary
24 does not object within 60 days after receipt of
25 such a notification, the Secretary is deemed to

1 allow the accredited person to perform such re-
2 view. If the Secretary objects to performance of
3 the review by the accredited person, the Sec-
4 retary shall specify in writing the basis for the
5 objection, including any reasons why the ac-
6 credited person is not capable of performing the
7 review in a manner which provides a reasonable
8 assurance of the safety and effectiveness of the
9 device for its intended purpose.”.

10 (d) ACCREDITATION.—Section 523(b) (21 U.S.C.
11 360m(b)) is amended—

12 (1) in paragraph (2)—

13 (A) in the heading of subparagraph (C), by
14 inserting “AND TRAINING” after “AUDITING”;

15 (B) in subparagraph (C)—

16 (i) in clause (i), by striking “and” at
17 the end;

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

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

22 “(ii) provide for the initial training
23 and periodic updating of training of such
24 person; and”;

25 (C) by adding at the end the following:

1 “(E) PERIODIC REACCREDITATION.—

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

7 “(ii) RESPONSE TO REACCREDITATION
8 REQUEST.—Upon the submission of a re-
9 quest by an accredited person for re-
10 accreditation under this section, the Sec-
11 retary shall approve or deny such request
12 not later than 60 days after receipt of the
13 request.

14 “(iii) CRITERIA.—Not later than 120
15 days after the date of the enactment of
16 this subparagraph, the Secretary shall es-
17 tablish and publish in the Federal Register
18 criteria to reaccredit or deny reaccredita-
19 tion to persons under this section. The re-
20 accreditation of persons under this section
21 shall specify the particular activities under
22 subsection (a) for which such persons are
23 reaccredited.”;

24 (2) in paragraph (3)—

1 (A) in subparagraph (A), by inserting “a
2 sole practitioner or” after “may not be”;

3 (B) in subparagraph (B), by striking
4 “such a manufacturer, supplier, or vendor” and
5 inserting “a manufacturer, supplier, or vendor
6 of devices of the type for which such person is
7 accredited”; and

8 (C) in subparagraph (D), by striking “de-
9 vices” and inserting “devices of the type for
10 which such person is accredited”;

11 (3) by striking paragraph (4) (relating to selec-
12 tion of accredited persons); and

13 (4) by redesignating paragraph (5) as para-
14 graph (4).

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

21 **SEC. 742. PERSONS ACCREDITED TO CONDUCT INSPEC-**
22 **TIONS.**

23 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-
24 ed by striking “October 1, 2012” and inserting “October
25 1, 2017”.

1 **Subtitle G—Humanitarian Device**
2 **Reform**

3 **SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DE-**
4 **VICES.**

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

6 (1) in paragraph (1), by striking “devices in-

7 tended to benefit” and all that follows through the

8 end of paragraph (1) and inserting the following:

9 “devices intended—

10 “(A) to benefit patients in the treatment and

11 diagnosis of diseases or conditions that affect fewer

12 than 4,000 individuals in the United States annu-

13 ally; or

14 “(B) to benefit patients in the treatment and

15 diagnosis of diseases or conditions that affect great-

16 er than 4,000 individuals in the United States annu-

17 ally, if the person requesting the exemption dem-

18 onstrates that the severity of the disease or condi-

19 tion is such that public health requires a greater

20 availability of the device to treat or diagnose such

21 patients.”;

22 (2) in paragraph (2)—

23 (A) by amending subparagraph (A) to read

24 as follows:

1 “(A)(i) the device is designed to treat or diag-
2 nose a disease or condition that affects fewer than
3 4,000 individuals in the United States annually, or

4 “(ii) the device is designed to treat or diagnose
5 a disease or condition that affects greater than
6 4,000 individuals in the United States annually and
7 the criteria in paragraph (1)(B) are met,”; and

8 (B) in the flush text at the end, by adding
9 at the end the following: “Any order approving
10 an application for an exemption under this sub-
11 section shall not prohibit or in any way limit
12 the number of devices that are medically nec-
13 essary to treat, diagnose, or monitor individuals
14 with diseases or conditions described in para-
15 graph (1).”;

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

17 (4) in paragraph (5), by striking “, if the Sec-
18 retary has reason to believe that the requirements of
19 paragraph (6) are no longer met,”;

20 (5) by amending paragraph (7) to read as fol-
21 lows:

22 “(7)(A) The Secretary shall refer any report of
23 an adverse event regarding a device described in
24 subparagraph (B) to the Office of Pediatric Thera-
25 peutics. In considering the report, the Director of

1 the Office of Pediatric Therapeutics, in consultation
2 with experts in the Center for Devices and Radio-
3 logical Health, shall provide for periodic review of
4 the report by the Pediatric Advisory Committee, in-
5 cluding obtaining any recommendations of such
6 Committee regarding whether the Secretary should
7 take action under this Act in response to the report.

8 “(B) A device is described in this subparagraph
9 if—

10 “(i) an exemption is granted under para-
11 graph (2) for the device for treatment or diag-
12 nosis of a disease or condition that occurs in
13 pediatric patients or in a pediatric subpopula-
14 tion; and

15 “(ii) the device is labeled for use in pedi-
16 atric patients or in a pediatric subpopulation in
17 which the disease or condition occurs.

18 “(C) In this paragraph:

19 “(i) The term ‘pediatric patients’ means
20 patients who are 21 years of age or younger at
21 the time of the diagnosis or treatment.

22 “(ii) The term ‘pediatric subpopulation’
23 means any of the following populations:

24 “(I) Neonates.

25 “(II) Infants.

1 “(III) Children.

2 “(IV) Adolescents.”;

3 (6) by amending paragraph (8) to read as fol-
4 lows:

5 “(8) The Secretary, acting through the Office
6 of Pediatric Therapeutics and the Center for Devices
7 and Radiological Health, shall provide for an annual
8 review by the Pediatric Advisory Committee of all
9 devices described in paragraph (5)(B) to ensure that
10 the exemption under paragraph (2) remains appro-
11 priate for pediatric populations.”; and

12 (7) by redesignating paragraphs (4), (5), (7),
13 and (8) as paragraphs (3), (4), (5) and (6), respec-
14 tively.

15 **TITLE VIII—DRUG REGULATORY**
16 **IMPROVEMENTS**
17 **Subtitle A—Pharmaceutical Supply**
18 **Chain**

19 **SEC. 801. [TO BE SUPPLIED].**

20 **[To be inserted]**

21 **Subtitle B—Medical Gas Safety**

22 **SEC. 811. REGULATION OF MEDICAL GASES.**

23 (a) ADULTERATION.—

24 (1) IN GENERAL.—Section 501(a) (21 U.S.C.
25 351(a)) is amended by striking “; or (3)” and in-

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

5 (2) APPLICABILITY.—The amendment made by
6 paragraph (1) applies beginning on the date that is
7 2 years after the date of the enactment of this Act.

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

10 **“Subchapter G—Medical Gases**

11 **“SEC. 575. DEFINITIONS.**

12 “In this subchapter:

13 “(1) The term ‘designated medical gas’ means
14 any of the following:

15 “(A) Oxygen, as defined in the United
16 States Pharmacopeia (or any successor publica-
17 tion).

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

20 “(C) Nitrous oxide, as defined in the
21 United States Pharmacopeia (or any successor
22 publication).

23 “(D) Carbon dioxide, as defined in the
24 United States Pharmacopeia (or any successor
25 publication).

1 “(E) Helium, as defined in the United
2 States Pharmacopeia (or any successor publica-
3 tion).

4 “(F) Medical air, as defined in the United
5 States Pharmacopeia (or any successor publica-
6 tion).

7 “(G) Any other medical gas deemed appro-
8 priate by the Secretary.

9 “(2) The term ‘medical gas’ means a drug
10 that—

11 “(A) is manufactured or stored in a lique-
12 fied, nonliquefied, or cryogenic state; and

13 “(B) is administered as a gas.

14 “(3) The term ‘Medical Gas Advisory Com-
15 mittee’ means the Medical Gas Advisory Committee
16 established under section 577.

17 “(4) The term ‘medical gas manufacturer’
18 means an entity that owns or operates an establish-
19 ment registered under section 510 that—

20 “(A) manufactures, prepares, processes,
21 packages, repackages, or labels a medical gas;

22 or

23 “(B) fills high-pressure medical gas cyl-
24 inders or cryogenic medical gas containers by

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

3 **“SEC. 576. REGULATION OF MEDICAL GASES.**

4 “(a) CERTIFICATION OF DESIGNATED MEDICAL
5 GASES.—

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

10 “(2) APPROVAL OF CERTIFICATION.—The Sec-
11 retary shall approve a certification submitted under
12 paragraph (1) with respect to a medical gas if the
13 certification demonstrates to the Secretary’s satis-
14 faction that the medical gas is a designated medical
15 gas.

16 “(3) EFFECT OF APPROVAL OF CERTIFI-
17 CATION.—

18 “(A) IN GENERAL.—A medical gas subject
19 to a certification for which an approval is in ef-
20 fect under paragraph (2) is deemed to be ap-
21 proved pursuant to an application under section
22 505(b) or 512(b)(1), as applicable, for—

23 “(i) those indications for which the
24 medical gas has been marketed to a mate-
25 rial extent for a material time; or

1 “(ii) for administration in a super-
2 vised clinical setting under the direction of
3 a medical or veterinary professional, as ap-
4 plicable.

5 “(B) INAPPLICABILITY OF EXCLUSIVITY
6 PROVISIONS.—Sections 505(c)(3)(E),
7 505(j)(5)(F), and 512(c)(2)(F) do not apply
8 with respect to the approval of a designated
9 medical gas under this subsection.

10 “(4) REGISTRATION AND LISTING UNDER SEC-
11 TION 510.—To the greatest extent possible, the Sec-
12 retary shall streamline the certification and approval
13 process under this subsection with the registration
14 and listing process under section 510.

15 “(b) APPROVAL OF NONDESIGNATED MEDICAL
16 GASES.—

17 “(1) PROCEDURES.—Not later than 2 years
18 after the date of the enactment of this subchapter,
19 the Secretary, in consultation with the Medical Gas
20 Advisory Committee, shall establish by rule appro-
21 priate procedures for the approval of medical gases
22 that are not designated medical gases pursuant to
23 section 505 or 512, as applicable.

24 “(2) SUBMISSION OF NEW DRUG APPLICATIONS
25 AND ABBREVIATED NEW DRUG APPLICATIONS.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), the Secretary shall not re-
3 quire the submission of a new drug application
4 or an abbreviated new drug application under
5 subsection (b) or (j) of section 505, or a new
6 animal drug application or an abbreviated new
7 animal drug application under subsection (b)(1)
8 or (b)(2) of section 512, for any medical gas
9 that is not a designated medical gas during the
10 period ending on the later of—

11 “(i) 4 years after the date of the en-
12 actment of this subchapter; or

13 “(ii) 2 years after the date on which
14 the Secretary establishes applicable proce-
15 dures under paragraph (1).

16 “(B) EXCEPTIONS.—Nothing in this sub-
17 chapter—

18 “(i) prohibits the voluntary submis-
19 sion of an application under subsection (b)
20 or (j) of section 505 or subsection (b)(1)
21 or (b)(2) of section 512 for a medical gas;
22 or

23 “(ii) constitutes an exemption from
24 the requirements under section 505(i) or
25 section 512(j) (relating to investigational

1 new drugs and investigational new animal
2 drugs, respectively).

3 “(c) SEPARATE REGULATIONS FOR MEDICAL
4 GASES.—

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

11 “(A) appropriate current good manufac-
12 turing practice requirements;

13 “(B) labeling requirements;

14 “(C) wholesale distribution requirements;

15 “(D) a streamlined electronic process for
16 registration and listing under section 510 by
17 medical gas manufacturers that are small busi-
18 ness concerns (as defined in section 3 of the
19 Small Business Act); and

20 “(E) appropriate product tracking and
21 anticounterfeiting rules.

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

1 of this subchapter or is proposed after such date, the
2 Secretary shall specifically evaluate the effect of
3 such regulation on, and the suitability of such regu-
4 lation for, medical gases and medical gas manufac-
5 turers. Based on such evaluation, the Secretary shall
6 include in the regulation an accommodation, unique
7 application, or exemption for medical gases and
8 medical gas manufacturers, as appropriate, given the
9 special characteristics of medical gases.

10 “(3) COORDINATION WITH STATES.—

11 “(A) IN GENERAL.—The Secretary, in con-
12 sultation with the Medical Gas Advisory Com-
13 mittee, shall—

14 “(i) establish a risk-based inspection
15 regime specific to medical gas manufactur-
16 ers that ensures coordination with State
17 and local inspection activities; and

18 “(ii) seek to enter into partnership
19 agreements with such States and localities
20 in order to improve the coordination and
21 efficiency of Federal and State efforts to
22 regulate medical gas manufacturers and
23 medical gases.

24 “(B) CONTENTS OF AGREEMENTS.—The
25 agreements under subparagraph (A)(ii) shall—

1 “(i) ensure that State and Federal au-
2 thorities provide consistent training to in-
3 spectors;

4 “(ii) eliminate, to the extent prac-
5 ticable, any overlapping fees or activities
6 between State and Federal inspectors;

7 “(iii) promote current good manufac-
8 turing practice compliance;

9 “(iv) ensure consistent application of
10 Federal regulations with respect to medical
11 gas manufacturers; and

12 “(v) include any mechanisms deter-
13 mined by the Secretary, in consultation
14 with the Medical Gas Advisory Committee,
15 to improve the coordination and efficiency
16 of Federal and State efforts to regulate
17 medical gas manufacturers and medical
18 gases.

19 “(C) DISSEMINATION OF INFORMATION.—
20 The Secretary shall disseminate appropriate in-
21 formation to States regarding the application of
22 Federal regulations to medical gas manufactur-
23 ers and medical gases in order to improve the
24 consistency of the enforcement of such regula-
25 tions.

1 **“SEC. 577. MEDICAL GAS ADVISORY COMMITTEE.**

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

6 “(b) MEMBERSHIP.—The Medical Gas Advisory
7 Committee—

8 “(1) shall include representatives of—

9 “(A) medical gas manufacturers; and

10 “(B) organizations that develop medical
11 gas safety standards; and

12 “(2) may include representatives of—

13 “(A) patient advocacy groups;

14 “(B) professional associations;

15 “(C) physicians;

16 “(D) scientists;

17 “(E) other medical professionals licensed
18 to manufacture or use medical gases (such as
19 pulmonologists, respiratory therapists, veteri-
20 narians, and anesthesiologists); and

21 “(F) other stakeholders, as determined ap-
22 propriate by the Secretary.

23 “(c) DUTIES.—The Medical Gas Advisory Committee
24 shall provide the Secretary with regular guidance and spe-
25 cific advice on medical gas regulatory initiatives, including
26 with respect to regulations concerning the approval of

1 medical gases under sections 505 and 512, the manufac-
2 ture of medical gases, and related activities.

3 “(d) FACA.—Section 14 of the Federal Advisory
4 Committee Act shall not apply to the duration of the Med-
5 ical Gas Advisory Committee.”.

6 **SEC. 812. FEES RELATING TO MEDICAL GAS REGULATION.**

7 (a) FINDING.—The Congress finds that the fees au-
8 thorized by the amendment made in subsection (b) will
9 be dedicated towards the costs of the Food and Drug Ad-
10 ministration’s regulation of nondesignated medical gases.

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

14 **“PART 9—FEES RELATING TO MEDICAL GASES**

15 **“SEC. 744K. AUTHORITY TO ASSESS AND COLLECT FEES.**

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

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

1 or collection of any fee with respect to drugs that are des-
2 ignated medical gases.

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

8 “(d) ESTABLISHMENT.—The Secretary shall, by reg-
9 ulation, establish the amount of fees under this section
10 for a fiscal year so as to generate a total revenue amount
11 not exceeding the Secretary’s estimate of 100 percent of
12 the costs of the Food and Drug Administration’s regula-
13 tion of nondesignated medical gases during such year. In
14 establishing the amount under this subsection, the Sec-
15 retary shall take into consideration the special characteris-
16 ties of nondesignated medical gases, including the unique
17 manufacturing and distribution system required to
18 produce nondesignated medical gases.

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

20 “(1) IN GENERAL.—Fees authorized under sub-
21 section (a) shall be collected and available for obliga-
22 tion only to the extent and in the amount provided
23 in advance in appropriation Acts. Such fees are au-
24 thorized to remain available until expended. Such
25 sums as may be necessary may be transferred from

1 the Food and Drug Administration salaries and ex-
2 penses appropriation account without fiscal year lim-
3 itation to such appropriation account for salaries
4 and expenses with such fiscal year limitation. The
5 sums transferred shall be available solely for the
6 costs of the Food and Drug Administration's regula-
7 tion of nondesignated medical gases.

8 “(2) COLLECTIONS AND APPROPRIATION
9 ACTS.—

10 “(A) IN GENERAL.—The fees authorized
11 by this section—

12 “(i) shall be retained in each fiscal
13 year in an amount not to exceed the
14 amount specified in appropriation Acts, or
15 otherwise made available for obligation, for
16 such fiscal year; and

17 “(ii) shall only be collected and avail-
18 able to pay the costs of the Food and Drug
19 Administration's regulation of nondes-
20 ignated medical gases.

21 “(B) COMPLIANCE.—The Secretary shall
22 be considered to have met the requirements of
23 subparagraph (A)(ii) in any fiscal year if the
24 costs funded by appropriations and allocated for
25 the costs of the Food and Drug Administra-

1 tion’s regulation of nondesignated medical
2 gases—

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

6 “(ii)(I) are more than 3 percent below
7 the level specified in subparagraph (A)(ii),
8 and fees assessed for the fiscal year fol-
9 lowing the subsequent fiscal year are de-
10 creased by the amount in excess of 3 per-
11 cent by which such costs fell below the
12 level specified in such subparagraph; and

13 “(II) such costs are not more than 5
14 percent below the level specified in such
15 subparagraph.

16 “(3) AUTHORIZATION 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 determined under subsection (d) for the fis-
21 cal year.

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

1 fiscal year 2016 exceeds the cumulative amount ap-
2 propriated under paragraph (3) for the fiscal years
3 2013 through 2016, the excess shall be credited to
4 the appropriation account of the Food and Drug Ad-
5 ministration as provided in paragraph (1), and shall
6 be subtracted from the amount of fees that would
7 otherwise be authorized to be collected under this
8 section pursuant to appropriation Acts for fiscal
9 year 2017.

10 “(f) DEFINITIONS.—In this section:

11 “(1) The terms ‘designated medical gas’ and
12 ‘medical gas’ have the meanings given to such terms
13 in section 575.

14 “(2) The term ‘nondesignated medical gas’
15 means a medical gas that is not a designated med-
16 ical gas.”.

17 (c) REAUTHORIZATION; REPORTING REQUIRE-
18 MENTS.—Part 9 of subchapter C of chapter VII, as added
19 by subsection (a), is further amended by adding at the
20 end the following:

21 **“SEC. 744L. REAUTHORIZATION; REPORTING REQUIRE-**
22 **MENTS.**

23 “(a) PERFORMANCE REPORT.—Beginning with fiscal
24 year 2013, not later than 120 days after the end of each
25 fiscal year for which fees are collected under this part,

1 the Secretary shall prepare and submit to the Committee
2 on Energy and Commerce of the House of Representatives
3 and the Committee on Health, Education, Labor, and
4 Pensions of the Senate a report concerning the progress
5 of the Food and Drug Administration in regulating non-
6 designated medical gases, as described in section 812(a)
7 of the _____ Act of 2012.

8 “(b) FISCAL REPORT.—Beginning with fiscal year
9 2013, not later than 120 days after the end of each fiscal
10 year for which fees are collected under this part, the Sec-
11 retary shall prepare and submit to the Committee on En-
12 ergy and Commerce of the House of Representatives and
13 the Committee on Health, Education, Labor, and Pen-
14 sions of the Senate a report on the implementation of the
15 authority for such fees during such fiscal year and the
16 use, by the Food and Drug Administration, of the fees
17 collected for such fiscal year.

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

22 “(d) REAUTHORIZATION.—

23 “(1) CONSULTATION.—In developing rec-
24 ommendations to present to the Congress with re-
25 spect to the goals, and plans for meeting the goals,

1 for the Food and Drug Administration’s regulation
2 of nondesignated medical gases for the first 5 fiscal
3 years after fiscal year 2017, and for the reauthoriza-
4 tion of this part for such fiscal years, the Secretary
5 shall consult with—

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

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

10 “(C) scientific and academic experts;

11 “(D) health care professionals;

12 “(E) representatives of patient and con-
13 sumer advocacy groups; and

14 “(F) the regulated industry.

15 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
16 negotiations with the regulated industry on the reau-
17 thorization of this part, the Secretary shall—

18 “(A) publish a notice in the Federal Reg-
19 ister requesting public input on the reauthoriza-
20 tion;

21 “(B) hold a public meeting at which the
22 public may present its views on the reauthoriza-
23 tion, including specific suggestions for changes
24 to the goals referred to in subsection (a);

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

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

6 “(3) PERIODIC CONSULTATION.—Not less fre-
7 quently than once every month during negotiations
8 with the regulated industry, the Secretary shall hold
9 discussions with representatives of patient and con-
10 sumer advocacy groups to continue discussions of
11 their views on the reauthorization and their sugges-
12 tions for changes to this part as expressed under
13 paragraph (2).

14 “(4) PUBLIC REVIEW OF RECOMMENDA-
15 TIONS.—After negotiations with the regulated indus-
16 try, the Secretary shall—

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

20 “(B) publish such recommendations in the
21 Federal Register;

22 “(C) provide for a period of 30 days for
23 the public to provide written comments on such
24 recommendations;

1 “(D) hold a meeting at which the public
2 may present its views on such recommenda-
3 tions; and

4 “(E) after consideration of such public
5 views and comments, revise such recommenda-
6 tions as necessary.

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

14 “(6) MINUTES OF NEGOTIATION MEETINGS.—

15 “(A) PUBLIC AVAILABILITY.—Before pre-
16 sented the recommendations developed under
17 paragraphs (1) through (5) to the Congress, the
18 Secretary shall make publicly available, on the
19 Internet Web site of the Food and Drug Ad-
20 ministration, minutes of all negotiation meet-
21 ings conducted under this subsection between
22 the Food and Drug Administration and the reg-
23 ulated industry.

24 “(B) CONTENT.—The minutes described
25 under subparagraph (A) shall summarize any

1 substantive proposal made by any party to the
2 negotiations as well as significant controversies
3 or differences of opinion during the negotiations
4 and their resolution.”.

5 (d) SUNSET DATES.—

6 (1) AUTHORIZATION.—The amendment made
7 by subsection (b) ceases to be effective October 1,
8 2017.

9 (2) REPORTING REQUIREMENTS.—The amend-
10 ment made by subsection (c) ceases to be effective
11 January 31, 2018.

12 **SEC. 813. MISCELLANEOUS PROVISIONS.**

13 (a) RULE OF CONSTRUCTION.—

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

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

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

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

3 (B) a mixture that—

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

8 (ii) is, as of the date of the enactment
9 of this Act, manufactured and distributed
10 by any medical gas manufacturer, to a ma-
11 terial extent and for a material period of
12 time.

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

20 **Subtitle C—Generating Antibiotic** 21 **Incentives Now**

22 **SEC. 821. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

23 (a) IN GENERAL.—The Federal Food, Drug, and
24 Cosmetic Act is amended by inserting after section 505D
25 (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 (e)(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 (e)(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; or

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.

13 “(d) DETERMINATION.—The manufacturer or spon-
14 sor of a drug may request that the Secretary designate
15 a drug as a qualified infectious disease product at any
16 time in the drug development process prior to the submis-
17 sion of an application under section 505(b) for the drug,
18 but not later than 45 days before the submission of such
19 application. The Secretary shall, not later than 30 days
20 after the submission of such request, determine whether
21 the drug is a qualified infectious disease product.

22 “(e) REGULATIONS.—The Secretary shall promulgate
23 regulations for carrying out this section. The Secretary
24 shall promulgate the initial regulations for carrying out

1 this section not later than 12 months after the date of
2 the enactment of this section.

3 “(f) DEFINITIONS.—In this section:

4 “(1) QUALIFIED INFECTIOUS DISEASE PROD-
5 UCT.—The term ‘qualified infectious disease prod-
6 uct’ means an antibacterial drug for human use that
7 treats or prevents an infection caused by a quali-
8 fying pathogen.

9 “(2) QUALIFYING PATHOGEN.—The term
10 ‘qualifying pathogen’ means—

11 “(A) resistant gram-positive pathogens, in-
12 cluding methicillin-resistant *Staphylococcus*
13 *aureus* (MRSA), vancomycin-resistant *Staphy-*
14 *lococcus aureus* (VRSA), and vancomycin-resist-
15 ant *enterococcus* (VRE);

16 “(B) multidrug resistant gram-negative
17 bacteria, including *Acinetobacter*, *Klebsiella*,
18 *Pseudomonas*, and *E. coli* species;

19 “(C) multi-drug resistant tuberculosis; or

20 “(D) any other infectious pathogen identi-
21 fied for purposes of this section by the Sec-
22 retary.”.

23 (b) APPLICATION.—Section 505E of the Federal
24 Food, Drug, and Cosmetic Act, as added by subsection
25 (a), applies only with respect to a drug that is first ap-

1 proved under section 505(c) of such Act (21 U.S.C.
2 355(c)) on or after the date of the enactment of this Act.

3 **SEC. 822. ADDITIONAL EXTENSION OF EXCLUSIVITY PE-**
4 **RIOD FOR QUALIFIED INFECTIOUS DISEASE**
5 **PRODUCTS FOR WHICH A QUALIFIED DIAG-**
6 **NOSTIC TEST IS CLEARED OR APPROVED.**

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

10 **“SEC. 505E-1. ADDITIONAL EXTENSION OF EXCLUSIVITY PE-**
11 **RIOD FOR QUALIFIED INFECTIOUS DISEASE**
12 **PRODUCTS FOR WHICH A QUALIFIED DIAG-**
13 **NOSTIC TEST IS CLEARED OR APPROVED.**

14 “(a) IN GENERAL.—If the sponsor or manufacturer
15 of a qualified infectious disease product identifies in ac-
16 cordance with subsection (b) a qualified diagnostic test de-
17 scribed in subsection (c), any period extended under sec-
18 tion 505E(a) with respect to such product shall be further
19 extended by 6 months.

20 “(b) IDENTIFICATION REQUIREMENTS.—For pur-
21 poses of subsection (a), the identification of a qualified
22 diagnostic test shall—

23 “(1) be made in such manner as the Secretary
24 may require; and

1 “(2) occur before the expiration of the period to
2 be extended under subsection (a), not counting any
3 extension to such period under section 505E(a) or
4 505A.

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

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

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

16 “(3) The device is cleared under section 510(k)
17 or approved under section 515.

18 “(4) The sponsor or manufacturer, as applica-
19 ble, of the qualified infectious disease product has
20 the exclusive rights to submit an identification under
21 subsection (a) with respect to the device.

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

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

3 “(e) LIMITATIONS.—After the extension of any pe-
4 riod under subsection (a) with respect to a qualified infec-
5 tious disease product pursuant to the identification of a
6 device as a qualified diagnostic test, subsection (a) does
7 not authorize—

8 “(1) any subsequent extension with respect to
9 such product; or

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

12 “(f) DETERMINATION.—The sponsor or manufac-
13 turer of a drug may request the Secretary to determine
14 that a device is a test for diagnosis of a qualifying patho-
15 gen. Such a request shall be made at least 45 days before
16 the submission of a notification under section 510(k) or
17 an application under section 515 for such device. The Sec-
18 retary shall, not later than 30 days after the submission
19 of such request, determine whether the device is a test
20 for diagnosis of a qualifying pathogen.

21 “(g) DEFINITIONS.—In this section:

22 “(1) The term ‘qualified infectious disease
23 product’ means a drug that is determined to be a
24 qualified infectious disease product under section
25 505E.

1 “and it demonstrates the potential to address unmet med-
2 ical needs for such a disease or condition” the following:
3 “or if the Secretary determines under section 505E that
4 the drug is a qualified infectious disease product”.

5 **SEC. 825. STUDY ON INCENTIVES FOR QUALIFIED INFEC-**
6 **TIOUS DISEASE BIOLOGICAL PRODUCTS.**

7 (a) IN GENERAL.—The Comptroller General of the
8 United States shall—

9 (1) conduct a study on the need for incentives
10 to encourage research on and development and mar-
11 keting of qualified infectious disease biological prod-
12 ucts; and

13 (2) not later than 1 year after the date of the
14 enactment of this Act, submit a report to the Con-
15 gress on the results of such study, including any rec-
16 ommendations of the Comptroller General on appro-
17 priate incentives for addressing such need.

18 (b) DEFINITIONS.—In this section:

19 (1) The term “biological product” has the
20 meaning given to such term in section 351 of the
21 Public Health Service Act (42 U.S.C. 262).

22 (2) The term “qualified infectious disease bio-
23 logical product” means a biological product for
24 human use that treats or prevents an infection
25 caused by a qualifying pathogen.

1 (3) The term “qualifying pathogen” has the
2 meaning given to such term in section 505E of the
3 Federal Food, Drug, and Cosmetic Act, as added by
4 section 821 of this Act.

5 **SEC. 826. CLINICAL TRIALS.**

6 (a) REVIEW AND REVISION OF GUIDELINES.—

7 (1) IN GENERAL.—Not later than 1 year after
8 the date of the enactment of this Act, and not later
9 than 4 years thereafter, the Secretary shall—

10 (A) review the guidelines of the Food and
11 Drug Administration for the conduct of clinical
12 trials with respect to antibiotic drugs; and

13 (B) as appropriate, revise such guidelines
14 to reflect developments in scientific and medical
15 information and technology and to ensure clar-
16 ity regarding the procedures and requirements
17 for approval of an antibiotic drug under chapter
18 V of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 351 et seq.).

20 (2) ISSUES FOR REVIEW.—At a minimum, the
21 review under paragraph (1) shall address the appro-
22 priate animal models of infection, in vitro tech-
23 niques, valid microbiological surrogate markers, the
24 use of noninferiority versus superiority trials, and
25 appropriate delta values for noninferiority trials.

1 (3) RULE OF CONSTRUCTION.—Except to the
2 extent to which the Secretary of Health and Human
3 Services makes revisions under paragraph (1)(B),
4 nothing in this section shall be construed to repeal
5 or otherwise affect the guidelines of the Food and
6 Drug Administration.

7 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

8 (1) REQUEST.—The sponsor of a drug intended
9 to be used to treat, detect, prevent, or identify a
10 qualifying pathogen may request that the Secretary
11 provide written recommendations for nonclinical and
12 clinical investigations which may be conducted with
13 the drug before it may be approved for such use
14 under section 505 of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355).

16 (2) RECOMMENDATIONS.—If the Secretary has
17 reason to believe that a drug for which a request is
18 made under this subsection is a qualified infectious
19 disease product, the Secretary shall provide the per-
20 son making the request written recommendations for
21 the nonclinical and clinical investigations which the
22 Secretary believes, on the basis of information avail-
23 able to the Secretary at the time of the request,
24 would be necessary for approval under section 505
25 of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 355) of such drug for the use described in
2 paragraph (1).

3 (c) DEFINITIONS.—In this section:

4 (1) The term “drug” has the meaning given to
5 such term in section 201 of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 321).

7 (2) The term “qualified infectious disease prod-
8 uct” has the meaning given to such term in section
9 505E of the Federal Food, Drug, and Cosmetic Act,
10 as added by section 821 of this Act.

11 (3) The term “qualifying pathogen” has the
12 meaning given to such term in section 505E of the
13 Federal Food, Drug, and Cosmetic Act, as added by
14 section 821 of this Act.

15 (4) The term “Secretary” means the Secretary
16 of Health and Human Services, acting through the
17 Commissioner of Food and Drugs.

18 **Subtitle D—Accelerated Approval**

19 **SEC. 831. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS** 20 **OR LIFE-THREATENING DISEASES OR CONDI-** 21 **TIONS.**

22 Section 506 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 356) is amended to read as follows:

1 **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**
2 **OR LIFE-THREATENING DISEASES OR CONDI-**
3 **TIONS.**

4 “(a) DESIGNATION OF DRUG AS A FAST TRACK
5 PRODUCT.—

6 “(1) IN GENERAL.—The Secretary shall, at the
7 request of the sponsor of a new drug, facilitate the
8 development and expedite the review of such drug if
9 it is intended, whether alone or in combination with
10 one or more other drugs, for the treatment of a seri-
11 ous or life-threatening disease or condition, and it
12 demonstrates the potential to address unmet medical
13 needs for such a disease or condition. (In this sec-
14 tion, such a drug is referred to as a ‘fast track prod-
15 uct’.)

16 “(2) REQUEST FOR DESIGNATION.—The spon-
17 sor of a new drug may request the Secretary to des-
18 ignate the drug as a fast track product. A request
19 for the designation may be made concurrently with,
20 or at any time after, submission of an application
21 for the investigation of the drug under section 505(i)
22 of this Act or section 351(a)(3) of the Public Health
23 Service Act.

24 “(3) DESIGNATION.—Within 60 calendar days
25 after the receipt of a request under paragraph (2),
26 the Secretary shall determine whether the drug that

1 is the subject of the request meets the criteria de-
2 scribed in paragraph (1). If the Secretary finds that
3 the drug meets the criteria, the Secretary shall des-
4 ignate the drug as a fast track product and shall
5 take such actions as are appropriate to expedite the
6 development and review of the application for ap-
7 proval of such product.

8 “(b) ACCELERATED APPROVAL OF A DRUG FOR A
9 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
10 TION, INCLUDING A FAST TRACK PRODUCT.—

11 “(1) IN GENERAL.—The Secretary may approve
12 an application for approval of a product for a seri-
13 ous or life-threatening disease or condition, including
14 a fast track product, under section 505(e) of this
15 Act or section 351(a) of the Public Health Service
16 Act upon making a determination (taking into ac-
17 count the severity or rarity of the disease or condi-
18 tion and the availability of alternative treatments)
19 that the product has an effect on—

20 “(A) a surrogate endpoint that is reason-
21 ably likely to predict clinical benefit; or

22 “(B) a clinical endpoint, including an end-
23 point that can be measured earlier than irre-
24 versible morbidity or mortality, that is reason-

1 ably likely to predict an effect on irreversible
2 morbidity or mortality or other clinical benefit.

3 The evidence to support that an endpoint is reason-
4 ably likely to predict clinical benefit may include epi-
5 demiological, pathophysiologic, pharmacologic, thera-
6 peutic or other evidence developed using, for exam-
7 ple, biomarkers, or other scientific methods or tools.

8 “(2) LIMITATION.—Approval of a product
9 under this subsection may, as determined by the
10 Secretary, be subject to the following require-
11 ments—

12 “(A) that the sponsor conduct appropriate
13 post-approval studies to verify and describe the
14 predicted effect of the product on irreversible
15 morbidity or mortality or other clinical benefit;
16 and

17 “(B) that the sponsor submit copies of all
18 promotional materials related to the product, at
19 least 30 days prior to dissemination of the ma-
20 terials—

21 “(i) during the preapproval review pe-
22 riod; and

23 “(ii) following approval, for a period
24 that the Secretary determines to be appro-
25 priate.

1 “(3) EXPEDITED WITHDRAWAL OF AP-
2 PROVAL.—The Secretary may withdraw approval of
3 a product approved pursuant to this subsection
4 using expedited procedures (as prescribed by the
5 Secretary in regulations, which shall include an op-
6 portunity for an informal hearing) if—

7 “(A) the sponsor fails to conduct any re-
8 quired post-approval study of the product with
9 due diligence;

10 “(B) a study required to verify and de-
11 scribe the predicted effect on irreversible mor-
12 bidity or mortality or other clinical benefit of
13 the product fails to verify and describe such ef-
14 fect or benefit;

15 “(C) other evidence demonstrates that the
16 product is not safe or effective under the condi-
17 tions of use; or

18 “(D) the sponsor disseminates false or
19 misleading promotional materials with respect
20 to the product.

21 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR
22 APPROVAL OF A FAST TRACK PRODUCT.—

23 “(1) IN GENERAL.—If the Secretary deter-
24 mines, after preliminary evaluation of clinical data
25 submitted by the sponsor, that a fast track product

1 may be effective, the Secretary shall evaluate for fil-
2 ing, and may commence review of portions of, an ap-
3 plication for the approval of the product before the
4 sponsor submits a complete application. The Sec-
5 retary shall commence such review only if the appli-
6 cant—

7 “(A) provides a schedule for submission of
8 information necessary to make the application
9 complete; and

10 “(B) pays any fee that may be required
11 under section 736.

12 “(2) EXCEPTION.—Any time period for review
13 of human drug applications that has been agreed to
14 by the Secretary and that has been set forth in goals
15 identified in letters of the Secretary (relating to the
16 use of fees collected under section 736 to expedite
17 the drug development process and the review of
18 human drug applications) shall not apply to an ap-
19 plication submitted under paragraph (1) until the
20 date on which the application is complete.

21 “(d) AWARENESS EFFORTS.—The Secretary shall—

22 “(1) develop and disseminate to physicians, pa-
23 tient organizations, pharmaceutical and bio-
24 technology companies, and other appropriate persons
25 a description of the provisions of this section appli-

1 cable to accelerated approval and fast track prod-
2 ucts; and

3 “(2) establish a program to encourage the de-
4 velopment of surrogate and clinical endpoints, in-
5 cluding biomarkers, and other scientific methods and
6 tools that can assist the Secretary in determining
7 whether the evidence submitted in an application is
8 reasonably likely to predict clinical benefit for seri-
9 ous or life-threatening conditions for which there
10 exist significant unmet medical needs.”.

11 **SEC. 832. GUIDANCE; AMENDED REGULATIONS.**

12 (a) INITIAL GUIDANCE.—Not later than one year
13 after the date of enactment of this Act, the Secretary of
14 Health and Human Services (in this subtitle referred to
15 as the “Secretary”) shall issue draft guidance to imple-
16 ment the amendments made by section 831.

17 (b) FINAL GUIDANCE.—Not later than one year after
18 the issuance of draft guidance under subsection (a), after
19 an opportunity for public comment, the Secretary shall—

20 (1) issue final guidance to implement the
21 amendments made by section 831; and

22 (2) amend the regulations governing accelerated
23 approval in parts 314 and 601 of title 21, Code of
24 Federal Regulations, as necessary to conform such

1 regulations with the amendments made by section
2 831.

3 (c) CONSIDERATIONS.—In developing the guidance
4 under subsections (a) and (b)(1) and the amendments
5 under subsection (b)(2), the Secretary shall consider—

6 (1) issues arising under the accelerated ap-
7 proval and fast track processes under section 506 of
8 the Federal Food, Drug, and Cosmetic Act (as
9 amended by section 831) for drugs designated for a
10 rare disease or condition under section 526 of the
11 Federal, Food, Drug, and Cosmetic Act; and

12 (2) how to incorporate novel approaches to the
13 review of surrogate endpoints based on patho-
14 physiologic and pharmacologic evidence in such guid-
15 ance, especially in instances where the low preva-
16 lence of a disease renders the existence or collection
17 of other types of data unlikely or impractical.

18 (d) NO DELAY IN REVIEW OR APPROVAL.—The
19 issuance (or non-issuance) of guidance or conforming reg-
20 ulations implementing the amendments made by section
21 831 shall not preclude the review of, or action on, a re-
22 quest for designation or an application for approval sub-
23 mitted pursuant to section 506 of the Federal Food, Drug,
24 and Cosmetic Act, as amended by section 831.

1 **SEC. 833. INDEPENDENT REVIEW.**

2 (a) IN GENERAL.—The Secretary shall, in conjunc-
3 tion with other planned reviews of the new drug review
4 process, contract with an independent entity with expertise
5 in assessing the quality and efficiency of biopharma-
6 ceutical development and regulatory review programs, to
7 evaluate the Food and Drug Administration’s application
8 of the processes described in section 506 of the Federal
9 Food, Drug, and Cosmetic Act, as amended by section
10 831, and the impact of such processes on the development
11 and timely availability of innovative treatments for pa-
12 tients suffering from serious or life-threatening conditions.

13 (b) CONSULTATION.—Any evaluation under sub-
14 section (a) shall include consultation with regulated indus-
15 tries, patient advocacy and disease research foundations,
16 and relevant academic medical centers.

17 **SEC. 834. RULE OF CONSTRUCTION.**

18 The amendments made to section 506(b) of the Fed-
19 eral Food, Drug and Cosmetic Act by section 831 shall
20 be construed in a manner that encourages the Secretary
21 to utilize innovative approaches for the assessment of
22 products under accelerated approval while maintaining ap-
23 propriate safety and effectiveness standards for such prod-
24 ucts.

1 **TITLE IX—DRUG SHORTAGES**

2 **SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF MAN-**
3 **UFACTURING OF CERTAIN DRUGS.**

4 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)
5 is amended to read as follows:

6 **“SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF**
7 **MANUFACTURING OF CERTAIN DRUGS.**

8 “(a) IN GENERAL.—A manufacturer of a drug—

9 “(1) that is—

10 “(A) life-supporting;

11 “(B) life-sustaining; or

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

14 “(2) for which an application has been ap-
15 proved under section 505(b) or 505(j); and

16 “(3) that is not a product that was originally
17 derived from human tissue and was replaced by a re-
18 combinant product;

19 shall notify the Secretary of a discontinuance of the manu-
20 facture of the drug, or an interruption of the manufacture
21 of the drug that is likely to produce a drug shortage, in
22 accordance with subsection (b).

23 “(b) TIMING.—A notice required by subsection (a)
24 shall be submitted to the Secretary—

1 “(1) at least 6 months prior to the date of the
2 discontinuance or interruption; or

3 “(2) if compliance with paragraph (1) is not
4 possible, as soon as practicable.

5 “(c) DISTRIBUTION.—To the maximum extent prac-
6 ticable, the Secretary shall distribute information on the
7 discontinuation or interruption of the manufacture of the
8 drugs described in subsection (a) to appropriate physician
9 and patient organizations, as described in section 506D.”.

10 (b) REGULATIONS.—

11 (1) IN GENERAL.—Not later than 18 months
12 after the date of the enactment of this Act, the Sec-
13 retary of Health and Human Services, after issuing
14 a notice of proposed rule and holding a public hear-
15 ing, shall promulgate final regulations that imple-
16 ment the amendment made by subsection (a).

17 (2) CONTENTS.—Such regulations shall—

18 (A) include a list of the drugs that are
19 subject to the requirements of section 506C(a)
20 of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 356e(a)), as amended by subsection
22 (a), if the manufacture of such drug is to be
23 discontinued, or an interruption of the manu-
24 facture of the drug that is likely to produce a
25 drug shortage; and

1 (B) define the terms “life-supporting”,
2 “life-sustaining”, and “intended for use in the
3 prevention of a debilitating disease or condi-
4 tion” for purposes of section 506C of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 356c).

7 **SEC. 902. DRUG SHORTAGE LIST.**

8 Title V (21 U.S.C. 351 et seq.) is amended by insert-
9 ing after section 506C the following new section:

10 **“SEC. 506D. DRUG SHORTAGE LIST.**

11 “(a) ESTABLISHMENT.—The Secretary shall main-
12 tain an up-to-date list of drugs that are verified to be in
13 shortage in the United States.

14 “(b) CONTENTS.—For each drug on such list, the
15 Secretary shall include the following information:

16 “(1) The name of the drug in shortage.

17 “(2) The name of each manufacturer of such
18 drug.

19 “(3) The reason for the shortage, as determined
20 by the Secretary, selecting from the following cat-
21 egories:

22 “(A) Requirements related to complying
23 with good manufacturing practices.

24 “(B) Regulatory delay.

25 “(C) Shortage of an active ingredient.

1 “(D) Shortage of a nonactive pharma-
2 ceutical ingredient component.

3 “(E) Discontinuation of the manufacture
4 of the drug.

5 “(F) Delay in shipping of the drug.

6 “(G) Demand increase for the drug.

7 “(4) The anticipated duration of the shortage
8 as determined by the Secretary.

9 “(c) PUBLIC AVAILABILITY.—

10 “(1) IN GENERAL.—Subject to paragraphs (2)
11 and (3), the Secretary shall make the information in
12 such list publicly available.

13 “(2) TRADE SECRETS AND CONFIDENTIAL IN-
14 FORMATION.—Nothing in this section alters or
15 amends section 1905 of title 18, United States Code,
16 or section 552(b)(4) of title 5 of such Code.

17 “(3) PUBLIC HEALTH EXCEPTION.—The Sec-
18 retary may choose not to make information collected
19 under this section publicly available under paragraph
20 (1) if the Secretary determines that disclosure of
21 such information would adversely affect the public
22 health.”.

1 **SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

2 Section 306 of the Controlled Substances Act (21
3 U.S.C. 826) is amended by adding at the end the fol-
4 lowing:

5 “(h)(1) Not later than 30 days after the receipt of
6 a request described in paragraph (2), the Attorney Gen-
7 eral shall—

8 “(A) complete review of such request; and

9 “(B) as necessary to address a shortage of a
10 controlled substance, increase the aggregate and in-
11 dividual production quotas under this section appli-
12 cable to such controlled substance and any ingre-
13 dient therein.

14 “(2) A request is described in this paragraph if—

15 “(A) the request pertains to a controlled sub-
16 stance on the list of drugs in shortage maintained
17 under section 506D of the Federal Food, Drug, and
18 Cosmetic Act;

19 “(B) the request is submitted by the manufac-
20 turer of the controlled substance; and

21 “(C) the controlled substance is in schedule
22 II.”.

1 **SEC. 904. EXPEDITED REVIEW OF MAJOR MANUFACTURING**
2 **CHANGES FOR POTENTIAL AND VERIFIED**
3 **SHORTAGES OF DRUGS THAT ARE LIFE-SUP-**
4 **PORTING, LIFE-SUSTAINING, OR INTENDED**
5 **FOR USE IN THE PREVENTION OF A DEBILI-**
6 **TATING DISEASE OR CONDITION.**

7 Subsection (c) of section 506A (21 U.S.C. 356a) is
8 amended by adding at the end the following new para-
9 graph:

10 “(3) CHANGES ADDRESSING A DRUG SHORT-
11 AGE.—

12 “(A) CERTIFICATION.—

13 “(i) DESCRIPTION.—A certification is
14 described in this subparagraph if the hold-
15 er of the approved application or license
16 for the drug involved certifies (in such cer-
17 tification) that the major manufacturing
18 change for which approval is being sought
19 may prevent or alleviate a verified or an-
20 ticipated shortage of a drug described in
21 section 506C(a)(1).

22 “(ii) BAD FAITH EXCEPTION.—Sub-
23 paragraphs (B) and (C) do not apply in
24 the case of a certification which the Sec-
25 retary determines to be made in bad faith.

1 “(B) EXPEDITED REVIEW.—If a certifi-
2 cation described in subparagraph (A) is sub-
3 mitted in connection with a supplemental appli-
4 cation for a major manufacturing change, the
5 Secretary shall—

6 “(i) expedite any technical review or
7 inspection necessary for consideration of
8 the supplemental application;

9 “(ii) provide any technical assistance
10 necessary to facilitate approval of the sup-
11 plemental application; and

12 “(iii) not later than 60 days after re-
13 ceipt of the certification, complete review
14 of the supplemental application.

15 “(C) GOOD MANUFACTURING PRACTICE.—
16 In approving a major manufacturing change for
17 which a certification described in subparagraph
18 (A) is submitted, the Secretary may, for the
19 purpose of preventing or alleviating the short-
20 age addressed by the certification, deem the
21 change to be in compliance with the require-
22 ments of this Act for current good manufac-
23 turing practice (within the meaning of section
24 501(a)(1)(B)) if the manufacturing facilities in-
25 volved—

1 “(i) have a plan to achieve full compli-
2 ance with such requirements, as in effect
3 at the time of the Secretary’s determina-
4 tion;

5 “(ii) have sufficient resources to
6 achieve, and demonstrate adequate
7 progress in achieving, such full compliance;
8 and

9 “(iii) are implementing adequate in-
10 terim controls, as determined by the Sec-
11 retary, in order to ensure the quality of the
12 drug.

13 “(D) INTERIM CONTROLS.—The interim
14 controls required by subparagraph (C)(iii) for a
15 drug shall include additional testing, such as in-
16 process or release testing of the drug or its ac-
17 tive ingredients, excipients, or components.”.

18 **SEC. 905. STUDY ON DRUG SHORTAGES.**

19 (a) STUDY.—The Comptroller General of the United
20 States shall conduct a study to examine the cause of drug
21 shortages and formulate recommendations on how to pre-
22 vent or alleviate such shortages.

23 (b) CONSIDERATION.—In conducting the study under
24 this section, the Comptroller General shall consider the
25 following questions:

1 (1) What are the dominant characteristics of
2 drugs that have gone into actual shortage over the
3 preceding three years?

4 (2) Are there systemic high-risk factors that
5 have led to the concentration of drug shortages in
6 certain drug products that have made such products
7 vulnerable to drug shortages?

8 (3) Is there a reason why drug shortages have
9 occurred primarily in the sterile injectable market
10 and in certain therapeutic areas?

11 (4) How have regulations, guidance documents,
12 regulatory practices, and other actions of Federal
13 departments and agencies affected drug shortages?

14 (5) How does hoarding affect drug shortages?

15 (6) How would incentives alleviate or prevent
16 drug shortages?

17 (c) CONSULTATION WITH STAKEHOLDERS.—In con-
18 ducting the study under this section, the Comptroller Gen-
19 eral shall consult with relevant stakeholders, including
20 physicians, pharmacists, hospitals, patients, and drug
21 manufacturers.

22 (d) REPORT.—Note later than 18 months after the
23 date of the enactment of this Act, the Comptroller General
24 shall submit a report to the Committee on Energy and
25 Commerce of the House of Representatives and the Com-

1 mittee on Health, Education, Labor, and Pensions of the
2 Senate on the results of the study under this section.

3 **SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.**

4 Not later than 6 months after the date of the enact-
5 ment of this Act, and annually thereafter, the Secretary
6 of Health and Human Services shall submit to the Com-
7 mittee on Energy and Commerce of the House of Rep-
8 resentatives and the Committee on Health, Education,
9 Labor, and Pensions of the Senate a report on drug short-
10 ages that—

11 (1) describes the communication between the
12 field investigators of the Food and Drug Administra-
13 tion and the staff of the Center for Drug Evaluation
14 and Research's Office of Compliance and Drug
15 Shortage Program, including the Food and Drug
16 Administration's procedures for enabling and ensur-
17 ing such communication;

18 (2) describes the Food and Drug Administra-
19 tion's efforts to expedite the review of new manufac-
20 turing sites, new suppliers, and specification changes
21 to prevent or alleviate a drug shortage;

22 (3) describes the coordination between the Food
23 and Drug Administration and the Drug Enforce-
24 ment Administration on efforts to prevent or allevi-
25 ate drug shortages;

1 (4) identifies the number of, and describes the,
2 instances in which the Food and Drug Administra-
3 tion exercised regulatory flexibility and discretion to
4 prevent or alleviate a drug shortage;

5 (5) identifies the number of instances in which
6 the Food and Drug Administration asked firms to
7 increase production to prevent or alleviate a short-
8 age;

9 (6) identifies the number of notifications sub-
10 mitted to the Secretary under section 506C of the
11 Federal Food, Drug, and Cosmetic Act, as amended
12 by section 901 of this Act, including the percentage
13 of such notifications for a drug that is a sterile
14 injectable;

15 (7) describes the Food and Drug Administra-
16 tion's implementation of section 506D of the Fed-
17 eral Food, Drug, and Cosmetic Act (relating to a
18 drug shortage list), as added by section 902 of this
19 Act, and identifies—

20 (A) the name of each drug on the list
21 under such section 506D at any point during
22 the period covered by the report;

23 (B) the name of each manufacturer of
24 each such drug;

1 (C) the reason for the shortage of each
2 such drug; and

3 (D) the anticipated or, if known, actual
4 duration of the shortage of each such drug;

5 (8) identifies whether, and how, the Food and
6 Drug Administration expedited the review of regu-
7 latory submissions to prevent or alleviate shortages,
8 including how the Administration utilized the au-
9 thority in section 506A(c)(3) of the Federal Food,
10 Drug, and Cosmetic Act, as added by section 904 of
11 this Act;

12 (9) identifies the number of certifications sub-
13 mitted under such section 506A(c)(3) and, for each
14 such certification, whether the Food and Drug Ad-
15 ministration completed expedited review within 60
16 days as required by subparagraph (B) of such sec-
17 tion 506A(c)(3);

18 (10) specifies—

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

1 (B) the number of waivers and reductions
2 for abbreviated new drug applications and prior
3 approval supplements requested under section
4 744A(o) of the Federal Food, Drug, and Cos-
5 metic Act, as added by section 302 of this Act,
6 and the number of such waivers and reductions
7 granted;

8 (11) describes the Secretary's public engage-
9 ment on drug shortages with stakeholders, including
10 physicians, pharmacists, patients, hospitals, and
11 drug manufacturers; and

12 (12) contains the Secretary's plan for address-
13 ing drug shortages in the upcoming year, including
14 with respect to the issues described in paragraphs
15 (1) through (11).