

112TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. HARKIN (for himself and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-free programs for prescription drugs and 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 “Food and Drug Ad-
5 ministration Safety and Innovation Act”.

6 **SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.**

7 (a) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents; 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. Short title; findings.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Savings clause.
- Sec. 206. Effective date.
- Sec. 207. Sunset clause.
- Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

TITLE III—FEES RELATING TO GENERIC DRUGS

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

- Sec. 501. Sense of the Senate regarding reauthorization of vital pediatric laws.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

- Sec. 601. Reclassification procedures.
- Sec. 602. Condition of approval studies.
- Sec. 603. Postmarket surveillance.
- Sec. 604. Sentinel.
- Sec. 605. Recalls.

3

- Sec. 606. Clinical holds on investigational device exemptions.
- Sec. 607. Unique device identifier.
- Sec. 608. Clarification of least burdensome standard.
- Sec. 609. Agency documentation and review of certain decisions regarding devices.
- Sec. 610. Good guidance practices relating to devices.
- Sec. 611. Modification of de novo application process.
- Sec. 612. Humanitarian use device exemptions.
- Sec. 613. Reauthorization of third-party review and inspections.
- Sec. 614. Advisory committee conflicts of interest.

TITLE VII—DRUG SUPPLY CHAIN

- Sec. 701. Registration of domestic drug establishments.
- Sec. 702. Registration of foreign establishments.
- Sec. 703. Registration of drug excipient information with product listing.
- Sec. 704. Electronic system for registration and listing.
- Sec. 705. Risk-based inspection frequency.
- Sec. 706. Records for inspection.
- Sec. 707. Failure to allow foreign inspection.
- Sec. 708. Exchange of information.
- Sec. 709. Enhancing the safety and quality of the drug supply.
- Sec. 710. Accreditation of third-party auditors for drug establishments.
- Sec. 711. Standards for admission of imported drugs.
- Sec. 712. Notification.
- Sec. 713. Destruction of unsafe drugs.
- Sec. 714. Protection against intentional adulteration.
- Sec. 715. Enhanced criminal penalty for counterfeiting drugs.
- Sec. 716. Extraterritorial jurisdiction.
- Sec. 717. Compliance with international agreements.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

- Sec. 801. Extension of exclusivity period for drugs.
- Sec. 802. Priority review.
- Sec. 803. Fast track product.
- Sec. 804. GAO study.
- Sec. 805. Clinical trials.
- Sec. 806. Regulatory certainty and predictability.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

- Sec. 901. Enhancement of accelerated patient access to new medical treatments.
- Sec. 902. Breakthrough therapies.
- Sec. 903. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
- Sec. 904. Accessibility of information on prescription drug container labels by visually-impaired and blind consumers.

TITLE X—DRUG SHORTAGES

- Sec. 1001. Drug shortages.

TITLE XI—OTHER PROVISIONS

- Sec. 1101. Guidance document regarding product promotion using the Internet.

Sec. 1102. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.

Sec. 1103. Reauthorization of the Critical Path Public-Private Partnerships.

Sec. 1104. Electronic submission of applications.

1 (b) REFERENCES IN ACT.—Except as otherwise spec-
2 ified, amendments made by this Act to a section or other
3 provision of law are amendments to such section or other
4 provision of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 301 et seq.).

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

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

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

11 (b) FINDING.—The Congress finds that the fees au-
12 thorized by the amendments made in this title will be dedi-
13 cated toward expediting the drug development process and
14 the process for the review of human drug applications, in-
15 cluding postmarket drug safety activities, as set forth in
16 the goals identified for purposes of part 2 of subchapter
17 C of chapter VII of the Federal Food, Drug, and Cosmetic
18 Act, in the letters from the Secretary of Health and
19 Human Services to the Chairman of the Committee on
20 Health, Education, Labor, and Pensions of the Senate and
21 the Chairman of the Committee on Energy and Commerce
22 of the House of Representatives, as set forth in the Con-
23 gressional Record.

1 **SEC. 102. DEFINITIONS.**

2 Paragraph (7) of section 735 (21 U.S.C. 379g) is
3 amended, in the matter preceding subparagraph (A), by
4 striking “incurred”.

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

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

7 (1) in subsection (a)—

8 (A) in the matter preceding paragraph (1),
9 by striking “fiscal year 2008” and inserting
10 “fiscal year 2013”;

11 (B) in paragraph (1), in clauses (i) and (ii)
12 of subparagraph (A), by striking “subsection
13 (c)(5)” each place such term appears and in-
14 serting “subsection (c)(4)”;

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

17 (i) by striking “subsection (c)(5)” and
18 inserting “subsection (c)(4)”; and

19 (ii) by striking “payable on or before
20 October 1 of each year” and inserting
21 “due on the later of the first business day
22 on or after October 1 of such fiscal year or
23 the first business day after the enactment
24 of an appropriations Act providing for the
25 collection and obligation of fees for such
26 fiscal year under this section”; and

1 (D) in paragraph (3)—

2 (i) in subparagraph (A)—

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

6 (II) by striking “payable on or
7 before October 1 of each year.” and
8 inserting “due on the later of the first
9 business day on or after October 1 of
10 each such fiscal year or the first busi-
11 ness day after the enactment of an
12 appropriations Act providing for the
13 collection and obligation of fees for
14 each such fiscal year under this sec-
15 tion.”; and

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

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

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

24 “(ii) the same product as another
25 product that—

1 “(I) was approved under an ap-
2 plication filed under section 505(b) or
3 505(j); and

4 “(II) is not in the list of discon-
5 tinued products compiled under sec-
6 tion 505(j)(7)(A);

7 “(iii) the same product as another
8 product that was approved under an abbrevi-
9 ated application filed under section 507
10 (as in effect on the day before the date of
11 enactment of the Food and Drug Adminis-
12 tration Modernization Act of 1997); or

13 “(iv) the same product as another
14 product that was approved under an abbrevi-
15 ated new drug application pursuant to
16 regulations in effect prior to the implemen-
17 tation of the Drug Price Competition and
18 Patent Term Restoration Act of 1984.”;

19 (2) in subsection (b)—

20 (A) in paragraph (1)—

21 (i) in the language preceding subpara-
22 graph (A), by striking “fiscal years 2008
23 through 2012” and inserting “fiscal years
24 2013 through 2017”;

1 (ii) in subparagraph (A), by striking
2 “\$392,783,000; and” and inserting
3 “\$693,099,000;”; and

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

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

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

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

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

19 “(A) INFLATION ADJUSTMENT.—The infla-
20 tion adjustment for fiscal year 2013 shall be
21 the sum of—

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

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

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

8 “(i) \$652,709,000 plus the amount of
9 the inflation adjustment calculated under
10 subparagraph (A); multiplied by

11 “(ii) the amount (if any) by which a
12 percentage workload adjustment for fiscal
13 year 2013, as determined using the meth-
14 odology described in subsection (c)(2)(A),
15 would exceed the percentage workload ad-
16 justment (as so determined) for fiscal year
17 2012, if both such adjustment percentages
18 were calculated using the 5-year base pe-
19 riod consisting of fiscal years 2003
20 through 2007.

21 “(C) LIMITATION.—Under no cir-
22 cumstances shall the adjustment under sub-
23 paragraph (B) result in fee revenues for fiscal
24 year 2013 that are less than the sum of the

1 amount under paragraph (1)(A) and the
2 amount under paragraph (1)(B).”;

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

5 “(c) ADJUSTMENTS.—

6 “(1) INFLATION ADJUSTMENT.—For fiscal year
7 2014 and subsequent fiscal years, the revenues es-
8 tablished in subsection (b) shall be adjusted by the
9 Secretary by notice, published in the Federal Reg-
10 ister, for a fiscal year by the amount equal to the
11 sum of—

12 “(A) one;

13 “(B) the average annual change in the
14 cost, per full-time equivalent position of the
15 Food and Drug Administration, of all personnel
16 compensation and benefits paid with respect to
17 such positions for the first 3 years of the pre-
18 ceding 4 fiscal years, multiplied by the propor-
19 tion of personnel compensation and benefits
20 costs to total costs of the process for the review
21 of human drug applications (as defined in sec-
22 tion 735(6)) for the first 3 years of the pre-
23 ceding 4 fiscal years; and

24 “(C) the average annual change that oc-
25 curred in the Consumer Price Index for urban

1 consumers (Washington-Baltimore, DC-MD-
2 VA-WV; Not Seasonally Adjusted; All items;
3 Annual Index) for the first 3 years of the pre-
4 ceding 4 years of available data multiplied by
5 the proportion of all costs other than personnel
6 compensation and benefits costs to total costs
7 of the process for the review of human drug ap-
8 plications (as defined in section 735(6)) for the
9 first 3 years of the preceding 4 fiscal years.

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

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

23 “(A) The adjustment shall be determined
24 by the Secretary based on a weighted average
25 of the change in the total number of human

1 drug applications (adjusted for changes in re-
2 view activities, as described in the notice that
3 the Secretary is required to publish in the Fed-
4 eral Register under this subparagraph), efficacy
5 supplements, and manufacturing supplements
6 submitted to the Secretary, and the change in
7 the total number of active commercial investiga-
8 tional new drug applications (adjusted for
9 changes in review activities, as so described)
10 during the most recent 12-month period for
11 which data on such submissions is available.
12 The Secretary shall publish in the Federal Reg-
13 ister the fee revenues and fees resulting from
14 the adjustment and the supporting methodolo-
15 gies.

16 “(B) Under no circumstances shall the ad-
17 justment result in fee revenues for a fiscal year
18 that are less than the sum of the amount under
19 subsection (b)(1)(A) and the amount under
20 subsection (b)(1)(B), as adjusted for inflation
21 under paragraph (1).

22 “(C) The Secretary shall contract with an
23 independent accounting or consulting firm to
24 periodically review the adequacy of the adjust-
25 ment and publish the results of those reviews.

1 The first review shall be conducted and pub-
2 lished by the end of fiscal year 2013 (to exam-
3 ine the performance of the adjustment since fis-
4 cal year 2009), and the second review shall be
5 conducted and published by the end of fiscal
6 year 2015 (to examine the continued perform-
7 ance of the adjustment). The reports shall
8 evaluate whether the adjustment reasonably
9 represents actual changes in workload volume
10 and complexity and present options to dis-
11 continue, retain, or modify any elements of the
12 adjustment. The reports shall be published for
13 public comment. After review of the reports and
14 receipt of public comments, the Secretary shall,
15 if warranted, adopt appropriate changes to the
16 methodology. If the Secretary adopts changes to
17 the methodology based on the first report, the
18 changes shall be effective for the first fiscal
19 year for which fees are set after the Secretary
20 adopts such changes and each subsequent fiscal
21 year.

22 “(3) FINAL YEAR ADJUSTMENT.—For fiscal
23 year 2017, the Secretary may, in addition to adjust-
24 ments under this paragraph and paragraphs (1) and
25 (2), further increase the fee revenues and fees estab-

1 lished in subsection (b) if such an adjustment is nec-
2 essary to provide for not more than 3 months of op-
3 erating reserves of carryover user fees for the proc-
4 ess for the review of human drug applications for
5 the first 3 months of fiscal year 2018. If such an
6 adjustment is necessary, the rationale for the
7 amount of the increase shall be contained in the an-
8 nual notice establishing fee revenues and fees for fis-
9 cal year 2017. If the Secretary has carryover bal-
10 ances for such process in excess of 3 months of such
11 operating reserves, the adjustment under this sub-
12 paragraph shall not be made.

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

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

1 (4) in subsection (g)—

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

5 (B) in paragraph (2)—

6 (i) in subparagraph (A)—

7 (I) in clause (i), by striking
8 “shall be retained” and inserting
9 “subject to subparagraph (C), shall be
10 collected and available”; and

11 (II) in clause (ii), by striking
12 “shall only be collected and available”
13 and inserting “shall be available”; and

14 (ii) by adding at the end the following
15 new subparagraph:

16 “(C) PROVISION FOR EARLY PAYMENTS.—
17 Payment of fees authorized under this section
18 for a fiscal year, prior to the due date for such
19 fees, may be accepted by the Secretary in ac-
20 cordance with authority provided in advance in
21 a prior year appropriations Act.”;

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

25 (D) in paragraph (4)—

1 (i) by striking “fiscal years 2008
2 through 2010” and inserting “fiscal years
3 2013 through 2015”;

4 (ii) by striking “fiscal year 2011” and
5 inserting “fiscal year 2016”;

6 (iii) by striking “fiscal years 2008
7 though 2011” and inserting “fiscal years
8 2013 through 2016”; and

9 (iv) by striking “fiscal year 2012”
10 and inserting “fiscal year 2017”.

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

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

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

15 “(a) PERFORMANCE REPORT.—

16 “(1) IN GENERAL.—Beginning with fiscal year
17 2013, not later than 120 days after the end of each
18 fiscal year for which fees are collected under this
19 part, the Secretary shall prepare and submit to the
20 Committee on Energy and Commerce of the House
21 of Representatives and the Committee on Health,
22 Education, Labor, and Pensions of the Senate a re-
23 port concerning the progress of the Food and Drug
24 Administration in achieving the goals identified in
25 the letters described in section 101(b) of the Pre-

1 scription Drug User Fee Amendments of 2012 dur-
2 ing such fiscal year and the future plans of the Food
3 and Drug Administration for meeting the goals. The
4 report under this subsection for a fiscal year shall
5 include information on all previous cohorts for which
6 the Secretary has not given a complete response on
7 all human drug applications and supplements in the
8 cohort.”;

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

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

13 **SEC. 105. SUNSET DATES.**

14 (a) AUTHORIZATION.—Sections 735 and 736 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
16 379h) shall cease to be effective October 1, 2017.

17 (b) REPORTING REQUIREMENTS.—Section 736B of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 379h–2) shall cease to be effective January 31, 2018.

20 (c) PREVIOUS SUNSET PROVISION.—The Prescrip-
21 tion Drug User Fee Amendments of 2007 is amended by
22 striking section 106.

23 **SEC. 106. EFFECTIVE DATE.**

24 The amendments made by this title shall take effect
25 on October 1, 2012, or the date of the enactment of this

1 Act, whichever is later, except that fees under part 2 of
2 subchapter C of chapter VII of the Federal Food, Drug,
3 and Cosmetic Act shall be assessed for all human drug
4 applications received on or after October 1, 2012, regard-
5 less of the date of the enactment of this Act.

6 **SEC. 107. SAVINGS CLAUSE.**

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

20 **TITLE II—FEES RELATING TO**
21 **DEVICES**

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

23 (a) **SHORT TITLE.**—This title may be cited as the
24 “Medical Device User Fee Amendments of 2012”.

1 (b) FINDINGS.—The Congress finds that the fees au-
2 thORIZED under the amendments made by this title will be
3 dedicated toward expediting the process for the review of
4 device applications and for assuring the safety and effec-
5 tiveness of devices, as set forth in the goals identified for
6 purposes of part 3 of subchapter C of chapter VII of the
7 Federal Food, Drug, and Cosmetic Act in the letters from
8 the Secretary of Health and Human Services to the Chair-
9 man of the Committee on Health, Education, Labor, and
10 Pensions of the Senate and the Chairman of the Com-
11 mittee on Energy and Commerce of the House of Rep-
12 resentatives, as set forth in the Congressional Record.

13 **SEC. 202. DEFINITIONS.**

14 Section 737 of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 379i) is amended—

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

18 (2) in paragraph (10), by striking “October
19 2001” and inserting “October 2011”; and

20 (3) in paragraph (13), by striking “is required
21 to register” and all that follows through the end of
22 paragraph (13) and inserting the following: “is reg-
23 istered (or is required to register) with the Secretary
24 under section 510 because such establishment is en-

1 gaged in the manufacture, preparation, propagation,
2 compounding, or processing of a device.”.

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

4 (a) TYPES OF FEES.—Section 738(a) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is
6 amended—

7 (1) in paragraph (1), by striking “fiscal year
8 2008” and inserting “fiscal year 2013”;

9 (2) in paragraph (2)(A)—

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

11 (i) by striking “subsections (d) and
12 (e)” and inserting “subsections (d), (e),
13 and (f)”;

14 (ii) by striking “October 1, 2002” and
15 inserting “October 1, 2012”; and

16 (iii) by striking “subsection (c)(1)”
17 and inserting “subsection (c)”;

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

20 (3) in paragraph (3)—

21 (A) in subparagraph (A), by inserting
22 “and subsection (f)” after “subparagraph (B)”;

23 and

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

4 “(i) the initial or annual registration
 5 (as applicable) of the establishment under
 6 section 510; or

7 “(ii) the first business day after the
 8 date of enactment of an appropriations Act
 9 providing for the collection and obligation
 10 of fees for such year under this section.”.

11 (b) FEE AMOUNTS.—Section 738(b) of the Federal
 12 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is
 13 amended to read as follows:

14 “(b) FEE AMOUNTS.—

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

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

“

Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application	\$248,000	\$252,960	\$258,019	\$263,180	\$268,443

“

Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Establishment Registration	\$2,575	\$3,200	\$3,750	\$3,872	\$3,872

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

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

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

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

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

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

9 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
10 738(c) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 379j(c)) is amended—

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

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

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

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

19 “(1) IN GENERAL.—The Secretary shall, 60
20 days before the start of each fiscal year after Sep-
21 tember 30, 2012, establish fees under subsection (a),
22 based on amounts specified under subsection (b) and

1 the adjustments provided under this subsection, and
2 publish such fees, and the rationale for any adjust-
3 ments to such fees, in the Federal Register.

4 “(2) INFLATION ADJUSTMENTS.—

5 “(A) ADJUSTMENT TO TOTAL REVENUE
6 AMOUNTS.—For fiscal year 2014 and each sub-
7 sequent fiscal year, the Secretary shall adjust
8 the total revenue amount specified in subsection
9 (b)(3) for such fiscal year by multiplying such
10 amount by the applicable inflation adjustment
11 under subparagraph (B) for such year.

12 “(B) APPLICABLE INFLATION ADJUST-
13 MENT TO TOTAL REVENUE AMOUNTS.—The ap-
14 plicable inflation adjustment for a fiscal year
15 is—

16 “(i) for fiscal year 2014, the base in-
17 flation adjustment under subparagraph (C)
18 for such fiscal year; and

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

21 “(I) the base inflation adjust-
22 ment under subparagraph (C) for
23 such fiscal year; and

24 “(II) the product of the base in-
25 flation adjustment under subpara-

1 graph (C) for each of the fiscal years
2 preceding such fiscal year, beginning
3 with fiscal year 2014.

4 “(C) BASE INFLATION ADJUSTMENT TO
5 TOTAL REVENUE AMOUNTS.—

6 “(i) IN GENERAL.—Subject to further
7 adjustment under clause (ii), the base in-
8 flation adjustment for a fiscal year is the
9 sum of one plus—

10 “(I) the average annual change
11 in the cost, per full-time equivalent
12 position of the Food and Drug Ad-
13 ministration, of all personnel com-
14 pensation and benefits paid with re-
15 spect to such positions for the first 3
16 years of the preceding 4 fiscal years,
17 multiplied by 0.60; and

18 “(II) the average annual change
19 that occurred in the Consumer Price
20 Index for urban consumers (Wash-
21 ington-Baltimore, DC–MD–VA–WV;
22 Not Seasonally Adjusted; All items;
23 Annual Index) for the first 3 years of
24 the preceding 4 years of available data
25 multiplied by 0.40.

1 “(ii) LIMITATIONS.—For purposes of
2 subparagraph (B), if the base inflation ad-
3 justment for a fiscal year under clause
4 (i)—

5 “(I) is less than 1, such adjust-
6 ment shall be considered to be equal
7 to 1; or

8 “(II) is greater than 1.04, such
9 adjustment shall be considered to be
10 equal to 1.04.

11 “(D) ADJUSTMENT TO BASE FEE
12 AMOUNTS.—For each of fiscal years 2014
13 through 2017, the base fee amounts specified in
14 subsection (b)(2) shall be adjusted as needed,
15 on a uniform proportionate basis, to generate
16 the total revenue amounts under subsection
17 (b)(3), as adjusted for inflation under subpara-
18 graph (A).

19 “(3) VOLUME-BASED ADJUSTMENTS TO ESTAB-
20 LISHMENT REGISTRATION BASE FEES.—For each of
21 fiscal years 2014 through 2017, after the base fee
22 amounts specified in subsection (b)(2) are adjusted
23 under paragraph (2)(D), the base establishment reg-
24 istration fee amounts specified in such subsection
25 shall be further adjusted, as the Secretary estimates

1 is necessary in order for total fee collections for such
2 fiscal year to generate the total revenue amounts, as
3 adjusted under paragraph (2).”.

4 (d) FEE WAIVER OR REDUCTION.—Section 738 of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379j) is amended by—

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

9 (2) by inserting after subsection (e) the fol-
10 lowing new subsection (f):

11 “(f) FEE WAIVER OR REDUCTION.—

12 “(1) IN GENERAL.—The Secretary may, at the
13 Secretary’s sole discretion, grant a waiver or reduc-
14 tion of fees under subsection (a)(2) or (a)(3) if the
15 Secretary finds that such waiver or reduction is in
16 the interest of public health.

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

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

24 (e) CONDITIONS.—Section 738(h)(1)(A) of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 379j(h)(1)(A)), as redesignated by subsection (d)(1), is
2 amended by striking “\$205,720,000” and inserting
3 “\$280,587,000”.

4 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
5 tion 738(i) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 379j(i)), as redesignated by subsection (d)(1),
7 is amended—

8 (1) in paragraph (1), by striking “Fees author-
9 ized” and inserting “Subject to paragraph (2)(C),
10 fees authorized”;

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in clause (i), by striking “shall be
14 retained” and inserting “subject to sub-
15 paragraph (C), shall be collected and avail-
16 able”; and

17 (ii) in clause (ii)—

18 (I) by striking “collected and”
19 after “shall only be”; and

20 (II) by striking “fiscal year
21 2002” and inserting “fiscal year
22 2009”; and

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

24 “(C) PROVISION FOR EARLY PAYMENTS.—

25 Payment of fees authorized under this section

1 for a fiscal year, prior to the due date for such
2 fees, may be accepted by the Secretary in ac-
3 cordance with authority provided in advance in
4 a prior year appropriations Act.”;

5 (3) in paragraph (3), by amending to read as
6 follows:

7 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—
8 For each of the fiscal years 2013 through 2017,
9 there is authorized to be appropriated for fees under
10 this section an amount equal to the total revenue
11 amount specified under subsection (b)(3) for the fis-
12 cal year, as adjusted under subsection (c) and, for
13 fiscal year 2017 only, as further adjusted under
14 paragraph (4).”; and

15 (4) in paragraph (4)—

16 (A) by striking “fiscal years 2008, 2009,
17 and 2010” and inserting “fiscal years 2013,
18 2014, and 2015”;

19 (B) by striking “fiscal year 2011” and in-
20 sserting “fiscal year 2016”;

21 (C) by striking “June 30, 2011” and in-
22 sserting “June 30, 2016”;

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

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

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

5 (g) CONFORMING AMENDMENT.—Section
6 515(e)(4)(A) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 360e(e)(4)(A)) is amended by striking
8 “738(g)” and inserting “738(h)”.

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

10 (a) REAUTHORIZATION.—Section 738A(b) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
12 1(b)) is amended—

13 (1) in paragraph (1), by striking “2012” and
14 inserting “2017”; and

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

17 (b) REPORTS.—Section 738A(a) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is amend-
19 ed by striking “2008 through 2012” each place it appears
20 and inserting “2013 through 2017”.

21 **SEC. 205. SAVINGS CLAUSE.**

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

1 title, shall continue to be in effect with respect to pre-
2 market applications, premarket reports, premarket notifi-
3 cation submissions, and supplements (as defined in such
4 part as of such day) that on or after October 1, 2007,
5 but before October 1, 2012, were accepted by the Food
6 and Drug Administration for filing with respect to assess-
7 ing and collecting any fee required by such part for a fiscal
8 year prior to fiscal year 2013.

9 **SEC. 206. EFFECTIVE DATE.**

10 The amendments made by this title shall take effect
11 on October 1, 2012, or the date of the enactment of this
12 Act, whichever is later, except that fees under part 3 of
13 subchapter C of chapter VII of the Federal Food, Drug,
14 and Cosmetic Act shall be assessed for all premarket ap-
15 plications, premarket reports, supplements, 30-day no-
16 tices, and premarket notification submissions received on
17 or after October 1, 2012, regardless of the date of the
18 enactment of this Act.

19 **SEC. 207. SUNSET CLAUSE.**

20 (a) **AUTHORIZATIONS.**—Sections 737 and 738 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;
22 739j) shall cease to be effective October 1, 2017.

23 (b) **REPORTING REQUIREMENTS.**—Section 738A of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 739j–1) shall cease to be effective January 31, 2018.

1 (c) PREVIOUS SUNSET PROVISION.—The Food and
2 Drug Administration Amendments Act of 2007 is amend-
3 ed by striking section 217.

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

7 Subchapter A of chapter VII of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
9 ed by inserting after section 713 the following new section:

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

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

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

24 “(c) OBJECTIVES SPECIFIED.—The objectives speci-
25 fied in this subsection are with respect to the activities

1 under subsection (b), the goals referred to in section
2 738A(a)(1).

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 III—FEES RELATING TO**
10 **GENERIC DRUGS**

11 **SEC. 301. SHORT TITLE.**

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

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

1 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
2 **NERIC DRUG FEES.**

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

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

6 **“SEC. 744A. DEFINITIONS.**

7 “For purposes of this part:

8 “(1) The term ‘abbreviated new drug applica-
9 tion’—

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

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

22 “(2) The term ‘active pharmaceutical ingre-
23 dient’ means—

24 “(A) a substance, or a mixture when the
25 substance is unstable or cannot be transported
26 on its own, intended—

1 “(i) to be used as a component of a
2 drug; and

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

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

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

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

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

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

3 “(5)(A) The term ‘facility’—

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

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

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

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

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

19 “(i) closely related to the same business
20 enterprise;

21 “(ii) under the supervision of the same
22 local management; and

23 “(iii) capable of being inspected by the
24 Food and Drug Administration during a single
25 inspection.

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

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

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

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

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

20 “(7) The term ‘generic drug submission’ means
21 an abbreviated new drug application, an amendment
22 to an abbreviated new drug application, or a prior
23 approval supplement to an abbreviated new drug ap-
24 plication.

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

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

9 “(B) The issuance of—

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

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

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

21 “(i) set forth in detail the specific de-
22 ficiencies in such submissions, and where
23 appropriate, the actions necessary to re-
24 solve those deficiencies; or

1 “(ii) document that no deficiencies
2 need to be addressed.

3 “(D) Inspections related to generic drugs.

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

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

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

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

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

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

1 those activities relate to abbreviated new
2 drug applications.

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

6 “(G) Regulatory science activities related
7 to generic drugs.

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

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

23 “(11) The term ‘resources allocated for human
24 generic drug activities’ means the expenses 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 and
5 employees and to contracts with such contrac-
6 tors;

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 subsection (a)
16 and accounting for resources allocated for the
17 review of abbreviated new drug applications and
18 supplements and inspection related to generic
19 drugs.

20 “(12) The term ‘Type II active pharmaceutical
21 ingredient drug master file’ means a submission of
22 information to the Secretary by a person that in-
23 tends to authorize the Food and Drug Administra-
24 tion to reference the information to support approval
25 of a generic drug submission without the submitter

1 having to disclose the information to the generic
2 drug submission applicant.

3 **“SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GE-**
4 **NERIC DRUG 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) ONE-TIME BACKLOG FEE FOR ABBRE-
9 VIATED NEW DRUG APPLICATIONS PENDING ON OC-
10 TOBER 1, 2012.—

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

18 “(B) METHOD OF FEE AMOUNT CALCULA-
19 TION.—The amount of each one-time backlog
20 fee shall be calculated by dividing \$50,000,000
21 by the total number of abbreviated new drug
22 applications pending on October 1, 2012, that
23 have not received a tentative approval as of that
24 date.

1 “(C) NOTICE.—Not later than October 31,
2 2012, the Secretary shall cause to be published
3 in the Federal Register a notice announcing the
4 amount of the fee required by subparagraph
5 (A).

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

10 “(2) DRUG MASTER FILE FEE.—

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

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

25 “(C) NOTICE.—

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

7 “(ii) FISCAL YEAR 2014 THROUGH
8 2017.—Not later than 60 days before the
9 start of each of fiscal years 2014 through
10 2017, the Secretary shall cause to be pub-
11 lished in the Federal Register the amount
12 of the drug master file fee established by
13 this paragraph for such fiscal year.

14 “(D) AVAILABILITY FOR REFERENCE.—

15 “(i) IN GENERAL.—Subject to sub-
16 section (g)(2)(C), for a generic drug sub-
17 mission to reference a Type II active phar-
18 maceutical ingredient drug master file, the
19 drug master file must be deemed available
20 for reference by the Secretary.

21 “(ii) CONDITIONS.—A drug master
22 file shall be deemed available for reference
23 by the Secretary if—

24 “(I) the person that owns a Type
25 II active pharmaceutical ingredient

1 drug master file has paid the fee re-
2 quired under subparagraph (A) within
3 20 calendar days after the applicable
4 due date under subparagraph (E);
5 and

6 “(II) the drug master file has not
7 failed an initial completeness assess-
8 ment by the Secretary, in accordance
9 with criteria to be published by the
10 Secretary.

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

20 “(E) FEE DUE DATE.—

21 “(i) IN GENERAL.—Subject to clause
22 (ii), a drug master file fee shall be due no
23 later than the date on which the first ge-
24 neric drug submission is submitted that

1 references the associated Type II active
2 pharmaceutical ingredient drug master file.

3 “(ii) LIMITATION.—No fee shall be
4 due under subparagraph (A) for a fiscal
5 year until the later of—

6 “(I) 30 calendar days after publi-
7 cation of the notice provided for in
8 clause (i) or (ii) of subparagraph (C),
9 as applicable; or

10 “(II) 30 calendar days after the
11 date of enactment of an appropria-
12 tions Act providing for the collection
13 and obligation of fees under this sec-
14 tion.

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

17 “(A) IN GENERAL.—Each applicant that
18 submits, on or after October 1, 2012, an abbrevi-
19 ated new drug application or a prior approval
20 supplement to an abbreviated new drug applica-
21 tion shall be subject to a fee for each such sub-
22 mission in the amount established under sub-
23 section (d).

24 “(B) NOTICE.—

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

7 “(ii) FISCAL YEARS 2014 THROUGH
8 2017.—Not later than 60 days before the
9 start of each of fiscal years 2014 through
10 2017, the Secretary shall cause to be pub-
11 lished in the Federal Register the amount
12 of the fees under subparagraph (A) for
13 such fiscal year.

14 “(C) FEE DUE DATE.—

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

22 “(ii) SPECIAL RULE FOR 2013.—For
23 fiscal year 2013, such fees shall be due on
24 the later of—

1 “(I) the date on which the fee is
2 due under clause (i);

3 “(II) 30 calendar days after pub-
4 lication of the notice referred to in
5 subparagraph (B)(i); or

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

15 “(D) REFUND OF FEE IF ABBREVIATED
16 NEW DRUG APPLICATION IS NOT CONSIDERED
17 TO HAVE BEEN RECEIVED.—The Secretary
18 shall refund 75 percent of the fee paid under
19 subparagraph (A) for any abbreviated new drug
20 application or prior approval supplement to an
21 abbreviated new drug application that the Sec-
22 retary considers not to have been received with-
23 in the meaning of section 505(j)(5)(A) for a
24 cause other than failure to pay fees.

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

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

22 “(i) such submission contains infor-
23 mation concerning the manufacture of an
24 active pharmaceutical ingredient at a facil-
25 ity by means other than reference by a let-

1 ter of authorization to a Type II active
2 pharmaceutical drug master file; and

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

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

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

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

24 “(ii) ACTIVE PHARMACEUTICAL IN-
25 GREDIENT FACILITY.—Each person that

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

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

23 “(B) AMOUNT.—The amount of fees estab-
24 lished under subparagraph (A) shall be estab-
25 lished under subsection (d).

1 “(C) NOTICE.—

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

9 “(ii) FISCAL YEARS 2014 THROUGH
10 2017.—Within the timeframe specified in
11 subsection (d)(2), the Secretary shall cause
12 to be published in the Federal Register the
13 amount of the fees under subparagraph
14 (A) for such fiscal year.

15 “(D) FREE DUE DATE.—

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

19 “(I) not later than 45 days after
20 the publication of the notice under
21 subparagraph (B); or

22 “(II) if an appropriations Act is
23 not enacted providing for the collec-
24 tion and obligation of fees under this
25 section by the date of the publication

1 of such notice, 30 days after the date
2 that such an appropriations Act is en-
3 acted.

4 “(ii) FISCAL YEARS 2014 THROUGH
5 2017.—For each of fiscal years 2014
6 through 2017, the fees under subpara-
7 graph (A) for such fiscal year shall be due
8 on the later of—

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

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

16 “(5) DATE OF SUBMISSION.—For purposes of
17 this Act, a generic drug submission or Type II phar-
18 maceutical master file is deemed to be ‘submitted’ to
19 the Food and Drug Administration—

20 “(A) if it is submitted via a Food and
21 Drug Administration electronic gateway, on the
22 day when transmission to that electronic gate-
23 way is completed, except that a submission or
24 master file that arrives on a weekend, Federal
25 holiday, or day when the Food and Drug Ad-

1 ministration office that will review that submis-
2 sion is not otherwise open for business shall be
3 deemed to be submitted on the next day when
4 that office is open for business; or

5 “(B) if it is submitted in physical media
6 form, on the day it arrives at the appropriate
7 designated document room of the Food and
8 Drug Administration.

9 “(b) FEE REVENUE AMOUNTS.—

10 “(1) IN GENERAL.—

11 “(A) FISCAL YEAR 2013.—For fiscal year
12 2013, fees under subsection (a) except as pro-
13 vided in subsection (o) (relating to waivers)
14 shall be established to generate a total esti-
15 mated revenue amount under such subsection of
16 \$299,000,000. Of that amount—

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

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

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

25 For each of the fiscal years 2014 through 2017,

1 fees under paragraphs (2) through (4) of sub-
2 section (a) shall be established to generate a
3 total estimated revenue amount under such sub-
4 section that is equal to \$299,000,000, as ad-
5 justed pursuant to subsection (c).

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

13 “(A) 6 percent shall be derived from fees
14 under subsection (a)(2) (relating to drug mas-
15 ter files).

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

22 “(C) 56 percent shall be derived from fees
23 under subsection (a)(4)(A)(i) (relating to ge-
24 neric drug facilities). The amount of the fee for
25 a facility located outside the United States and

1 its territories and possessions shall be not less
2 than \$15,000 and not more than \$30,000 high-
3 er than the amount of the fee for a facility lo-
4 cated in the United States and its territories
5 and possessions, as determined by the Secretary
6 on the basis of data concerning the difference
7 in cost between inspections of facilities located
8 in the United States, including its territories
9 and possessions, and those located outside of
10 the United States and its territories and posses-
11 sions.

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

1 those located outside of the United States and
2 its territories and possessions.

3 “(c) ADJUSTMENTS.—

4 “(1) INFLATION ADJUSTMENT.—For fiscal year
5 2014 and subsequent fiscal years, the revenues es-
6 tablished in subsection (b) shall be adjusted by the
7 Secretary by notice, published in the Federal Reg-
8 ister, for a fiscal year, by an amount equal to the
9 sum of—

10 “(A) one;

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

21 “(C) the average annual change that oc-
22 curred in the Consumer Price Index for urban
23 consumers (Washington-Baltimore, DC–MD–
24 VA–WV; Not Seasonally Adjusted; All items;
25 Annual Index) for the first 3 years of the pre-

1 ceding 4 years of available data multiplied by
2 the proportion of all costs other than personnel
3 compensation and benefits costs to total costs
4 of human generic drug activities for the first 3
5 years of the preceding 4 fiscal years.

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

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

1 “(d) ANNUAL FEE SETTING.—

2 “(1) FISCAL YEAR 2013.—For fiscal year
3 2013—

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

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

19 “(2) FISCAL YEARS 2014 THROUGH 2017.—Not
20 more than 60 days before the first day of each of
21 fiscal years 2014 through 2017, the Secretary shall
22 establish the drug master file fee, the abbreviated
23 new drug application fee, the prior approval supple-
24 ment fee, the generic drug facility fee, and the active
25 pharmaceutical ingredient facility fee under sub-

1 section (a) for such fiscal year, based on the revenue
2 amounts established under subsection (b) and the
3 adjustments provided under subsection (c).

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

11 “(A) the sum of—

12 “(i) the total number of such active
13 pharmaceutical ingredients in such submis-
14 sion; and

15 “(ii) for each such ingredient that is
16 manufactured at more than one such facil-
17 ity, the total number of such additional fa-
18 cilities; and

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

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

1 “(f) IDENTIFICATION OF FACILITIES.—

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

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

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

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

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

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

10 “(B) whether the facility manufactures ac-
11 tive pharmaceutical ingredients or finished dos-
12 age forms, or both;

13 “(C) whether or not the facility is located
14 within the United States and its territories and
15 possessions;

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

19 “(E) whether the facility manufactures
20 drugs that are not generic drugs.

21 “(4) CERTAIN SITES AND ORGANIZATIONS.—

22 “(A) IN GENERAL.—Any person that owns
23 or operates a site or organization described in
24 subparagraph (B) shall submit to the Secretary

1 information concerning the ownership, name,
2 and address of the site or organization.

3 “(B) SITES AND ORGANIZATIONS.—A site
4 or organization is described in this subpara-
5 graph if it is identified in a generic drug sub-
6 mission and is—

7 “(i) a site in which a bioanalytical
8 study is conducted;

9 “(ii) a clinical research organization;

10 “(iii) a contract analytical testing site;

11 or

12 “(iv) a contract repackager site.

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

20 “(D) INSPECTION AUTHORITY.—The Sec-
21 retary’s inspection authority under section
22 704(a)(1) shall extend to all such sites and or-
23 ganizations.

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

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

11 “(2) DRUG MASTER FILE FEE.—

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

19 “(B)(i) Any generic drug submission sub-
20 mitted on or after October 1, 2012, that ref-
21 erences, by a letter of authorization, a Type II
22 active pharmaceutical ingredient drug master
23 file that has not been deemed available for ref-
24 erence shall not be received within the meaning

1 of section 505(j)(5)(A) unless the condition
2 specified in clause (ii) is met.

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

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

23 “(ii) If such fee is not paid within 20 cal-
24 endar days of the Secretary providing the noti-
25 fication, the abbreviated new drug application

1 or supplement to an abbreviated new drug ap-
2 plication shall not be received within the mean-
3 ing of 505(j)(5)(A).

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

14 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
15 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

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

21 “(i) The Secretary shall place the fa-
22 cility on a publicly available arrears list,
23 such that no new abbreviated new drug ap-
24 plication or supplement submitted on or
25 after October 1, 2012, from the person

1 that is responsible for paying such fee, or
2 any affiliate of that person, will be received
3 within the meaning of section 505(j)(5)(A).

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

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

19 “(B) APPLICATION OF PENALTIES.—The
20 penalties under this paragraph shall apply until
21 the fee established by subsection (a)(4) is paid
22 or the facility is removed from all generic drug
23 submissions that refer to the facility.

24 “(C) NONRECEIVAL FOR NONPAYMENT.—

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

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

19 “(h) LIMITATIONS.—

20 “(1) IN GENERAL.—Fees under subsection (a)
21 shall be refunded for a fiscal year beginning after
22 fiscal year 2012, unless appropriations for salaries
23 and expenses of the Food and Drug Administration
24 for such fiscal year (excluding the amount of fees
25 appropriated for such fiscal year) are equal to or

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

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

19 “(i) 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 appropriations Acts, subject to para-
24 graph (2). Such fees are authorized to remain avail-
25 able until expended. Such sums as may be necessary

1 may be transferred from the Food and Drug Admin-
2 istration salaries and expenses appropriation account
3 without fiscal year limitation to such appropriation
4 account for salaries and expenses with such fiscal
5 year limitation. The sums transferred shall be avail-
6 able solely for human generic drug activities.

7 “(2) COLLECTIONS AND APPROPRIATION
8 ACTS.—

9 “(A) IN GENERAL.—The fees authorized
10 by this section—

11 “(i) subject to subparagraphs (C) and
12 (D), shall be collected and available in each
13 fiscal 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 be available for a fiscal year
18 beginning after fiscal year 2012 to defray
19 the costs of human generic drug activities
20 (including such costs for an additional
21 number of full-time equivalent positions in
22 the Department of Health and Human
23 Services to be engaged in such activities),
24 only if the Secretary allocates for such
25 purpose an amount for such fiscal year

1 (excluding amounts from fees collected
2 under this section) no less than
3 \$97,000,000 multiplied by the adjustment
4 factor defined in subsection (p)(3) applica-
5 ble to the fiscal year involved.

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

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

22 “(D) PROVISION FOR EARLY PAYMENTS IN
23 SUBSEQUENT YEARS.—Payment of fees author-
24 ized under this section for a fiscal year (after
25 fiscal year 2013), prior to the due date for such

1 fees, may be accepted by the Secretary in ac-
2 cordance with authority provided in advance in
3 a prior year appropriations Act.

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

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

18 “(k) 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, employees, and advisory committees not
22 engaged in human generic drug activities, be reduced to
23 offset the number of officers, employees, and advisory
24 committees so engaged.

25 “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

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

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

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

19 “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—
20 An abbreviated new drug application that is not consid-
21 ered to be received within the meaning of section
22 505(j)(5)(A) because of failure to pay an applicable fee
23 under this provision within the time period specified in
24 subsection (g) shall be deemed not to have been ‘substan-
25 tially complete’ on the date of its submission within the

1 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbrevi-
2 viated new drug application that is not substantially com-
3 plete on the date of its submission solely because of failure
4 to pay an applicable fee under the preceding sentence shall
5 be deemed substantially complete and received within the
6 meaning of section 505(j)(5)(A) as of the date such appli-
7 cable fee is received.”.

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

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

12 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**
13 **MENTS.**

14 “(a) **PERFORMANCE REPORT.**—Beginning with fiscal
15 year 2013, not later than 120 days after the end of each
16 fiscal year for which fees are collected under this part,
17 the Secretary shall prepare and submit to the Committee
18 on Energy and Commerce of the House of Representatives
19 and the Committee on Health, Education, Labor, and
20 Pensions of the Senate a report concerning the progress
21 of the Food and Drug Administration in achieving the
22 goals identified in the letters described in section 301(b)
23 of the Generic Drug User Fee Amendments of 2012 dur-
24 ing such fiscal year and the future plans of the Food and
25 Drug Administration for meeting the goals.

1 “(b) FISCAL REPORT.—Beginning with fiscal year
2 2013, not later than 120 days after the end of each fiscal
3 year for which fees are collected under this part, the Sec-
4 retary shall prepare and submit to the Committee on En-
5 ergy and Commerce of the House of Representatives and
6 the Committee on Health, Education, Labor, and Pen-
7 sions of the Senate a report on the implementation of the
8 authority for such fees during such fiscal year and the
9 use, by the Food and Drug Administration, of the fees
10 collected for such fiscal year.

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

15 “(d) REAUTHORIZATION.—

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

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

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

3 “(C) scientific and academic experts;

4 “(D) health care professionals;

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

7 “(F) the generic drug industry.

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

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

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

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

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

23 “(3) PERIODIC CONSULTATION.—Not less fre-
24 quently than once every month during negotiations
25 with the generic drug industry, the Secretary shall

1 hold discussions with representatives of patient and
2 consumer advocacy groups to continue discussions of
3 their views on the reauthorization and their sugges-
4 tions for changes to this part as expressed under
5 paragraph (2).

6 “(4) PUBLIC REVIEW OF RECOMMENDA-
7 TIONS.—After negotiations with the generic drug in-
8 dustry, the Secretary shall—

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

12 “(B) publish such recommendations in the
13 Federal Register;

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

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

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

23 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
24 Not later than January 15, 2017, the Secretary
25 shall transmit to the Congress the revised rec-

1 ommendations under paragraph (4), a summary of
2 the views and comments received under such para-
3 graph, and any changes made to the recommenda-
4 tions in response to such views and comments.

5 “(6) MINUTES OF NEGOTIATION MEETINGS.—

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

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

21 **SEC. 304. SUNSET DATES.**

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

1 (b) REPORTING REQUIREMENTS.—The amendments
2 made by section 303 cease to be effective January 31,
3 2018.

4 **SEC. 305. EFFECTIVE DATE.**

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

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

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

15 “(aa) If it is a drug, or an active pharmaceutical in-
16 gredient, and it was manufactured, prepared, propagated,
17 compounded, or processed in a facility for which fees have
18 not been paid as required by section 744A(a)(4) or for
19 which identifying information required by section 744B(f)
20 has not been submitted, or it contains an active pharma-
21 ceutical ingredient that was manufactured, prepared,
22 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 “(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 pa-
22 ragraph (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), each person that is named
19 as the applicant in a biosimilar biological prod-
20 uct application shall be assessed an annual fee
21 established under subsection (b)(1)(E) for each
22 biosimilar biological product establishment that
23 is listed in the approved biosimilar biological
24 product application as an establishment that

1 manufactures the biosimilar biological product
2 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—PEDIATRIC**
5 **REAUTHORIZATIONS**

6 **SEC. 501. SENSE OF THE SENATE REGARDING REAUTHOR-**
7 **IZATION OF VITAL PEDIATRIC LAWS.**

8 (a) FINDINGS.—The Senate finds as follows:

9 (1) Since 1997, the Pediatric Rule, the Best
10 Pharmaceuticals for Children Act (Public Law 107–
11 109), and the Pediatric Research Equity Act of
12 2003 (Public Law 108–155) have resulted in 427
13 drug labeling changes that have included important
14 pediatric information about the safety and effective-
15 ness of drugs used in children.

16 (2) Before the Best Pharmaceuticals for Chil-
17 dren Act and the Pediatric Research Equity Act of
18 2003 more than 80 percent of drugs used in chil-
19 dren lacked sufficient information or labeling for pe-
20 diatric use, but today that number has been dra-
21 matically reduced in most pediatric subpopulations.

22 (3) The lives of children with cancer, HIV/
23 AIDS, diabetes, allergy and asthma, juvenile arthri-
24 tis, and many other conditions have been saved and
25 improved as a result of the data and labeling
26 changes generated by the Best Pharmaceuticals for

1 Children Act and the Pediatric Research Equity Act
2 of 2003.

3 (4) There is bipartisan legislation that would
4 renew and strengthen these laws by improving the
5 timing, quality, and transparency of pediatric drug
6 research and that would continue promising research
7 of older, off-patent drugs at the National Institutes
8 of Health.

9 (5) Such bipartisan legislation would also renew
10 and extend a successful pediatric incentive for med-
11 ical devices designed specifically for children and a
12 Pediatric Device Consortia initiative.

13 (b) SENSE OF THE SENATE.—It is the sense of the
14 Senate that Congress should reauthorize the Best Phar-
15 maceuticals for Children Act, the Pediatric Research Eq-
16 uity Act of 2003, and the Pediatric Medical Device Safety
17 and Improvement Act of 2007 as part of the comprehen-
18 sive Food and Drug Administration user fee legislation.

19 **TITLE VI—MEDICAL DEVICE**
20 **REGULATORY IMPROVEMENTS**

21 **SEC. 601. RECLASSIFICATION PROCEDURES.**

22 (a) CLASSIFICATION CHANGES.—

23 (1) IN GENERAL.—Section 513(e)(1) (21
24 U.S.C. 360e(e)(1)) is amended to read as follows:

1 “(e)(1)(A) Based on new information respecting a de-
2 vice, the Secretary may, upon the initiative of the Sec-
3 retary or upon petition of an interested person, change
4 the classification of such device, and revoke, on account
5 of the change in classification, any regulation or require-
6 ment in effect under section 514 or 515 with respect to
7 such device, by administrative order published in the Fed-
8 eral Register following publication of a proposed reclassi-
9 fication order in the Federal Register, a meeting of a de-
10 vice classification panel described in subsection (b), and
11 consideration of comments to a public docket, notwith-
12 standing subchapter II of Chapter 5 of title 5 of the
13 United States Code. An order under this subsection
14 changing the classification of a device from class III to
15 class II may provide that such classification shall not take
16 effect until the effective date of a performance standard
17 established under section 514 for such device.

18 “(B) Authority to issue such administrative order
19 shall not be delegated below the Commissioner. The Com-
20 missioner shall issue such an order as proposed by the Di-
21 rector of the Center for Devices and Radiological Health
22 unless the Commissioner, in consultation with the Office
23 of the Secretary of Health and Human Services, concludes
24 that the order exceeds the legal authority of the Food and

1 Drug Administration or that the order would be lawful,
2 but unlikely to advance the public health.”.

3 (2) TECHNICAL AND CONFORMING AMEND-
4 MENTS.—

5 (A) Section 513(e)(2) (21 U.S.C.
6 360c(e)(2)) is amended by striking “regulation
7 promulgated” and inserting “an order issued”.

8 (B) Section 514(a)(1) (21 U.S.C.
9 360d(a)(1)) is amended in paragraph (1), by
10 striking “under a regulation under section
11 513(e) but such regulation” and inserting
12 “under an administrative order under section
13 513(e) (or a regulation promulgated under such
14 section prior to the date of enactment of the
15 Food and Drug Administration Safety and In-
16 novation Act) but such order (or regulation)”;

17 (C) Section 517(a)(1) (21 U.S.C. 360g(a))
18 is amended by striking “or changing the classi-
19 fication of a device to class I” and inserting “,
20 an administrative order changing the classifica-
21 tion of a device to class I,”.

22 (3) DEVICES RECLASSIFIED PRIOR TO THE
23 DATE OF ENACTMENT OF THIS ACT.—

24 (A) IN GENERAL.—The amendments made
25 by this subsection shall have no effect on a reg-

1 ulation promulgated with respect to the classi-
2 fication of a device under section 513(e) of the
3 Federal Food, Drug, and Cosmetic Act prior to
4 the date of enactment of this Act.

5 (B) APPLICABILITY OF OTHER PROVI-
6 SIONS.—In the case of a device reclassified
7 under section 513(e) of the Federal Food,
8 Drug, and Cosmetic Act by regulation prior to
9 the date of enactment of this Act, section
10 517(a)(1) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 360g(a)(1)) shall apply to
12 such regulation promulgated under section
13 513(e) of such Act with respect to such device
14 in the same manner such section 517(a)(1) ap-
15 plies to an administrative order issued with re-
16 spect to a device reclassified after the date of
17 enactment of this Act.

18 (b) DEVICES MARKETED BEFORE MAY 28, 1976.—

19 (1) PREMARKET APPROVAL.—Section 515 (21
20 U.S.C. 360e) is amended—

21 (A) in subsection (a), by striking “regula-
22 tion promulgated under subsection (b)” and in-
23 serting “an order issued under subsection (b)
24 (or a regulation promulgated under such sub-
25 section prior to the date of enactment of the

1 Food and Drug Administration Safety and In-
2 novation Act)”;

3 (B) in subsection (b)—

4 (i) in paragraph (1)—

5 (I) in the heading, by striking
6 “Regulation” and inserting “Order”;
7 and

8 (II) in the matter following sub-
9 paragraph (B)—

10 (aa) by striking “by regula-
11 tion, promulgated in accordance
12 with this subsection” and insert-
13 ing “by administrative order fol-
14 lowing publication of a proposed
15 order in the Federal Register, a
16 meeting of a device classification
17 panel described in section 513(b),
18 and consideration of comments
19 from all affected stakeholders, in-
20 cluding patients, payors, and pro-
21 viders, notwithstanding sub-
22 chapter II of chapter 5 of title 5,
23 United States Code,”; and

24 (bb) by adding at the end
25 the following:

1 “Authority to issue such administrative order shall not be
2 delegated below the Commissioner. Before publishing such
3 administrative order, the Commissioner shall consult with
4 the Office of the Secretary of Health and Human Services.
5 The Commissioner shall issue such an order as proposed
6 by the Director of the Center for Devices and Radiological
7 Health unless the Commissioner, in consultation with the
8 Office of the Secretary of Health and Human Services,
9 concludes that the order exceeds the legal authority of the
10 Food and Drug Administration or that the order would
11 be lawful, but unlikely to advance the public health.”;

12 (ii) in paragraph (2)—

13 (I) by striking subparagraph (B);

14 and

15 (II) in subparagraph (A)—

16 (aa) by striking “(2)(A) A
17 proceeding for the promulgation
18 of a regulation under paragraph
19 (1) respecting a device shall be
20 initiated by the publication in the
21 Federal Register of a notice of
22 proposed rulemaking. Such notice
23 shall contain—” and inserting
24 “(2) A proposed order required

1 under paragraph (1) shall con-
2 tain—”;

3 (bb) by redesignating
4 clauses (i) through (iv) as sub-
5 paragraphs (A) through (D), re-
6 spectively;

7 (cc) in subparagraph (A), as
8 so redesignated, by striking “reg-
9 ulation” and inserting “order”;
10 and

11 (dd) in subparagraph (C), as
12 so redesignated, by striking “reg-
13 ulation” and inserting “order”;
14 and

15 (iii) in paragraph (3)—

16 (I) by striking “proposed regula-
17 tion” each place such term appears
18 and inserting “proposed order”;

19 (II) by striking “paragraph (2)
20 and after” and inserting “paragraph
21 (2),”;

22 (III) by inserting “and a meeting
23 of a device classification panel de-
24 scribed in section 513(b),” after “such
25 proposed regulation and findings,”;

1 (IV) by striking “(A) promulgate
2 such regulation” and inserting “(A)
3 issue an administrative order under
4 paragraph (1)”;

5 (V) by striking “paragraph
6 (2)(A)(ii)” and inserting “paragraph
7 (2)(B)”;

8 (VI) by striking “promulgation of
9 the regulation” and inserting
10 “issuance of the administrative
11 order”;

12 (iv) by striking paragraph (4); and

13 (C) in subsection (i)—

14 (i) in paragraph (2)—

15 (I) in the matter preceding sub-
16 paragraph (A)—

17 (aa) by striking “December
18 1, 1995” and inserting “the date
19 that is 2 years after the date of
20 enactment of the Food and Drug
21 Administration Safety and Inno-
22 vation Act”;

23 (bb) by striking “publish a
24 regulation in the Federal Reg-
25 ister” and inserting “issue an ad-

1 administrative order following pub-
2 lication of a proposed order in
3 the Federal Register, a meeting
4 of a device classification panel
5 described in section 513(b), and
6 consideration of comments from
7 all affected stakeholders, includ-
8 ing patients, payors, and pro-
9 viders, notwithstanding sub-
10 chapter II of chapter 5 of title 5,
11 United States Code,”;

12 (II) in subparagraph (B) by
13 striking “final regulation has been
14 promulgated under section 515(b)”
15 and inserting “administrative order
16 has been issued under subsection (b)
17 (or no regulation has been promul-
18 gated under such subsection prior to
19 the date of enactment of the Food
20 and Drug Administration Safety and
21 Innovation Act)”;

22 (III) in the matter following sub-
23 paragraph (B), by striking “regula-
24 tion requires” and inserting “adminis-

1 trative order issued under this para-
2 graph requires”; and

3 (IV) by striking the third and
4 fourth sentences; and

5 (ii) in paragraph (3)—

6 (I) by striking “regulation requir-
7 ing” each place such term appears
8 and inserting “order requiring”; and

9 (II) by striking “promulgation of
10 a section 515(b) regulation” and in-
11 sserting “issuance of an administrative
12 order under subsection (b)”.

13 (2) TECHNICAL AND CONFORMING AMEND-
14 MENTS.—Section 501(f) (21 U.S.C. 351) is amend-
15 ed—

16 (A) in subparagraph (1)(A)—

17 (i) in subclause (i), by striking “a reg-
18 ulation promulgated” and inserting “an
19 order issued”; and

20 (ii) in subclause (ii), by striking “pro-
21 mulgation of such regulation” and insert-
22 ing “issuance of such order”;

23 (B) in subparagraph (2)(B)—

1 (i) by striking “a regulation promul-
2 gated” and inserting “an order issued”;
3 and

4 (ii) by striking “promulgation of such
5 regulation” and inserting “issuance of
6 such order”; and

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

8 “(3) In the case of a device with respect to
9 which a regulation was promulgated under section
10 515(b) prior to the date of enactment of the Food
11 and Drug Administration Safety and Innovation Act,
12 a reference in this subsection to an order issued
13 under section 515(b) shall be deemed to include such
14 regulation.”.

15 (3) APPROVAL BY REGULATION PRIOR TO THE
16 DATE OF ENACTMENT OF THIS ACT.—The amend-
17 ments made by this subsection shall have no effect
18 on a regulation that was promulgated prior to the
19 date of enactment of this Act requiring that a device
20 have an approval under section 515 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of
22 an application for premarket approval.

23 (c) REPORTING.—The Secretary of Health and
24 Human Services shall annually post on the Internet web
25 site of the Food and Drug Administration—

1 (1) the number and type of class I and class II
2 devices reclassified as class II or class III in the pre-
3 vious calendar year under section 513(e)(1) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 360e(e)(1));

6 (2) the number and type of class II and class
7 III devices reclassified as class I or class II in the
8 previous calendar year under such section 513(e)(1);
9 and

10 (3) the number and type of devices reclassified
11 in the previous calendar year under section 515.

12 **SEC. 602. CONDITION OF APPROVAL STUDIES.**

13 Section 515(d)(1)(B)(ii) (21 U.S.C.
14 360e(d)(1)(B)(ii)) is amended—

15 (1) by striking “(ii)” and inserting “(ii)(I)”;
16 and

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

18 “(II) An order approving an application for a device
19 may require as a condition to such approval that the appli-
20 cant conduct a postmarket study regarding the device.”.

21 **SEC. 603. POSTMARKET SURVEILLANCE.**

22 Section 522 (21 U.S.C. 360l) is amended—

23 (1) in subsection (a)(1)(A), in the matter pre-
24 ceding clause (i), by inserting “, at the time of ap-

1 proval or clearance of a device or at any time there-
2 after,” after “by order”; and

3 (2) in subsection (b)(1), by inserting “The
4 manufacturer shall commence surveillance under this
5 section not later than 15 months after the day on
6 which the Secretary issues an order under this sec-
7 tion.” after the second sentence.

8 **SEC. 604. SENTINEL.**

9 Section 519 (21 U.S.C. 360i) is amended by adding
10 at the end the following:

11 “(h) INCLUSION OF DEVICES IN THE POSTMARKET
12 RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

13 “(1) IN GENERAL.—

14 “(A) APPLICATION TO DEVICES.—The Sec-
15 retary shall amend the procedures established
16 and maintained under clauses (i), (ii), (iii), and
17 (v) of section 505(k)(3)(C) in order to expand
18 the postmarket risk identification and analysis
19 system established under such section to include
20 and apply to devices.

21 “(B) EXCEPTION.—Clause (i)(II) of sec-
22 tion 505(k)(3)(C) shall not apply to devices.

23 “(C) CLARIFICATION.—With respect to de-
24 vices, the private sector health-related electronic
25 data provided under section

1 505(k)(3)(C)(i)(III)(bb) may include medical
2 device utilization data, health insurance claims
3 data, and procedure and device registries.

4 “(2) DATA.—In expanding the system as de-
5 scribed in subsection (a), the Secretary shall use rel-
6 evant data with respect to devices cleared under sec-
7 tion 510(k) or approved under section 515, including
8 claims data, patient survey data, and any other data
9 deemed appropriate by the Secretary.

10 “(3) STAKEHOLDER INPUT.—To help ensure ef-
11 fective implementation of the system described in
12 subsection (a), the Secretary shall engage outside
13 stakeholders in development of the system through a
14 public hearing, advisory committee meeting, public
15 docket, or other like measures, as appropriate.

16 “(4) VOLUNTARY SURVEYS.—Chapter 35 of
17 title 44, United States Code, shall not apply to the
18 collection of voluntary information from health care
19 providers, such as voluntary surveys or question-
20 naires, initiated by the Secretary for purposes of
21 postmarket risk identification for devices.”.

22 **SEC. 605. RECALLS.**

23 (a) ASSESSMENT OF DEVICE RECALL INFORMA-
24 TION.—

25 (1) IN GENERAL.—

1 (A) ASSESSMENT PROGRAM.—The Sec-
2 retary of Health and Human Services (referred
3 to in this section as the “Secretary”) shall en-
4 hance the Food and Drug Administration’s re-
5 call program to routinely and systematically as-
6 sess—

7 (i) information submitted to the Sec-
8 retary pursuant to a device recall order
9 under section 518(e) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C.
11 360h(e)); and

12 (ii) information required to be re-
13 ported to the Secretary regarding a correc-
14 tion or removal of a device under section
15 519(g) of such Act (21 U.S.C. 360i(g)).

16 (B) USE.—The Secretary shall use the as-
17 sessment of information described under sub-
18 paragraph (A) to proactively identify strategies
19 for mitigating health risks presented by defec-
20 tive or unsafe devices.

21 (2) DESIGN.—The program under paragraph
22 (1) shall, at a minimum, identify—

23 (A) trends in the numbers and types of de-
24 vice recalls;

1 (B) the types of devices in each device
2 class that are most frequently recalled;

3 (C) the causes of device recalls; and

4 (D) any other information as the Secretary
5 determines appropriate.

6 (b) AUDIT CHECK PROCEDURES.—The Secretary
7 shall clarify procedures for conducting device recall audit
8 checks to improve the ability of investigators to perform
9 these checks in a consistent manner.

10 (c) ASSESSMENT CRITERIA.—The Secretary shall de-
11 velop explicit criteria for assessing whether a person sub-
12 ject to a recall order under section 518(e) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to
14 a requirement under section 519(g) of such Act (21
15 U.S.C. 360i(g)) has performed an effective correction or
16 removal action under such section 519(g).

17 (d) TERMINATION OF RECALLS.—The Secretary shall
18 document the basis for the termination by the Food and
19 Drug Administration of—

20 (1) an individual device recall ordered under
21 section 518(e) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360h(e)); and

23 (2) any correction or removal action for which
24 a report is required to be submitted to the Secretary

1 under section 519(g) of such Act (21 U.S.C.
2 360i(g)).

3 **SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE**
4 **EXEMPTIONS.**

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

7 “(8)(A) At any time, the Secretary may prohibit the
8 sponsor of an investigation from conducting the investiga-
9 tion (referred to in this paragraph as a ‘clinical hold’) if
10 the Secretary makes a determination described in sub-
11 paragraph (B). The Secretary shall specify the basis for
12 the clinical hold, including the specific information avail-
13 able to the Secretary which served as the basis for such
14 clinical hold, and confirm such determination in writing.

15 “(B) For purposes of subparagraph (A), a determina-
16 tion described in this subparagraph with respect to a clin-
17 ical hold is that—

18 “(i) the device involved represents an unreason-
19 able risk to the safety of the persons who are the
20 subjects of the clinical investigation, taking into ac-
21 count the qualifications of the clinical investigators,
22 information about the device, the design of the clin-
23 ical investigation, the condition for which the device
24 is to be investigated, and the health status of the
25 subjects involved; or

1 “(ii) the clinical hold should be issued for such
2 other reasons as the Secretary may by regulation es-
3 tablish.

4 “(C) Any written request to the Secretary from the
5 sponsor of an investigation that a clinical hold be removed
6 shall receive a decision, in writing and specifying the rea-
7 sons therefor, within 30 days after receipt of such request.
8 Any such request shall include sufficient information to
9 support the removal of such clinical hold.”.

10 **SEC. 607. UNIQUE DEVICE IDENTIFIER.**

11 Section 519(f) (21 U.S.C. 360i(f)) is amended—

12 (1) by striking “The Secretary shall promul-
13 gate” and inserting “Not later than December 31,
14 2012, the Secretary shall issue final”; and

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

16 “The Secretary shall implement the unique device identi-
17 fication system under this subsection as soon as prac-
18 ticable.”.

19 **SEC. 608. CLARIFICATION OF LEAST BURDENSOME STAND-**
20 **ARD.**

21 (a) **PREMARKET APPROVAL.**—Section 513(a)(3)(D)
22 (21 U.S.C. 360c(a)(3)(D)) is amended—

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

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

1 “(iii) For purposes of clause (ii) , the
2 term ‘necessary’ means the minimum re-
3 quired information that would support a
4 determination by the Secretary that an ap-
5 plication provides reasonable assurance of
6 the effectiveness of the device.

7 “(iv) Nothing in this subparagraph
8 shall alter the criteria for evaluating an
9 application for premarket approval of a de-
10 vice.”.

11 (b) PREMARKET NOTIFICATION UNDER SECTION
12 510(K).—Section 513(i)(1)(D) (21 U.S.C. 360e(i)(1)(D))
13 is amended—

14 (1) by striking “(D) Whenever” and inserting
15 “(D)(i) Whenever”; and

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

17 “(ii) For purposes of clause (i), the term ‘necessary’
18 means the minimum required information that would sup-
19 port a determination of substantial equivalence between
20 a new device and a predicate device.

21 “(iii) Nothing in this subparagraph shall alter the
22 standard for determining substantial equivalence between
23 a new device and a predicate device.”.

1 **SEC. 609. AGENCY DOCUMENTATION AND REVIEW OF CER-**
2 **TAIN DECISIONS REGARDING DEVICES.**

3 Chapter V (21 U.S.C. 351 et seq.) is amended by
4 inserting after section 517 the following:

5 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**
6 **CERTAIN DECISIONS REGARDING DEVICES.**

7 “(a) DOCUMENTATION OF RATIONALE FOR DE-
8 NIAL.—If the Secretary renders a final decision to deny
9 clearance of a premarket notification under section 510(k)
10 or approval of a premarket application under section 515,
11 or when the Secretary disapproves an application for an
12 investigational exemption under 520(g), the written cor-
13 respondence to the applicant communicating that decision
14 shall provide a substantive summary of the scientific and
15 regulatory rationale for the decision.

16 “(b) REVIEW OF DENIAL.—

17 “(1) IN GENERAL.—A person who has sub-
18 mitted a report under section 510(k), an application
19 under section 515, or an application for an exemp-
20 tion under section 520(g) and for whom clearance of
21 the report or approval of the application is denied
22 may request a supervisory review of the decision to
23 deny such clearance or approval. Such review shall
24 be conducted by an individual at the organizational
25 level above the organization level at which the deci-

1 sion to deny the clearance of the report or approval
2 of the application is made.

3 “(2) SUBMISSION OF REQUEST.—A person re-
4 questing a supervisory review under paragraph (1)
5 shall submit such request to the Secretary not later
6 than 30 days after such denial and shall indicate in
7 the request whether such person seeks an in-person
8 meeting or a teleconference review.

9 “(3) TIMEFRAME.—

10 “(A) IN GENERAL.—Except as provided in
11 subparagraph (B), the Secretary shall schedule
12 an in-person or teleconference review, if so re-
13 quested, not later than 30 days after such re-
14 quest is made. The Secretary shall issue a deci-
15 sion to the person requesting a review under
16 this subsection not later than 45 days after the
17 request is made under paragraph (1), or, in the
18 case of a person who requests an in-person
19 meeting or teleconference, 30 days after such
20 meeting or teleconference.

21 “(B) EXCEPTION.—Subparagraph (A)
22 shall not apply in cases that involve consulta-
23 tion with experts outside of the Food and Drug
24 Administration, or in cases in which the spon-
25 sor seeks to introduce evidence not already in

1 the administrative record at the time the denial
 2 decision was made.”.

3 **SEC. 610. GOOD GUIDANCE PRACTICES RELATING TO DE-**
 4 **VICES.**

5 Subparagraph C of section 701(h)(1) (21 U.S.C.
 6 371(h)(1)) is amended—

7 (1) by striking “(C) For guidance documents”
 8 and inserting “(C)(i) For guidance documents”; and
 9 (2) by adding at the end the following:

10 “(ii) With respect to devices, if a notice to in-
 11 dustry guidance letter, a notice to industry advisory
 12 letter, or any similar notice sets forth initial inter-
 13 pretations of a regulation or policy or sets forth
 14 changes in interpretation or policy, such notice shall
 15 be treated as a guidance document for purposes of
 16 this subparagraph.”.

17 **SEC. 611. MODIFICATION OF DE NOVO APPLICATION PROC-**
 18 **ESS.**

19 (a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.
 20 360c(f)(2)) is amended—

21 (1) by redesignating subparagraphs (B) and
 22 (C) as subparagraphs (C) and (D), respectively;

23 (2) by amending subparagraph (A) to read as
 24 follows:

1 “(A) In the case of a type of device that has not pre-
2 viously been classified under this Act, a person may do
3 one of the following:

4 “(i) Submit a report under section 510(k), and,
5 if the device is classified into class III under para-
6 graph (1), such person may request, not later than
7 30 days after receiving written notice of such a clas-
8 sification, the Secretary to classify the device under
9 the criteria set forth in subparagraphs (A) through
10 (C) of subsection (a)(1). The person may, in the re-
11 quest, recommend to the Secretary a classification
12 for the device. Any such request shall describe the
13 device and provide detailed information and reasons
14 for the recommended classification.

15 “(ii) Submit a request for initial classification
16 of the device under this subparagraph, if the person
17 declares that there is no legally marketed device
18 upon which to base a substantial equivalence deter-
19 mination as that term is defined in subsection (i).
20 Subject to subparagraph (B), the Secretary shall
21 classify the device under the criteria set forth in sub-
22 paragraphs (A) through (C) of subsection (a)(1).
23 The person submitting the request for classification
24 under this subparagraph may recommend to the
25 Secretary a classification for the device and shall in-

1 clude in the request an initial draft proposal for ap-
2 plicable special controls, as described in subsection
3 (a)(1)(B), that are necessary, in conjunction with
4 general controls, to provide reasonable assurance of
5 safety and effectiveness and a description of how the
6 special controls provide such assurance. Requests
7 under this clause shall be subject to the electronic
8 copy requirements of section 745A(b).”;

9 (3) by inserting after subparagraph (A) the fol-
10 lowing:

11 “(B) The Secretary may decline to undertake a clas-
12 sification request submitted under clause (2)(A)(ii) if the
13 Secretary identifies a legally marketed device that could
14 provide a reasonable basis for review of substantial equiva-
15 lence under paragraph (1), or when the Secretary deter-
16 mines that the device submitted is not of low-moderate
17 risk.”; and

18 (4) in subparagraph (C), as so redesignated—

19 (A) in clause (i), by striking “Not later
20 than 60 days after the date of the submission
21 of the request under subparagraph (A),” and
22 inserting “Not later than 120 days after the
23 date of the submission of the request under
24 subparagraph (A)(i) or 150 days after the date

1 of the submission of the request under subpara-
2 graph (A)(ii),”; and

3 (B) in clause (ii), by inserting “or is classi-
4 fied in” after “remains in”.

5 (b) GAO REPORT.—Not later than 2 years after the
6 date of enactment of this Act, the Comptroller General
7 of the United States shall complete a study and submit
8 to Congress a report on the effectiveness of the review
9 pathway under section 513(f)(2)(A) of the Federal Food,
10 Drug, and Cosmetic Act, as amended by this Act.

11 (c) CONFORMING AMENDMENT.—Section
12 513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by in-
13 serting “a request under paragraph (2) or” after “re-
14 sponse to”.

15 **SEC. 612. HUMANITARIAN USE DEVICE EXEMPTIONS.**

16 (a) IN GENERAL.—Section 520(m) (21 U.S.C.
17 360j(m)) is amended—

18 (1) in paragraph (6)—

19 (A) in subparagraph (A)—

20 (i) in the matter preceding clause (i),
21 by striking “subparagraph (D)” and in-
22 serting “subparagraph (C)”;

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

1 “(i) The device with respect to which the ex-
2 emption is granted—

3 “(I) is intended for the treatment or diag-
4 nosis of a disease or condition that occurs in
5 pediatric patients or in a pediatric subpopula-
6 tion, and such device is labeled for use in pedi-
7 atric patients or in a pediatric subpopulation in
8 which the disease or condition occurs; or

9 “(II) is intended for the treatment or diag-
10 nosis of a disease or condition that does not
11 occur in pediatric patients or that occurs in pe-
12 diatric patients in such numbers that the devel-
13 opment of the device for such patients is impos-
14 sible, highly impracticable, or unsafe.”;

15 (iii) by striking clause (ii) and insert-
16 ing the following:

17 “(ii) During any calendar year, the number of
18 such devices distributed during that year under each
19 exemption granted under this subsection does not
20 exceed the number of such devices needed to treat,
21 diagnose, or cure a population of 4,000 individuals
22 in the United States (referred to in this paragraph
23 as the ‘annual distribution number’).”; and

24 (iv) in clause (iv), by striking “2012”
25 and inserting “2017”;

1 (B) by striking subparagraph (C);

2 (C) by redesignating subparagraphs (D)

3 and (E) as subparagraphs (C) and (D), respec-

4 tively; and

5 (D) in subparagraph (C), as so redesign-

6 nated, by striking “and modified under sub-

7 paragraph (C), if applicable,”;

8 (2) in paragraph (7), by striking “regarding a

9 device” and inserting “regarding a device described

10 in paragraph (6)(A)(i)(I)”;

11 (3) in paragraph (8), by striking “of all devices

12 described in paragraph (6)” and inserting “of all de-

13 vices described in paragraph (6)(A)(i)(I)”.

14 (b) APPLICABILITY TO EXISTING DEVICES.—A spon-

15 sor of a device for which an exemption was approved under

16 paragraph (2) of section 520(m) of the Federal Food,

17 Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the

18 date of enactment of this Act may seek a determination

19 under subclause (I) or (II) of section 520(m)(6)(A)(i) (as

20 amended by subsection (a)). If the Secretary determines

21 that such subclause (I) or (II) applies with respect to a

22 device, clauses (ii), (iii), and (iv) of subparagraph (A) and

23 subparagraphs (B), (C), and (D) of paragraph (6) of such

24 section 520(m) shall apply to such device.

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

4 (1) the effectiveness of the amendments made
5 by subsection (a) in stimulating innovation with re-
6 spect to medical devices, including any favorable or
7 adverse impact on pediatric device development;

8 (2) the impact of such amendments on pediatric
9 device approvals for devices that received a humani-
10 tarian use designation under section 520(m) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 360j(m)) prior to the date of enactment of this Act;

13 (3) the status of public and private insurance
14 coverage of devices granted an exemption under
15 paragraph (2) of such section 520(m) (as amended
16 by subsection (a)) and costs to patients of such de-
17 vices;

18 (4) the impact that paragraph (4) of such sec-
19 tion 520(m) has had on access to and insurance cov-
20 erage of devices granted an exemption under para-
21 graph (2) of such section 520(m); and

22 (5) the effect of the amendments made by sub-
23 section (a) on patients described in such section
24 520(m).

1 **SEC. 613. REAUTHORIZATION OF THIRD-PARTY REVIEW**
2 **AND INSPECTIONS.**

3 (a) **THIRD PARTY REVIEW.**—Section 523(c) (21
4 U.S.C. 360m(c)) is amended by striking “2012” and in-
5 serting “2017”.

6 (b) **THIRD PARTY INSPECTIONS.**—Section
7 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking
8 “2012” and inserting “2017”.

9 **SEC. 614. ADVISORY COMMITTEE CONFLICTS OF INTEREST.**

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

11 (1) in subsection (b)—

12 (A) by striking paragraph (2); and

13 (B) in paragraph (1)—

14 (i) by redesignating subparagraph (B)
15 as paragraph (2);

16 (ii) in subparagraph (A), by redesignig-
17 nating clauses (i) through (iii) as subpara-
18 graphs (A) through (C), respectively;

19 (iii) by striking “(1) RECRUITMENT”
20 and inserting “(1) RECRUITMENT IN GEN-
21 ERAL—The Secretary shall—”;

22 (iv) by striking “(A) IN GENERAL—
23 The Secretary shall—”;

24 (v) by redesignating clauses (i)
25 through (iii) of paragraph (2) (as so redesi-

1 ignated) as subparagraphs (A) through
2 (C), respectively; and

3 (vi) in paragraph (2) (as so redesign-
4 nated), in the matter before subparagraph
5 (A) (as so redesignated), by striking “sub-
6 paragraph (A)” and inserting “paragraph
7 (1)”;

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

10 “(C) CONSIDERATION BY SECRETARY.—

11 The Secretary shall ensure that each determina-
12 tion made under subparagraph (B) considers
13 the type, nature, and magnitude of the financial
14 interests at issue and the public health interest
15 in having the expertise of the member with re-
16 spect to the particular matter before the advi-
17 sory committee.”;

18 (3) in subsection (e), by inserting “, and shall
19 make publicly available,” after “House of Represent-
20 atives”; and

21 (4) by adding at the end the following:

22 “(g) GUIDANCE ON REPORTED FINANCIAL INTEREST
23 OR INVOLVEMENT.—The Secretary shall issue guidance
24 that describes how the Secretary reviews the financial in-
25 terests and involvement of advisory committee members

1 that are reported under subsection (c)(1) but that the Sec-
2 retary determines not to meet the definition of a disquali-
3 fying interest under section 208 of title 18, United States
4 Code for the purposes of participating in a particular mat-
5 ter.”.

6 **TITLE VII—DRUG SUPPLY CHAIN**

7 **SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISH-** 8 **MENTS.**

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

10 (1) in subsection (b)—

11 (A) in paragraph (1), by striking “On or
12 before” and all that follows through the period
13 at the end and inserting the following “During
14 the period beginning on October 1 and ending
15 on December 31 of each year, every person who
16 owns or operates any establishment in any
17 State engaged in the manufacture, preparation,
18 propagation, compounding, or processing of a
19 drug or drugs shall register with the Sec-
20 retary—

21 “(A) the name of such person, places of busi-
22 ness of such person, all such establishments, the
23 unique facility identifier of each such establishment,
24 and a point of contact e-mail address; and

1 “(B) the name and place of business of each
2 drug importer or broker that takes physical posses-
3 sion of a finished drug product or active pharma-
4 ceutical ingredient with which the person conducts
5 business, including all establishments of each such
6 drug importer or broker, the unique facility identi-
7 fier of each such establishment, and a point of con-
8 tact e-mail address for each such drug importer or
9 broker.”; and

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

11 “(3) The Secretary may specify the unique facility
12 identifier system that shall be used by registrants under
13 paragraph (1).”; and

14 (2) in subsection (e), by striking “with the Sec-
15 retary his name, place of business, and such estab-
16 lishment” and inserting “with the Secretary—

17 “(1) with respect to drugs, the information de-
18 scribed under subsection (b)(1); and

19 “(2) with respect to devices, the information de-
20 scribed under subsection (b)(2).”.

21 **SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

22 (a) ENFORCEMENT OF REGISTRATION OF FOREIGN
23 ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is
24 amended by striking “in any State”.

1 (b) REGISTRATION OF FOREIGN DRUG ESTABLISH-
2 MENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

3 (1) in paragraph (1)—

4 (A) by amending the matter preceding sub-
5 paragraph (A) to read as follows: “Every per-
6 son who owns or operates any establishment
7 within any foreign country engaged in the man-
8 ufacture, preparation, propagation,
9 compounding, or processing of a drug or device
10 that is imported or offered for import into the
11 United States shall, through electronic means
12 in accordance with the criteria of the Sec-
13 retary—”;

14 (B) by amending subparagraph (A) to read
15 as follows:

16 “(A) upon first engaging in any such activity,
17 immediately submit a registration to the Secretary
18 that includes—

19 “(i) with respect to drugs, the name and
20 place of business of such person, all such estab-
21 lishments, the unique facility identifier of each
22 such establishment, a point of contact e-mail
23 address, the name of the United States agent of
24 each such establishment, the name and place of
25 business of each drug importer with which such

1 person conducts business, including all estab-
2 lishments of each such drug importer, the
3 unique facility identifier of each such establish-
4 ment, and a point of contact e-mail address for
5 each such drug importer; and

6 “(ii) with respect to devices, the name and
7 place of business of the establishment, the name
8 of the United States agent for the establish-
9 ment, the name of each importer of such device
10 in the United States that is known to the estab-
11 lishment, and the name of each person who im-
12 ports or offers for import such device to the
13 United States for purposes of importation;
14 and”;

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

17 “(B) each establishment subject to the require-
18 ments of subparagraph (A) shall thereafter register
19 with the Secretary during the period beginning on
20 October 1 and ending on December 31 of each
21 year.”;

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

23 “(4) The Secretary may specify the unique facility
24 identifier system that shall be used by registrants under
25 paragraph (1) with respect to drugs.”.

1 **SEC. 703. REGISTRATION OF DRUG EXCIPIENT INFORMA-**
2 **TION WITH PRODUCT LISTING.**

3 Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amend-
4 ed—

5 (1) in subparagraph (C), by striking “; and”
6 and inserting a semicolon;

7 (2) in subparagraph (D), by striking the period
8 at the end and inserting “; and”; and

9 (3) by adding at the end the following:

10 “(E) in the case of a drug contained in the ap-
11 plicable list and subject to section 505 or 512, the
12 name and place of business of each manufacturer of
13 an excipient of the drug with which the person so
14 registered conducts business, including all establish-
15 ments of each such excipient manufacturer, the
16 unique facility identifier of each such establishment,
17 and a point of contact e-mail address for each such
18 excipient manufacturer.”.

19 **SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND**
20 **LISTING.**

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

22 (1) by striking “(p) Registrations and listings”
23 and inserting the following:

24 “(p) ELECTRONIC REGISTRATION AND LISTING.—

25 “(1) IN GENERAL.—Registration and listing”;

26 and

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

2 “(2) ELECTRONIC DATABASE.—Not later than
3 2 years after the Secretary specifies a unique facility
4 identifier system under subsections (b) and (i), the
5 Secretary shall maintain an electronic database,
6 which shall not be subject to inspection under sub-
7 section (f), populated with the information submitted
8 as described under paragraph (1) that—

9 “(A) enables personnel of the Food and
10 Drug Administration to search the database by
11 any field of information submitted in a registra-
12 tion described under paragraph (1), or com-
13 bination of such fields; and

14 “(B) uses the unique facility identifier sys-
15 tem to link with other relevant databases within
16 the Food and Drug Administration, including
17 the database for submission of information
18 under section 801(r).

19 “(3) RISK-BASED INFORMATION AND COORDI-
20 NATION.—The Secretary shall ensure the accuracy
21 and coordination of relevant Food and Drug Admin-
22 istration databases in order to identify and inform
23 risk-based inspections under section 510(h).”.

1 **SEC. 705. RISK-BASED INSPECTION FREQUENCY.**

2 Section 510(h) (21 U.S.C. 360(h)) is amended to
3 read as follows:

4 “(h) INSPECTIONS.—

5 “(1) IN GENERAL.—Every establishment that is
6 required to be registered with the Secretary under
7 this section shall be subject to inspection pursuant
8 to section 704.

9 “(2) RISK-BASED SCHEDULE.—The Secretary,
10 acting through one or more officers or employees
11 duly designated by the Secretary, shall inspect estab-
12 lishments described in paragraph (1) that are en-
13 gaged in the manufacture, preparation, propagation,
14 compounding, or processing of a drug or drugs (re-
15 ferred to in this subsection as a ‘drug establish-
16 ments’) in accordance with a risk-based schedule es-
17 tablished by the Secretary.

18 “(3) RISK FACTORS.—In establishing the risk-
19 based scheduled under paragraph (2), the Secretary
20 shall allocate resources to inspect establishments ac-
21 cording to the known safety risks of such establish-
22 ments, which shall be based on the following factors:

23 “(A) The compliance history of the estab-
24 lishment.

25 “(B) The record, history, and nature of re-
26 calls linked to the establishment.

1 “(C) The inherent risk of the drug manu-
2 factured, prepared, propagated, compounded, or
3 processed at the establishment.

4 “(D) The certifications described under
5 sections 801(r) and 809 for the establishment.

6 “(E) Whether the establishment has been
7 inspected in the preceding 4-year period.

8 “(F) Any other criteria deemed necessary
9 and appropriate by the Secretary for purposes
10 of allocating inspection resources.

11 “(4) EFFECT OF STATUS.—In determining the
12 risk associated with an establishment for purposes of
13 establishing a risk-based schedule under paragraph
14 (2), the Secretary shall not consider whether the
15 drugs manufactured, prepared, propagated, com-
16 pounded, or processed by such establishment are
17 drugs described in section 503(b).

18 “(5) ANNUAL REPORT ON INSPECTIONS OF ES-
19 TABLISHMENTS.—Not later than February 1 of each
20 year, the Secretary shall submit a report to Con-
21 gress regarding—

22 “(A)(i) the number of domestic and foreign
23 establishments registered pursuant to this sec-
24 tion in the previous fiscal year; and

1 “(ii) the number of such domestic estab-
2 lishments and the number of such foreign es-
3 tablishments that the Secretary inspected in the
4 previous fiscal year;

5 “(B) with respect to establishments that
6 manufacture, prepare, propagate, compound, or
7 process an active ingredient of a drug, a fin-
8 ished drug product, or an excipient of a drug,
9 the number of each such type of establishment;
10 and

11 “(C) the percentage of the budget of the
12 Food and Drug Administration used to fund
13 the inspections described under subparagraph
14 (A).

15 “(6) PUBLIC AVAILABILITY OF ANNUAL RE-
16 PORTS.—The Secretary shall make the report re-
17 quired under paragraph (5) available to the public
18 on the Internet Web site of the Food and Drug Ad-
19 ministration.”.

20 **SEC. 706. RECORDS FOR INSPECTION.**

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

23 “(4)(A) Any records or other information that the
24 Secretary is entitled to request under this section from
25 a person that owns or operates an establishment that is

1 engaged in the manufacture, preparation, propagation,
2 compounding, or processing of a drug shall, upon the re-
3 quest of the Secretary, be provided to the Secretary by
4 such person within a reasonable time frame, within rea-
5 sonable limits and in a reasonable manner, and in elec-
6 tronic form, at the expense of such person. The Sec-
7 retary's request shall include a clear description of the
8 records requested.

9 “(B) Upon receipt of the records requested under
10 subparagraph (A), the Secretary shall provide to the per-
11 son confirmation of the receipt of such records.

12 “(C) Nothing in this paragraph supplants the author-
13 ity of the Secretary to conduct inspections otherwise per-
14 mitted under this Act in order to ensure compliance by
15 an establishment with this Act.”.

16 **SEC. 707. FAILURE TO ALLOW FOREIGN INSPECTION.**

17 Section 801(a) (21 U.S.C. 381(a)) is amended by
18 adding at the end the following: “Notwithstanding any
19 other provision of this subsection, the Secretary of Home-
20 land Security shall, upon request from the Secretary of
21 Health and Human Services refuse to admit into the
22 United States any article if the article was manufactured,
23 prepared, propagated, compounded, processed, or held at
24 an establishment that has refused to permit the Secretary
25 of Health and Human Services to enter or inspect the es-

1 tabishment in the same manner and to the same extent
2 as the Secretary may inspect establishments under section
3 704.”.

4 **SEC. 708. EXCHANGE OF INFORMATION.**

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

6 (1) by striking “CONFIDENTIAL INFORMATION”
7 and all that follows through “The Secretary” and in-
8 serting “**CONFIDENTIAL INFORMATION.**

9 “(a) CONTRACTORS.—The Secretary”; and

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

11 “(b) ABILITY TO RECEIVE AND PROTECT CONFIDEN-
12 TIAL INFORMATION.—The Secretary shall not be required
13 to disclose under section 552 of title 5, United States
14 Code, or any other provision of law, any information relat-
15 ing to drugs obtained from a Federal, State or local gov-
16 ernment agency, or from a foreign government agency, if
17 the agency has requested that the information be kept con-
18 fidential, except pursuant to an order of a court of the
19 United States. For purposes of section 552 of title 5,
20 United States Code, this subsection shall be considered a
21 statute described in section 552(b)(3)(B).

22 “(c) AUTHORITY TO ENTER INTO MEMORANDA OF
23 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-
24 CHANGE.—The Secretary may enter into written agree-

1 ments regarding the exchange of information referenced
2 in section 301(j) subject to the following criteria:

3 “(1) CERTIFICATION.—The Secretary may only
4 enter into written agreements under this subsection
5 with foreign governments that the Secretary has cer-
6 tified as having the authority and demonstrated abil-
7 ity to protect trade secret information from disclo-
8 sure. Responsibility for this certification shall not be
9 delegated to any officer or employee other than the
10 Commissioner.

11 “(2) WRITTEN AGREEMENT.—The written
12 agreement under this subsection shall include a com-
13 mitment by the foreign government to protect infor-
14 mation exchanged under this subsection from disclo-
15 sure unless and until the sponsor gives written per-
16 mission for disclosure or the Secretary makes a dec-
17 laration of a public health emergency pursuant to
18 section 319 of the Public Health Service Act that is
19 relevant to the information.

20 “(3) INFORMATION EXCHANGE.—The Secretary
21 may provide to a foreign government that has been
22 certified under paragraph (1) and that has executed
23 a written agreement under paragraph (2) informa-
24 tion referenced in section 301(j) in the following cir-
25 cumstances:

1 “(A) Information concerning the inspection
2 of a facility may be provided if—

3 “(i) the Secretary reasonably believes,
4 or that the written agreement described in
5 paragraph (2) establishes, that the govern-
6 ment has authority to otherwise obtain
7 such information; and

8 “(ii) the written agreement executed
9 under paragraph (2) limits the recipient’s
10 use of the information to the recipient’s
11 civil regulatory purposes.

12 “(B) Information not described in sub-
13 paragraph (A) may be provided as part of an
14 investigation, or to alert the foreign government
15 to the potential need for an investigation, if the
16 Secretary has reasonable grounds to believe
17 that a drug has a reasonable probability of
18 causing serious adverse health consequences or
19 death to humans or animals.

20 “(4) EFFECT OF SUBSECTION.—Nothing in this
21 subsection affects the ability of the Secretary to
22 enter into any written agreement authorized by
23 other provisions of law to share confidential informa-
24 tion.”.

1 **SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE**
2 **DRUG SUPPLY.**

3 Section 501 (21 U.S.C. 351) is amended by adding
4 at the end the following flush text:

5 “For purposes of subsection (a)(2)(B), the term ‘current
6 good manufacturing practice’ includes the implementation
7 of oversight and controls over the manufacture of drugs
8 to ensure quality, including managing the risk of and es-
9 tablishing the safety of raw materials, materials used in
10 the manufacturing of drugs, and finished drug products.”.

11 **SEC. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR**
12 **DRUG ESTABLISHMENTS.**

13 (a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et
14 seq.) is amended by adding at the end the following:

15 **“SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS**
16 **FOR DRUG ESTABLISHMENTS.**

17 “(a) DEFINITIONS.—In this section:

18 “(1) ACCREDITATION BODY.—The term ‘ac-
19 creditation body’ means an authority that performs
20 accreditation of third-party auditors.

21 “(2) ACCREDITED THIRD-PARTY AUDITOR.—

22 The term ‘accredited third-party auditor’ means a
23 third-party auditor (which may be an individual) ac-
24 credited by an accreditation body to conduct drug
25 safety and quality audits.

1 “(3) AUDIT AGENT.—The term ‘audit agent’
2 means an individual who is an employee or agent of
3 an accredited third-party auditor and, although not
4 individually accredited, is qualified to conduct drug
5 safety and quality audits on behalf of an accredited
6 third-party auditor.

7 “(4) CONSULTATIVE AUDIT.—The term ‘con-
8 sultative audit’ means an audit of an eligible entity
9 intended for internal purposes only to determine
10 whether an establishment is in compliance with the
11 provisions of this Act and applicable industry prac-
12 tices, or any other such service.

13 “(5) DRUG SAFETY AND QUALITY AUDIT.—The
14 term ‘drug safety and quality audit’—

15 “(A) means an audit of an eligible entity
16 to certify that the eligible entity meets the re-
17 quirements of this Act applicable to drugs, in-
18 cluding the requirements of section 501 with re-
19 spect to drugs; and

20 “(B) is not a consultative audit.

21 “(6) ELIGIBLE ENTITY.—The term ‘eligible en-
22 tity’ means an entity, including a foreign drug estab-
23 lishment registered under section 510(c), in the drug
24 supply chain that chooses to be audited by an ac-

1 credited third-party auditor or the audit agent of
2 such accredited third-party auditor.

3 “(7) THIRD-PARTY AUDITOR.—The term ‘third-
4 party auditor’ means a foreign government, agency
5 of a foreign government or any other third party
6 (which may be an individual), as the Secretary de-
7 termines appropriate in accordance with the criteria
8 described in subsection (c)(1), that is eligible to be
9 considered for accreditation to conduct drug safety
10 and quality audits.

11 “(b) ACCREDITATION SYSTEM.—

12 “(1) RECOGNITION OF ACCREDITATION BOD-
13 IES.—

14 “(A) IN GENERAL.—Not later than 2 years
15 after date of enactment of the Food and Drug
16 Administration Safety and Innovation Act, the
17 Secretary shall establish a system for the rec-
18 ognition of accreditation bodies that accredit
19 third-party auditors to conduct drug safety and
20 quality audits.

21 “(B) DIRECT ACCREDITATION.—

22 “(i) IN GENERAL.—If, by the date
23 that is 2 years after the date of establish-
24 ment of the system described in subpara-
25 graph (A), the Secretary has not identified

1 and recognized an accreditation body to
2 meet the requirements of this section, the
3 Secretary may directly accredit third-party
4 auditors.

5 “(ii) CERTAIN DIRECT ACCREDITA-
6 TIONS.—Notwithstanding subparagraph
7 (A) or clause (i), the Secretary may di-
8 rectly accredit any foreign government or
9 any agency of a foreign government as a
10 third-party auditor at any time after the
11 date of enactment of the Food and Drug
12 Administration Safety and Innovation Act.

13 “(2) NOTIFICATION.—Each accreditation body
14 recognized by the Secretary shall submit to the Sec-
15 retary—

16 “(A) a list of all accredited third-party
17 auditors accredited by such body (including the
18 name, contact information, and scope and dura-
19 tion of accreditation for each such auditor), and
20 the audit agents of such auditors; and

21 “(B) updated lists as needed to ensure the
22 list held by the Secretary is accurate.

23 “(3) REVOCATION OF RECOGNITION AS AN AC-
24 CREDITATION BODY.—The Secretary shall promptly
25 revoke, after the opportunity for an informal hear-

1 ing, the recognition of any accreditation body found
2 not to be in compliance with the requirements of this
3 section.

4 “(4) REINSTATEMENT.—The Secretary shall es-
5 tablish procedures to reinstate recognition of an ac-
6 creditation body if the Secretary determines, based
7 on evidence presented by such accreditation body,
8 that revocation was inappropriate or that the body
9 meets the requirements for recognition under this
10 section.

11 “(5) MODEL ACCREDITATION STANDARDS.—

12 “(A) IN GENERAL.—Not later than 18
13 months after the date of enactment of the Food
14 and Drug Administration Safety and Innova-
15 tion Act, the Secretary shall develop model
16 standards, including standards for drug safety
17 and quality audit results, reports, and certifi-
18 cations, and each recognized accreditation body
19 shall ensure that third-party auditors and audit
20 agents of such auditors meet such standards in
21 order to qualify such third-party auditors as ac-
22 credited third-party auditors under this section.

23 “(B) CONTENT.—The standards developed
24 under subparagraph (A) may—

1 “(i) include a description of required
2 standards relating to the training proce-
3 dures, competency, management respon-
4 sibilities, quality control, and conflict of in-
5 terest requirements of accredited third-
6 party auditors; and

7 “(ii) set forth procedures for the peri-
8 odic renewal of the accreditation of accred-
9 ited third-party auditors.

10 “(C) REQUIREMENT TO PROVIDE RESULTS
11 AND REPORTS TO THE SECRETARY.—An ac-
12 creditation body (or, in the case of direct ac-
13 creditation under subsection (b)(1)(B), the Sec-
14 retary) may not accredit a third-party auditor
15 unless such third-party auditor agrees to pro-
16 vide to the Secretary, upon request, the results
17 and reports of any drug safety and quality
18 audit conducted pursuant to the accreditation
19 provided under this section.

20 “(6) DISCLOSURE.—The Secretary shall main-
21 tain on the Internet Web site of the Food and Drug
22 Administration a list of recognized accreditation
23 bodies and accredited third-party auditors under this
24 section.

25 “(c) ACCREDITED THIRD-PARTY AUDITORS.—

1 “(1) REQUIREMENTS FOR ACCREDITATION AS A
2 THIRD-PARTY AUDITOR.—

3 “(A) FOREIGN GOVERNMENTS.—Prior to
4 accrediting a foreign government or an agency
5 of a foreign government as an accredited third-
6 party auditor, the accreditation body (or, in the
7 case of direct accreditation under subsection
8 (b)(1)(B), the Secretary) shall perform such re-
9 views and audits of drug safety programs, sys-
10 tems, and standards of the government or agen-
11 cy of the government as the Secretary deems
12 necessary, including requirements under the
13 standards developed under subsection (b)(5), to
14 determine that the foreign government or agen-
15 cy of the foreign government is capable of ade-
16 quately ensuring that eligible entities or drugs
17 certified by such government or agency meet
18 the requirements of this Act.

19 “(B) OTHER THIRD PARTIES.—Prior to
20 accrediting any other third party to be an ac-
21 credited third-party auditor, the accreditation
22 body (or, in the case of direct accreditation
23 under subsection (b)(1)(B), the Secretary) shall
24 perform such reviews and audits of the training
25 and qualifications of audit agents used by that

1 party and conduct such reviews of internal sys-
2 tems and such other investigation of the party
3 as the Secretary deems necessary, including re-
4 quirements under the standards developed
5 under subsection (b)(5), to determine that the
6 third party auditor is capable of adequately en-
7 suring that an eligible entity or drug certified
8 by such third party auditor meets the require-
9 ments of this Act.

10 “(2) USE OF AUDIT AGENTS.—An accredited
11 third-party auditor may conduct drug safety and
12 quality audits and may employ or use audit agents
13 to conduct drug safety and quality audits, but must
14 ensure that such audit agents comply with all re-
15 quirements the Secretary deems necessary, including
16 requirements under subsections (c)(1) and (b)(5).

17 “(3) REVOCATION OF ACCREDITATION.—

18 “(A) IN GENERAL.—The Secretary shall
19 promptly revoke, after the opportunity for an
20 informal hearing, the accreditation of an ac-
21 credited third-party auditor—

22 “(i) if, following an evaluation, the
23 Secretary finds that the accredited third-
24 party auditor is not in compliance with the
25 requirements of this section; or

1 “(ii) following a refusal to allow
2 United States officials to conduct such au-
3 dits and investigations as may be necessary
4 to determine compliance with the require-
5 ments set forth in this section.

6 “(B) ADDITIONAL BASIS FOR REVOCATION
7 OF ACCREDITATION.—The Secretary may re-
8 voke accreditation from an accredited third-
9 party auditor in the case that such third-party
10 auditor is accredited by an accreditation body
11 for which recognition as an accreditation body
12 under subsection (b)(3) is revoked, if the Sec-
13 retary determines that there is good cause for
14 the revocation of accreditation.

15 “(4) REACCREDITATION.—The Secretary shall
16 establish procedures to reinstate the accreditation of
17 a third-party auditor for which accreditation has
18 been revoked under paragraph (3)—

19 “(A) if the Secretary determines, based on
20 evidence presented, that—

21 “(i) the third-party auditor satisfies
22 the requirements of this section; and

23 “(ii) adequate grounds for revocation
24 no longer exist; and

1 “(B) in the case of a third-party auditor
2 accredited by an accreditation body for which
3 recognition as an accreditation body is revoked
4 under subsection (b)(3)—

5 “(i) if the third-party auditor becomes
6 accredited not later than 1 year after rev-
7 ocation of accreditation under paragraph
8 (3), through direct accreditation under
9 subsection (b)(1)(B), or by an accredita-
10 tion body in good standing; or

11 “(ii) under such other conditions as
12 the Secretary may require.

13 “(5) REQUIREMENT TO ISSUE CERTIFICATION
14 OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CUR-
15 RENT GOOD MANUFACTURING PRACTICE.—

16 “(A) IN GENERAL.—An accreditation body
17 (or, in the case of direct accreditation under
18 subsection (b)(1)(B), the Secretary) may not
19 accredit a third-party auditor unless such third-
20 party auditor agrees to issue a written and, as
21 appropriate, electronic, document or certifi-
22 cation, as the Secretary may require under this
23 Act, regarding compliance with section 501.
24 The Secretary may consider any such document
25 or certification to satisfy requirements under

1 section 801(r) and to target inspection re-
2 sources under section 510(h).

3 “(B) REQUIREMENTS FOR ISSUING CER-
4 TIFICATION.—

5 “(i) IN GENERAL.—An accredited
6 third-party auditor shall issue a drug cer-
7 tification described in subparagraph (A)
8 and subsection (h) only after conducting a
9 drug safety and quality audit and such
10 other activities that may be necessary to
11 establish compliance with the provisions of
12 section 501.

13 “(ii) PROVISION OF CERTIFICATION.—
14 Only an accredited third-party auditor or
15 the Secretary may provide a drug certifi-
16 cation described in subparagraph (A).

17 “(C) RECORDS.—Following any accredita-
18 tion of a third-party auditor, the Secretary
19 may, at any time, require the accredited third-
20 party auditor or any audit agent of such audi-
21 tor to submit to the Secretary a drug safety
22 and quality audit report and such other reports
23 or documents required as part of the drug safe-
24 ty and quality audit process, for any eligible en-
25 tity for which the accredited third-party auditor

1 or audit agent of such auditor performed a
2 drug safety and quality audit. The Secretary
3 may require documentation that the eligible en-
4 tity is in compliance with any applicable reg-
5 istration requirements.

6 “(D) LIMITATION.—The requirement
7 under subparagraph (C) shall not include any
8 report or other documents resulting from a con-
9 sultative audit, except that the Secretary may
10 access the results of a consultative audit in ac-
11 cordance with section 704.

12 “(E) DECLARATION OF AUDIT TYPE.—Be-
13 fore an accredited third-party auditor begins
14 any audit or provides any consultative service to
15 an eligible entity, both the accredited third-
16 party auditor and eligible entity shall establish
17 in writing whether the audit is intended to be
18 a drug safety and quality audit. Any audit, in-
19 spection, or consultative service of any type pro-
20 vided by an accredited third-party auditor on
21 behalf of an eligible entity shall be presumed to
22 be a drug safety and quality audit in the ab-
23 sence of such a written agreement. Once a drug
24 safety and quality audit is initiated, it shall be
25 subject to the requirements of this section, and

1 no person may withhold from the Secretary any
2 document subject to subparagraph (C) on the
3 grounds that the audit was a consultative audit
4 or otherwise not a drug safety and quality
5 audit.

6 “(F) RULE OF CONSTRUCTION.—Nothing
7 in this section shall be construed to limit the
8 authority of the Secretary under section 704.

9 “(6) REQUIREMENTS REGARDING SERIOUS
10 RISKS TO THE PUBLIC HEALTH.—If, at any time
11 during a drug safety and quality audit, an accredited
12 third-party auditor or an audit agent of such auditor
13 discovers a condition that could cause or contribute
14 to a serious risk to the public health, such auditor
15 shall immediately notify the Secretary of—

16 “(A) the identity and location of the eligi-
17 ble entity subject to the drug safety and quality
18 audit; and

19 “(B) such condition.

20 “(7) LIMITATIONS.—

21 “(A) IN GENERAL.—An audit agent of an
22 accredited third party auditor may not perform
23 a drug safety and quality audit of an eligible
24 entity if such audit agent has performed a drug
25 safety and quality audit or consultative audit of

1 such eligible entity during the previous 13-
2 month period.

3 “(B) WAIVER.—The Secretary may waive
4 the application of subparagraph (A) if the Sec-
5 retary determines that there is insufficient ac-
6 cess to accredited third-party auditors in a
7 country or region or that the use of the same
8 audit agent or accredited third party auditor is
9 otherwise necessary.

10 “(8) CONFLICTS OF INTEREST.—

11 “(A) ACCREDITATION BODIES.—A recog-
12 nized accreditation body shall—

13 “(i) not be owned, managed, or con-
14 trolled by any person that owns or operates
15 an third-party auditor to be accredited by
16 such body;

17 “(ii) in carrying out accreditation of
18 third-party auditors under this section,
19 have procedures to ensure against the use
20 of any officer or employee of such body
21 that has a financial conflict of interest re-
22 garding a third-party auditor to be accred-
23 ited by such body; and

24 “(iii) annually make available to the
25 Secretary disclosures of the extent to

1 which such body and the officers and em-
2 ployees of such body have maintained com-
3 pliance with clauses (i) and (ii) relating to
4 financial conflicts of interest.

5 “(B) ACCREDITED THIRD-PARTY AUDI-
6 TORS.—An accredited third-party auditor
7 shall—

8 “(i) not be owned, managed, or con-
9 trolled by any person that owns or operates
10 an eligible entity to be certified by such
11 auditor;

12 “(ii) in carrying out drug safety and
13 quality audits of eligible entities under this
14 section, have procedures to ensure against
15 the use of any officer or employee of such
16 auditor that has a financial conflict of in-
17 terest regarding an eligible entity to be
18 certified by such auditor; and

19 “(iii) annually make available to the
20 Secretary disclosures of the extent to
21 which such auditor and the officers and
22 employees of such auditor have maintained
23 compliance with clauses (i) and (ii) relat-
24 ing to financial conflicts of interest.

1 “(C) AUDIT AGENTS.—An audit agent
2 shall—

3 “(i) not own or operate an eligible en-
4 tity to be audited by such agent;

5 “(ii) in carrying out audits of eligible
6 entities under this section, have procedures
7 to ensure that such agent does not have a
8 financial conflict of interest regarding an
9 eligible entity to be audited by such agent;
10 and

11 “(iii) annually make available to the
12 Secretary disclosures of the extent to
13 which such agent has maintained compli-
14 ance with clauses (i) and (ii) relating to fi-
15 nancial conflicts of interest.

16 “(D) REGULATIONS.—The Secretary shall
17 promulgate regulations not later than 18
18 months after the date of enactment of the Food
19 and Drug Administration Safety and Innova-
20 tion Act to implement this section and to en-
21 sure that there are protections against conflicts
22 of interest between a recognized accreditation
23 body and the third-party auditor to be accred-
24 ited by such accreditation body, and between an
25 accredited third-party auditor and the eligible

1 entity to be audited by such auditor or audited
2 by such audit agent. Such regulations shall in-
3 clude—

4 “(i) requiring that, to the extent prac-
5 ticable, drug safety and quality audits per-
6 formed under this section be unannounced;

7 “(ii) a structure to decrease the po-
8 tential for conflicts of interest, including
9 timing and public disclosure, for fees paid
10 by eligible entities to accredited third-party
11 auditors; and

12 “(iii) appropriate limits on financial
13 affiliations between an accredited third-
14 party auditor or audit agents of such audi-
15 tor and any person that owns or operates
16 an eligible entity to be audited by such
17 auditor, as described in subparagraphs (A)
18 and (B).

19 “(d) FALSE STATEMENTS.—Any statement or rep-
20 resentation made—

21 “(1) by an employee or agent of an eligible enti-
22 ty to an accredited third-party auditor or audit
23 agent; or

24 “(2) by an accreditation body, accredited third-
25 party auditor, or audit agent of such auditor to the

1 Secretary, shall be subject to section 1001 of title
2 18, United States Code.

3 “(e) MONITORING.—To ensure compliance with the
4 requirements of this section, the Secretary—

5 “(1) shall periodically, or at least once every 4
6 years, reevaluate the accreditation bodies described
7 in subsection (b)(1);

8 “(2) shall periodically, or at least once every 4
9 years, evaluate the performance of each accredited
10 third-party auditor, through the review of regulatory
11 audit reports by such auditors, the compliance his-
12 tory as available of eligible entities certified by such
13 auditors, and any other measures deemed necessary
14 by the Secretary;

15 “(3) may at any time, conduct an onsite audit
16 of any eligible entity certified by an accredited third-
17 party auditor, with or without the auditor present;
18 and

19 “(4) shall take any other measures deemed nec-
20 essary by the Secretary.

21 “(f) EFFECT OF AUDIT.—The results of a drug safe-
22 ty and quality audit by an accredited third-party auditor
23 under this section—

24 “(1) may be used by the eligible entity—

1 “(A) as documentation of compliance with
2 section 501(a)(2)(B) or section 801(r); and

3 “(B) for other purposes as determined ap-
4 propriate by the Secretary; and

5 “(2) shall be used by the Secretary in estab-
6 lishing the risk-based inspection schedules under sec-
7 tion 510(h).

8 “(g) COSTS.—

9 “(1) AUTHORIZED FEES OF SECRETARY.—The
10 Secretary may assess fees on accreditation bodies
11 and accredited third-party auditors in such an
12 amount necessary to establish and administer the
13 recognition and accreditation program under this
14 section. The Secretary may require accredited third-
15 party auditors and audit agents to reimburse the
16 Food and Drug Administration for the work per-
17 formed to carry out this section. The Secretary shall
18 not generate surplus revenue from such a reimburse-
19 ment mechanism. Fees authorized under this para-
20 graph shall be collected and available for obligation
21 only to the extent and in the amount provided in ad-
22 vance in appropriation Acts. Such fees are author-
23 ized to remain available until expended.

24 “(2) AUTHORIZED FEES FOR RECOGNIZED AC-
25 CREDITATION BODIES.—An accreditation body rec-

1 ognized by the Secretary under subsection (b) may
2 assess a reasonable fee to accredit third-party audi-
3 tors.

4 “(h) LIMITATIONS.—

5 “(1) NO EFFECT ON SECTION 704 INSPEC-
6 TIONS.—The drug safety and quality audits per-
7 formed under this section shall not be considered in-
8 spections under section 704.

9 “(2) NO EFFECT ON INSPECTION AUTHOR-
10 ITY.—Nothing in this section affects the authority of
11 the Secretary to inspect any eligible entity pursuant
12 to this Act.”.

13 (b) REPORT ON ACCREDITED THIRD-PARTY AUDI-
14 TORS.—Not later than January 20, 2017, the Comptroller
15 General of the United States shall submit to Congress a
16 report that addresses the following, with respect to the pe-
17 riod beginning on the date of implementation of section
18 809 of the Federal Food, Drug, and Cosmetic Act (as
19 added by subsection (a)) and ending on the date of such
20 report:

21 (1) The extent to which drug safety and quality
22 audits completed by accredited third-party auditors
23 under such section 809 are being used by the Sec-
24 retary of Health and Human Services (referred to in
25 this subsection as the “Secretary”) in establishing or

1 applying the risk-based inspection schedules under
2 section 510(h) of such Act (as amended by section
3 705).

4 (2) The extent to which drug safety and quality
5 audits completed by accredited third-party auditors
6 or agents are assisting the Food and Drug Adminis-
7 tration in evaluating compliance with sections
8 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B))
9 and 801(r) of such Act (as added by section 711).

10 (3) Whether the Secretary has been able to ac-
11 cess drug safety and quality audit reports completed
12 by accredited third-party auditors under such section
13 809.

14 (4) Whether accredited third-party auditors ac-
15 credited under such section 809 have adhered to the
16 conflict of interest provisions set forth in such sec-
17 tion.

18 (5) The extent to which the Secretary has au-
19 dited recognized accreditation bodies or accredited
20 third-party auditors to ensure compliance with the
21 requirements of such section 809.

22 (6) The number of waivers under subsection
23 (c)(7)(B) of such section 809 issued during the most
24 recent 12-month period and the official justification
25 by the Secretary for each determination that there

1 was insufficient access to an accredited third-party
2 auditor.

3 (7) The number of times a manufacturer has
4 used the same accredited third-party auditor for 2 or
5 more consecutive drug safety and quality audits
6 under such section 809.

7 (8) Recommendations to Congress regarding
8 the accreditation program under such section 809,
9 including whether Congress should continue, modify,
10 or terminate the program.

11 **SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED**
12 **DRUGS.**

13 Section 801 (21 U.S.C. 381) is amended—

14 (1) in subsection (o), by striking “drug or”;
15 and

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

17 “(r)(1) The Secretary may require, as a condition of
18 granting admission to a drug imported or offered for im-
19 port into the United States (other than an unapproved
20 drug imported or offered for import into the United States
21 for use in preclinical research or in a clinical investigation
22 under an investigational new drug exemption under sec-
23 tion 505(i)) that the importer electronically submit infor-
24 mation demonstrating that the drug complies with applica-
25 ble requirements of this Act.

1 “(2) The information described under paragraph (1)
2 may include—

3 “(A) information demonstrating the regulatory
4 status of the drug, such as the new drug application,
5 abbreviated new drug application, or investigational
6 new drug or Drug Master File number;

7 “(B) facility information, such as proof of reg-
8 istration and the unique facility identifier;

9 “(C) indication of compliance with current good
10 manufacturing practice, testing results, certifications
11 relating to satisfactory inspections, and compliance
12 with the country of export regulations; and

13 “(D) any other information deemed necessary
14 and appropriate by the Secretary to assess compli-
15 ance of the article being offered for import.

16 “(3) Information requirements referred to in para-
17 graph (2)(C) may, at the discretion of the Secretary, be
18 satisfied—

19 “(A) by certifications from accredited third par-
20 ties, as described under section 809;

21 “(B) through representation by a foreign gov-
22 ernment, if such inspection is conducted using
23 standards and practices as agreed to by the Sec-
24 retary; or

1 “(C) other appropriate documentation or evi-
2 dence as described by the Secretary.

3 “(4) Not later than 18 months after the date of en-
4 actment of the Food and Drug Administration Safety and
5 Innovation Act, the Secretary shall publish a notice of pro-
6 posed rulemaking in the Federal Register to promulgate
7 regulations with respect to the requirements described in
8 paragraph (1). Such requirements shall not be effective
9 before 180 days after the Secretary promulgates the final
10 rule.”.

11 **SEC. 712. NOTIFICATION.**

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

14 “(aaa) The failure to notify the Secretary in violation
15 of section 569.”.

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

19 **“SEC. 569. NOTIFICATION.**

20 “(a) NOTIFICATION TO SECRETARY.—With respect
21 to a drug, the Secretary may require notification to the
22 Secretary by a covered person if the covered person
23 knows—

24 “(1) of a substantial loss or known theft of
25 such drug in the United States; or

1 “(2) that such drug—

2 “(A) has been or is being counterfeited;

3 and

4 “(B)(i) is the counterfeit product in com-
5 merce in the United States; or

6 “(ii) has been or is being imported into the
7 United States.

8 “(b) MANNER OF NOTIFICATION.—Notification
9 under this section shall be made in a reasonable time, in
10 such reasonable manner, and by such reasonable means
11 as the Secretary may require by regulation or specify in
12 guidance.

13 “(c) DEFINITION.—In this section, the term ‘covered
14 person’ means—

15 “(1) a person who is required to register under
16 section 510 with respect to an establishment en-
17 gaged in the manufacture, preparation, propagation,
18 compounding, or processing of a drug; or

19 “(2) a person engaged in the wholesale distribu-
20 tion (as defined in section 503(e)(3)(B)) of a drug.”.

21 **SEC. 713. DESTRUCTION OF UNSAFE DRUGS.**

22 (a) IN GENERAL.—The sixth sentence of section
23 801(a) (21 U.S.C. 381(a)) is amended by inserting before
24 the period at the end the following: “, except that the Sec-
25 retary of Health and Human Services, in collaboration

1 with the Secretary of Homeland Security, may cause the
2 destruction, without the opportunity for export, of any
3 drug refused admission that has reasonable probability of
4 causing serious adverse health consequences or death to
5 humans or animals, as determined by the Secretary of
6 Health and Human Services, or that is valued at an
7 amount that is \$2,000 or less (or such higher amount as
8 the Secretary of Homeland Security may set by regulation
9 pursuant to section 1498 of title 19, United States
10 Code)''.

11 (b) NOTICE.—Subsection (a) of section 801 (21
12 U.S.C. 381), as amended by subsection (a), is further
13 amended by inserting after the sixth sentence the fol-
14 lowing: “The Secretary of Health and Human Services
15 shall issue regulations providing for notice and an oppor-
16 tunity for an informal hearing, as described in the first
17 sentence of this subsection, on destruction of a drug under
18 the sixth sentence of this subsection. The regulations shall
19 provide notice and an opportunity for an informal hearing
20 to the owner or consignee before the destruction occurs.”.

21 (c) APPLICABILITY.—The amendment made by sub-
22 section (a) shall apply beginning on the effective date of
23 the regulations promulgated under the amendment made
24 by subsection (b).

1 **SEC. 714. PROTECTION AGAINST INTENTIONAL ADULTERA-**
2 **TION.**

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

5 “(7) Notwithstanding subsection (a)(2), any person
6 that knowingly and intentionally adulterates a drug such
7 that the drug is adulterated under subsection (a)(1), (b),
8 (c), or (d) of section 501 and has a reasonable probability
9 of causing serious adverse health consequences or death
10 to humans or animals shall be imprisoned for not more
11 than 20 years or fined not more than \$1,000,000, or
12 both.”.

13 **SEC. 715. ENHANCED CRIMINAL PENALTY FOR COUNTER-**
14 **FEITING DRUGS.**

15 Section 303(b) (21 U.S.C. 333(b)), as amended by
16 section 714, is further amended by adding at the end the
17 following:

18 “(8) Notwithstanding subsection (a)(2), any person
19 who knowingly and intentionally violates section 301(i)
20 shall be imprisoned for not more than 20 years or fined
21 not more than \$4,000,000 or both.”.

22 **SEC. 716. EXTRATERRITORIAL JURISDICTION.**

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

1 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

2 “There is extraterritorial jurisdiction over any viola-
3 tion of this Act relating to any article regulated under this
4 Act if such article was intended for import into the United
5 States or if any act in furtherance of the violation was
6 committed in the United States.”.

7 **SEC. 717. COMPLIANCE WITH INTERNATIONAL AGREE-**
8 **MENTS.**

9 Nothing in this title (or an amendment made by this
10 title) shall be construed in a manner inconsistent with the
11 agreement establishing the World Trade Organization or
12 any other treaty or international agreement to which the
13 United States is a party.

14 **TITLE VIII—GENERATING**
15 **ANTIBIOTIC INCENTIVES NOW**

16 **SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

17 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.)
18 is amended by inserting after section 505D the following:

19 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**
20 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

21 “(a) EXTENSION.—If the Secretary approves an ap-
22 plication pursuant to section 505 for a drug that has been
23 designated as a qualified infectious disease product under
24 subsection (d), the 4- and 5-year periods described in sub-
25 sections(c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the
26 3-year periods described in clauses (iii) and (iv) of sub-

1 section (c)(3)(E) and clauses (iii) and (iv) of subsection
2 (j)(5)(F) of section 505, or the 7-year period described
3 in section 527, as applicable, shall be extended by 5 years.

4 “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
5 extension under subsection (a) of a period shall be in addi-
6 tion to any extension of the period under section 505A
7 with respect to the drug.

8 “(c) LIMITATIONS.—Subsection (a) does not apply to
9 the approval of—

10 “(1) a supplement to an application under sec-
11 tion 505(b) for any qualified infectious disease prod-
12 uct for which an extension described in subsection
13 (a) is in effect or has expired;

14 “(2) a subsequent application filed with respect
15 to a product approved under section 505 for a
16 change that results in a new indication, route of ad-
17 ministration, dosing schedule, dosage form, delivery
18 system, delivery device, or strength; or

19 “(3) an application for a product that is not ap-
20 proved for the use for which it received a designa-
21 tion under subsection (d).

22 “(d) DESIGNATION.—

23 “(1) IN GENERAL.—The manufacturer or spon-
24 sor of a drug may request the Secretary to designate
25 a drug as a qualified infectious disease product at

1 any time before the submission of an application
2 under section 505(b) for such drug. The Secretary
3 shall, not later than 60 days after the submission of
4 such a request, determine whether the drug is a
5 qualified infectious disease product.

6 “(2) LIMITATION.—Except as provided in para-
7 graph (3), a designation under this subsection shall
8 not be withdrawn for any reason, including modifica-
9 tions to the list of qualifying pathogens under sub-
10 section (f)(2)(C).

11 “(3) REVOCATION OF DESIGNATION.—The Sec-
12 retary may revoke a designation of a drug as a
13 qualified infectious disease product if the Secretary
14 finds that the request for such designation contained
15 an untrue statement of material fact.

16 “(e) REGULATIONS.—

17 “(1) IN GENERAL.—Not later than 2 years
18 after the date of enactment of the Food and Drug
19 Administration Safety and Innovation Act, the Sec-
20 retary shall adopt final regulations implementing
21 this section.

22 “(2) PROCEDURE.—In promulgating a regula-
23 tion implementing this section, the Secretary shall—

24 “(A) issue a notice of proposed rulemaking
25 that includes a copy of the proposed regulation;

1 “(B) provide a period of not less than 60
2 days for comments on the proposed regulation;
3 and

4 “(C) publish the final regulation not less
5 than 30 days before the effective date of the
6 regulation.

7 “(3) RESTRICTIONS.—Notwithstanding any
8 other provision of law, the Secretary shall promul-
9 gate regulations implementing this section only as
10 described in paragraph (2), except that the Sec-
11 retary may issue interim guidance for sponsors seek-
12 ing designation under subsection (d) prior to the
13 promulgation of such regulations.

14 “(4) DESIGNATION PRIOR TO REGULATIONS.—
15 The Secretary may designate drugs as qualified in-
16 fectious disease products under subsection (d) prior
17 to the promulgation of regulations under this sub-
18 section.

19 “(f) QUALIFYING PATHOGEN.—

20 “(1) DEFINITION.—In this section, the term
21 ‘qualifying pathogen’ means a pathogen identified
22 and listed by the Secretary under paragraph (2) that
23 has the potential to pose a serious threat to public
24 health, such as—

1 “(A) resistant gram positive pathogens, in-
2 cluding methicillin-resistant *Staphylococcus*
3 aureus, vancomycin-resistant *Staphylococcus*
4 aureus, and vancomycin-resistant enterococcus;

5 “(B) multi-drug resistant gram negative
6 bacteria, including *Acinetobacter*, *Klebsiella*,
7 *Pseudomonas*, and *E. coli* species;

8 “(C) multi-drug resistant tuberculosis; and

9 “(D) *Clostridium difficile*.

10 “(2) LIST OF QUALIFYING PATHOGENS.—

11 “(A) IN GENERAL.—The Secretary shall
12 establish and maintain a list of qualifying
13 pathogens.

14 “(B) CONSIDERATIONS.—In establishing
15 and maintaining the list of pathogens described
16 under this section the Secretary shall—

17 “(i) consider—

18 “(I) the impact on the public
19 health due to drug-resistant orga-
20 nisms in humans;

21 “(II) the rate of growth of drug-
22 resistant organisms in humans;

23 “(III) the increase in resistance
24 rates in humans; and

1 “(IV) the morbidity and mor-
2 tality in humans; and

3 “(ii) consult with experts in infectious
4 diseases, including the Centers for Disease
5 Control and Prevention, the Food and
6 Drug Administration, medical profes-
7 sionals, and the clinical research commu-
8 nity.

9 “(C) REVIEW.—Every 5 years, or more
10 often as needed, the Secretary shall review, pro-
11 vide modifications to, and publish the list of
12 qualifying pathogens under subparagraph (A)
13 and shall by regulation revise the list as nec-
14 essary, in accordance with subsection (e).

15 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
16 The term ‘qualified infectious disease product’ means an
17 antibacterial or antifungal drug for human use intended
18 to treat serious or life-threatening infections, including
19 those caused by—

20 “(1) an antibacterial or antifungal resistant
21 pathogen, including novel or emerging infectious
22 pathogens; or

23 “(2) qualifying pathogens listed by the Sec-
24 retary under subsection (f).”.

1 (b) APPLICATION.—Section 505E of the Federal
2 Food, Drug, and Cosmetic Act, as added by subsection
3 (a), applies only with respect to a drug that is first ap-
4 proved under section 505(c) of such Act (21 U.S.C.
5 355(c)) on or after the date of the enactment of this Act.

6 **SEC. 802. PRIORITY REVIEW.**

7 (a) AMENDMENT.—Chapter V (21 U.S.C. 351 et
8 seq.) is further amended by inserting after section 524 the
9 following:

10 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**
11 **DISEASE PRODUCTS.**

12 “If the Secretary designates a drug under section
13 505E(d) as a qualified infectious disease product, then the
14 Secretary shall give priority review to any application sub-
15 mitted for approval for such drug under section 505(b).”.

16 (b) APPLICATION.—Section 524A of the Federal
17 Food, Drug, and Cosmetic Act, as added by subsection
18 (a), applies only with respect to an application that is sub-
19 mitted under section 505(b) of such Act (21 U.S.C.
20 355(b)) on or after the date of the enactment of this Act.

21 **SEC. 803. FAST TRACK PRODUCT.**

22 Section 506(a)(1) (21 U.S.C. 356(a)(1)) is amended
23 by inserting “or if the Secretary designates the drug as
24 a qualified infectious disease product under section
25 505E(d)” after “such a condition”.

1 **SEC. 804. GAO STUDY.**

2 (a) IN GENERAL.—The Comptroller General of the
3 United States shall—

4 (1) conduct a study—

5 (A) on the need for incentives to encourage
6 the research, development, and marketing of
7 qualified infectious disease biological products
8 and antifungal products; and

9 (B) consistent with trade and confiden-
10 tiality data protections, assessing, for all anti-
11 bacterial and antifungal drugs, including bio-
12 logical products, the average or aggregate—

13 (i) costs of all clinical trials for each
14 phase;

15 (ii) percentage of success or failure at
16 each phase of clinical trials; and

17 (iii) public versus private funding lev-
18 els of the trials for each phase; and

19 (2) not later than 1 year after the date of en-
20 actment of this Act, submit a report to Congress on
21 the results of such study, including any rec-
22 ommendations of the Comptroller General on appro-
23 priate incentives for addressing such need.

24 (b) CONTENTS.—The part of the study described in
25 subsection (a)(1)(A) shall include—

1 (1) an assessment of any underlying regulatory
2 issues related to qualified infectious disease prod-
3 ucts, including qualified infectious disease biological
4 products;

5 (2) an assessment of the management by the
6 Food and Drug Administration of the review of
7 qualified infectious disease products, including quali-
8 fied infectious disease biological products and the
9 regulatory certainty of related regulatory pathways
10 for such products;

11 (3) a description of any regulatory impediments
12 to the clinical development of new qualified infec-
13 tious disease products, including qualified infectious
14 disease biological products, and the efforts of the
15 Food and Drug Administration to address such im-
16 pediments; and

17 (4) recommendations with respect to—

18 (A) improving the review and predictability
19 of regulatory pathways for such products; and

20 (B) overcoming any regulatory impedi-
21 ments identified in paragraph (3).

22 (c) DEFINITIONS.—In this section:

23 (1) The term “biological product” has the
24 meaning given to such term in section 351 of the
25 Public Health Service Act (42 U.S.C. 262).

1 (2) The term “qualified infectious disease bio-
2 logical product” means a biological product intended
3 to treat a serious or life-threatening infection de-
4 scribed in section 505E(g) of the Federal Food,
5 Drug, and Cosmetic Act, as added by section 3.

6 (3) The term “qualified infectious disease prod-
7 uct” has the meaning given such term in section
8 505E(g) of the Federal Food, Drug, and Cosmetic
9 Act, as added by section 3.

10 **SEC. 805. CLINICAL TRIALS.**

11 (a) REVIEW AND REVISION OF GUIDANCE DOCU-
12 MENTS.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services (referred to in this section as the
15 “Secretary”) shall review and, as appropriate, revise
16 not fewer than 3 guidance documents per year,
17 which shall include—

18 (A) reviewing the guidance documents of
19 the Food and Drug Administration for the con-
20 duct of clinical trials with respect to antibiotic
21 drugs; and

22 (B) as appropriate, revising such guidance
23 documents to reflect developments in scientific
24 and medical information and technology and to
25 ensure clarity regarding the procedures and re-

1 requirements for approval of an antibiotic drug
2 under chapter V of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 351 et seq.).

4 (2) ISSUES FOR REVIEW.—At a minimum, the
5 review under paragraph (1) shall address the appro-
6 priate animal models of infection, in vitro tech-
7 niques, valid micro-biological surrogate markers, the
8 use of non-inferiority versus superiority trials, trial
9 enrollment, data requirements, and appropriate delta
10 values for non-inferiority trials.

11 (3) RULE OF CONSTRUCTION.—Except to the
12 extent to which the Secretary makes revisions under
13 paragraph (1)(B), nothing in this section shall be
14 construed to repeal or otherwise affect the guidance
15 documents of the Food and Drug Administration.

16 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

17 (1) REQUEST.—The sponsor of a drug intended
18 to be designated as a qualified infectious disease
19 product may request that the Secretary provide writ-
20 ten recommendations for nonclinical and clinical in-
21 vestigations which the Secretary believes may be
22 necessary to be conducted with the drug before such
23 drug may be approved under section 505 of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)
25 for use in treating, detecting, preventing, or identi-

1 fying a qualifying pathogen, as defined in section
2 505E of such Act.

3 (2) RECOMMENDATIONS.—If the Secretary has
4 reason to believe that a drug for which a request is
5 made under this subsection is a qualified infectious
6 disease product, the Secretary shall provide the per-
7 son making the request written recommendations for
8 the nonclinical and clinical investigations which the
9 Secretary believes, on the basis of information avail-
10 able to the Secretary at the time of the request,
11 would be necessary for approval under section 505
12 of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 355) of such drug for the use described in
14 paragraph (1).

15 (c) GAO STUDY.—Not later than January 1, 2016,
16 the Comptroller General of the United States shall submit
17 to Congress a report—

18 (1) regarding the review and revision of the
19 clinical trial guidance documents required under
20 subsection (a) and the impact such review and revi-
21 sion has had on the review and approval of qualified
22 infectious disease products;

23 (2) assessing—

24 (A) the effectiveness of the results-oriented
25 metrics managers employ to ensure that review-

1 ers of such products are familiar with, and con-
2 sistently applying, clinical trial guidance docu-
3 ments; and

4 (B) the predictability of related regulatory
5 pathways and review;

6 (3) identifying any outstanding regulatory im-
7 pediments to the clinical development of qualified in-
8 fectious disease products;

9 (4) reporting on the progress the Food and
10 Drug Administration has made in addressing the im-
11 pediments identified under paragraph (3); and

12 (5) containing recommendations regarding how
13 to improve the review of, and regulatory pathway
14 for, such products.

15 **SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.**

16 (a) INITIAL STRATEGY AND IMPLEMENTATION
17 PLAN.—Not later than 1 year after the date of enactment
18 of this Act, the Secretary of Health and Human Services
19 (referred to in this section as the “Secretary”) shall sub-
20 mit to Congress a strategy and implementation plan with
21 respect to the requirements of this Act. The strategy and
22 implementation plan shall include—

23 (1) a description of the regulatory challenges to
24 clinical development, approval, and licensure of
25 qualified infectious disease products;

1 (2) the regulatory and scientific priorities of the
2 Secretary with respect to such challenges; and

3 (3) the steps the Secretary will take to ensure
4 regulatory certainty and predictability with respect
5 to qualified infectious disease products, including
6 steps the Secretary will take to ensure managers and
7 reviewers are familiar with related regulatory path-
8 ways, requirements of the Food and Drug Adminis-
9 tration, guidance documents related to such prod-
10 ucts, and applying such requirements consistently.

11 (b) SUBSEQUENT REPORT.—Not later than 3 years
12 after the date of enactment of this Act, the Secretary shall
13 submit to Congress a report on—

14 (1) the progress made toward the priorities
15 identified under subsection (a)(2);

16 (2) the number of qualified infectious disease
17 products that have been submitted for approval or li-
18 censure on or after the date of enactment of this
19 Act;

20 (3) a list of qualified infectious disease products
21 with information on the types of exclusivity granted
22 for each product, consistent with the information
23 published under section 505(j)(7)(A)(iii) of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C.
25 355(j)(7)(A)(iii));

1 (4) the number of such qualified infectious dis-
2 ease products and that have been approved or li-
3 censed on or after the date of enactment of this Act;
4 and

5 (5) the number of calendar days it took for the
6 approval or licensure of the qualified infectious dis-
7 ease products approved or licensed on or after the
8 date of enactment of this Act.

9 **TITLE IX—DRUG APPROVAL AND**
10 **PATIENT ACCESS**

11 **SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT AC-**
12 **CESS TO NEW MEDICAL TREATMENTS.**

13 (a) FINDINGS; SENSE OF CONGRESS.—

14 (1) FINDINGS.—Congress finds as follows:

15 (A) The Food and Drug Administration
16 (referred to in this section as the “FDA”)
17 serves a critical role in helping to assure that
18 new medicines are safe and effective. Regu-
19 latory innovation is 1 element of the Nation’s
20 strategy to address serious and life-threatening
21 diseases or conditions by promoting investment
22 in and development of innovative treatments for
23 unmet medical needs.

24 (B) During the 2 decades following the es-
25 tablishment of the accelerated approval mecha-

1 nism, advances in medical sciences, including
2 genomics, molecular biology, and bioinformatics,
3 have provided an unprecedented understanding
4 of the underlying biological mechanism and
5 pathogenesis of disease. A new generation of
6 modern, targeted medicines is under develop-
7 ment to treat serious and life-threatening dis-
8 eases, some applying drug development strate-
9 gies based on biomarkers or pharmacogenomics,
10 predictive toxicology, clinical trial enrichment
11 techniques, and novel clinical trial designs, such
12 as adaptive clinical trials.

13 (C) As a result of these remarkable sci-
14 entific and medical advances, the FDA should
15 be encouraged to implement more broadly effec-
16 tive processes for the expedited development
17 and review of innovative new medicines in-
18 tended to address unmet medical needs for seri-
19 ous or life-threatening diseases or conditions,
20 including those for rare diseases or conditions,
21 using a broad range of surrogate or clinical
22 endpoints and modern scientific tools earlier in
23 the drug development cycle when appropriate.
24 This may result in fewer, smaller, or shorter
25 clinical trials for the intended patient popu-

1 lation or targeted subpopulation without com-
2 promising or altering the high standards of the
3 FDA for the approval of drugs.

4 (D) Patients benefit from expedited access
5 to safe and effective innovative therapies to
6 treat unmet medical needs for serious or life-
7 threatening diseases or conditions.

8 (E) For these reasons, the statutory au-
9 thority in effect on the day before the date of
10 enactment of this Act governing expedited ap-
11 proval of drugs for serious or life-threatening
12 diseases or conditions should be amended in
13 order to enhance the authority of the FDA to
14 consider appropriate scientific data, methods,
15 and tools, and to expedite development and ac-
16 cess to novel treatments for patients with a
17 broad range of serious or life-threatening dis-
18 eases or conditions.

19 (2) SENSE OF CONGRESS.—It is the sense of
20 Congress that the Food and Drug Administration
21 should apply the accelerated approval and fast track
22 provisions set forth in section 506 of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 356), as
24 amended by this section, to help expedite the devel-
25 opment and availability to patients of treatments for

1 serious or life-threatening diseases or conditions
2 while maintaining safety and effectiveness standards
3 for such treatments.

4 (b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS
5 OR LIFE-THREATENING DISEASES OR CONDITIONS.—Sec-
6 tion 506 (21 U.S.C. 356) is amended to read as follows:

7 **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**
8 **OR LIFE-THREATENING DISEASES OR CONDI-**
9 **TIONS.**

10 “(a) DESIGNATION OF DRUG AS FAST TRACK PROD-
11 UCT.—

12 “(1) IN GENERAL.—The Secretary shall, at the
13 request of the sponsor of a new drug, facilitate the
14 development and expedite the review of such drug if
15 it is intended, whether alone or in combination with
16 one or more other drugs, for the treatment of a seri-
17 ous or life-threatening disease or condition, and it
18 demonstrates the potential to address unmet medical
19 needs for such a disease or condition. (In this sec-
20 tion, such a drug is referred to as a ‘fast track prod-
21 uct’.)

22 “(2) REQUEST FOR DESIGNATION.—The spon-
23 sor of a new drug may request the Secretary to des-
24 ignate the drug as a fast track product. A request
25 for the designation may be made concurrently with,

1 or at any time after, submission of an application
2 for the investigation of the drug under section 505(i)
3 or section 351(a)(3) of the Public Health Service
4 Act.

5 “(3) DESIGNATION.—Within 60 calendar days
6 after the receipt of a request under paragraph (2),
7 the Secretary shall determine whether the drug that
8 is the subject of the request meets the criteria de-
9 scribed in paragraph (1). If the Secretary finds that
10 the drug meets the criteria, the Secretary shall des-
11 ignate the drug as a fast track product and shall
12 take such actions as are appropriate to expedite the
13 development and review of the application for ap-
14 proval of such product.

15 “(b) ACCELERATED APPROVAL OF A DRUG FOR A
16 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-
17 TION, INCLUDING A FAST TRACK PRODUCT.—

18 “(1) IN GENERAL.—

19 “(A) ACCELERATED APPROVAL.—The Sec-
20 retary may approve an application for approval
21 of a product for a serious or life-threatening
22 disease or condition, including a fast track
23 product, under section 505(c) or section 351(a)
24 of the Public Health Service Act upon a deter-
25 mination that the product has an effect on a

1 surrogate endpoint that is reasonably likely to
2 predict clinical benefit, or on a clinical endpoint
3 that can be measured earlier than irreversible
4 morbidity or mortality, that is reasonably likely
5 to predict an effect on irreversible morbidity or
6 mortality or other clinical benefit, taking into
7 account the severity, rarity, or prevalence of the
8 condition and the availability or lack of alter-
9 native treatments. The approval described in
10 the preceding sentence is referred to in this sec-
11 tion as ‘accelerated approval’.

12 “(B) EVIDENCE.—The evidence to support
13 that an endpoint is reasonably likely to predict
14 clinical benefit under subparagraph (A) may in-
15 clude epidemiological, pathophysiological, thera-
16 peutic, pharmacologic, or other evidence devel-
17 oped using biomarkers, for example, or other
18 scientific methods or tools.

19 “(2) LIMITATION.—Approval of a product
20 under this subsection may be subject to 1 or both
21 of the following requirements:

22 “(A) That the sponsor conduct appropriate
23 post-approval studies to verify and describe the
24 predicted effect on irreversible morbidity or
25 mortality or other clinical benefit.

1 “(B) That the sponsor submit copies of all
2 promotional materials related to the product
3 during the preapproval review period and, fol-
4 lowing approval and for such period thereafter
5 as the Secretary determines to be appropriate,
6 at least 30 days prior to dissemination of the
7 materials.

8 “(3) EXPEDITED WITHDRAWAL OF AP-
9 PROVAL.—The Secretary may withdraw approval of
10 a product approved under accelerated approval using
11 expedited procedures (as prescribed by the Secretary
12 in regulations which shall include an opportunity for
13 an informal hearing) if—

14 “(A) the sponsor fails to conduct any re-
15 quired post-approval study of the drug with due
16 diligence;

17 “(B) a study required to verify and de-
18 scribe the predicted effect on irreversible mor-
19 bidity or mortality or other clinical benefit of
20 the product fails to verify and describe such ef-
21 fect or benefit;

22 “(C) other evidence demonstrates that the
23 product is not safe or effective under the condi-
24 tions of use; or

1 “(D) the sponsor disseminates false or
2 misleading promotional materials with respect
3 to the product.

4 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR
5 APPROVAL OF A FAST TRACK PRODUCT.—

6 “(1) IN GENERAL.—If the Secretary deter-
7 mines, after preliminary evaluation of clinical data
8 submitted by the sponsor, that a fast track product
9 may be effective, the Secretary shall evaluate for fil-
10 ing, and may commence review of portions of, an ap-
11 plication for the approval of the product before the
12 sponsor submits a complete application. The Sec-
13 retary shall commence such review only if the appli-
14 cant—

15 “(A) provides a schedule for submission of
16 information necessary to make the application
17 complete; and

18 “(B) pays any fee that may be required
19 under section 736.

20 “(2) EXCEPTION.—Any time period for review
21 of human drug applications that has been agreed to
22 by the Secretary and that has been set forth in goals
23 identified in letters of the Secretary (relating to the
24 use of fees collected under section 736 to expedite
25 the drug development process and the review of

1 human drug applications) shall not apply to an ap-
2 plication submitted under paragraph (1) until the
3 date on which the application is complete.

4 “(d) AWARENESS EFFORTS.—The Secretary shall—

5 “(1) develop and disseminate to physicians, pa-
6 tient organizations, pharmaceutical and bio-
7 technology companies, and other appropriate persons
8 a description of the provisions of this section appli-
9 cable to accelerated approval and fast track prod-
10 ucts; and

11 “(2) establish a program to encourage the de-
12 velopment of surrogate and clinical endpoints, in-
13 cluding biomarkers, and other scientific methods and
14 tools that can assist the Secretary in determining
15 whether the evidence submitted in an application is
16 reasonably likely to predict clinical benefit for seri-
17 ous or life-threatening conditions for which signifi-
18 cant unmet medical needs exist.

19 “(e) CONSTRUCTION.—

20 “(1) PURPOSE.—The amendments made by the
21 Food and Drug Administration Safety and Innova-
22 tion Act to this section are intended to encourage
23 the Secretary to utilize innovative and flexible ap-
24 proaches to the assessment of products under accel-
25 erated approval for treatments for patients with seri-

1 ous or life-threatening diseases or conditions and
2 unmet medical needs.

3 “(2) CONSTRUCTION.—Nothing in this section
4 shall be construed to alter the standards of evidence
5 under subsection (c) or (d) of section 505 (including
6 the substantial evidence standard in section 505(d))
7 of this Act or under section 351(a) of the Public
8 Health Service Act. Such sections and standards of
9 evidence apply to the review and approval of prod-
10 ucts under this section, including whether a product
11 is safe and effective. Nothing in this section alters
12 the ability of the Secretary to rely on evidence that
13 does not come from adequate and well-controlled in-
14 vestigations for the purpose of determining whether
15 an endpoint is reasonably likely to predict clinical
16 benefit as described in subsection (b)(1)(B).”.

17 (c) GUIDANCE; AMENDED REGULATIONS.—

18 (1) DRAFT GUIDANCE.—Not later than 1 year
19 after the date of enactment of this Act, the Sec-
20 retary of Health and Human Services (referred to in
21 this section as the “Secretary”) shall issue draft
22 guidance to implement the amendments made by
23 this section. In developing such guidance, the Sec-
24 retary shall specifically consider issues arising under
25 the accelerated approval and fast track processes

1 under section 506 of the Federal Food, Drug, and
2 Cosmetic Act, as amended by subsection (b), for
3 drugs designated for a rare disease or condition
4 under section 526 of such Act (21 U.S.C. 360bb)
5 and shall also consider any unique issues associated
6 with very rare diseases.

7 (2) FINAL GUIDANCE.—Not later than 1 year
8 after the issuance of draft guidance under para-
9 graph (1), and after an opportunity for public com-
10 ment, the Secretary shall issue final guidance.

11 (3) CONFORMING CHANGES.—The Secretary
12 shall issue, as necessary, conforming amendments to
13 the applicable regulations under title 21, Code of
14 Federal Regulations, governing accelerated approval.

15 (4) NO EFFECT OF INACTION ON REQUESTS.—
16 If the Secretary fails to issue final guidance or
17 amended regulations as required by this subsection,
18 such failure shall not preclude the review of, or ac-
19 tion on, a request for designation or an application
20 for approval submitted pursuant to section 506 of
21 the Federal Food, Drug, and Cosmetic Act, as
22 amended by subsection (b).

23 (d) INDEPENDENT REVIEW.—The Secretary may, in
24 conjunction with other planned reviews, contract with an
25 independent entity with expertise in assessing the quality

1 and efficiency of biopharmaceutical development and regu-
2 latory review programs to evaluate the Food and Drug Ad-
3 ministration's application of the processes described in
4 section 506 of the Federal Food, Drug, and Cosmetic Act,
5 as amended by subsection (b), and the impact of such
6 processes on the development and timely availability of in-
7 novative treatments for patients suffering from serious or
8 life-threatening conditions. Any such evaluation shall in-
9 clude consultation with regulated industries, patient advo-
10 cacy and disease research foundations, and relevant aca-
11 demic medical centers.

12 **SEC. 902. BREAKTHROUGH THERAPIES.**

13 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as
14 amended by section 2, is further amended—

15 (1) by redesignating subsections (a) through (c)
16 as subsections (b) through (d), respectively;

17 (2) by redesignating subsection (d) as sub-
18 section (f);

19 (3) by inserting before subsection (b), as so re-
20 designated, the following:

21 “(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH
22 THERAPY.—

23 “(1) IN GENERAL.—The Secretary shall, at the
24 request of the sponsor of a drug, expedite the devel-
25 opment and review of such drug if the drug is in-

1 tended, alone or in combination with 1 or more other
2 drugs, to treat a serious or life-threatening disease
3 or condition and preliminary clinical evidence indi-
4 cates that the drug may demonstrate substantial im-
5 provement over existing therapies on 1 or more clini-
6 cally significant endpoints, such as substantial treat-
7 ment effects observed early in clinical development.
8 (In this section, such a drug is referred to as a
9 ‘breakthrough therapy’.)

10 “(2) REQUEST FOR DESIGNATION.—The spon-
11 sor of a drug may request the Secretary to designate
12 the drug as a breakthrough therapy. A request for
13 the designation may be made concurrently with, or
14 at any time after, the submission of an application
15 for the investigation of the drug under section 505(i)
16 or section 351(a)(3) of the Public Health Service
17 Act.

18 “(3) DESIGNATION.—

19 “(A) IN GENERAL.—Not later than 60 cal-
20 endar days after the receipt of a request under
21 paragraph (2), the Secretary shall determine
22 whether the drug that is the subject of the re-
23 quest meets the criteria described in paragraph
24 (1). If the Secretary finds that the drug meets
25 the criteria, the Secretary shall designate the

1 drug as a breakthrough therapy and shall take
2 such actions as are appropriate to expedite the
3 development and review of the application for
4 approval of such drug.

5 “(B) ACTIONS.—The actions to expedite
6 the development and review of an application
7 under subparagraph (A) may include, as appro-
8 priate—

9 “(i) holding meetings with the sponsor
10 and the review team throughout the devel-
11 opment of the drug;

12 “(ii) providing timely advice to, and
13 interactive communication with, the spon-
14 sor regarding the development of the drug
15 to ensure that the development program to
16 gather the non-clinical and clinical data
17 necessary for approval is as efficient as
18 practicable;

19 “(iii) involving senior managers and
20 experienced review staff, as appropriate, in
21 a collaborative, cross-disciplinary review;

22 “(iv) assigning a cross-disciplinary
23 project lead for the Food and Drug Ad-
24 ministration review team to facilitate an
25 efficient review of the development pro-

1 gram and to serve as a scientific liaison be-
2 tween the review team and the sponsor;
3 and

4 “(v) taking steps to ensure that the
5 design of the clinical trials is as efficient as
6 practicable, when scientifically appropriate,
7 such as by minimizing the number of pa-
8 tients exposed to a potentially less effica-
9 cious treatment.”;

10 (4) in subsection (f)(1), as so redesignated, by
11 striking “applicable to accelerated approval” and in-
12 serting “applicable to breakthrough therapies, accel-
13 erated approval, and”; and

14 (5) by adding at the end the following:

15 “(g) REPORT.—Beginning in fiscal year 2013, the
16 Secretary shall annually prepare and submit to the Com-
17 mittee on Health, Education, Labor, and Pensions of the
18 Senate and the Committee on Energy and Commerce of
19 the House of Representatives, and make publicly available,
20 with respect to this section for the previous fiscal year—

21 “(1) the number of drugs for which a sponsor
22 requested designation as a breakthrough therapy;

23 “(2) the number of products designated as a
24 breakthrough therapy; and

1 “(3) for each product designated as a break-
2 through therapy, a summary of the actions taken
3 under subsection (a)(3).”.

4 (b) GUIDANCE; AMENDED REGULATIONS.—

5 (1) IN GENERAL.—

6 (A) GUIDANCE.—Not later than 18
7 months after the date of enactment of this Act,
8 the Secretary of Health and Human Services
9 (referred to in this section as the “Secretary”)
10 shall issue draft guidance on implementing the
11 requirements with respect to breakthrough
12 therapies, as set forth in section 506(a) of the
13 Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 356(a)), as amended by this section.
15 The Secretary shall issue final guidance not
16 later than 1 year after the close of the comment
17 period for the draft guidance.

18 (B) AMENDED REGULATIONS.—If the Sec-
19 retary determines that it is necessary to amend
20 the regulations under title 21, Code of Federal
21 Regulations in order to implement the amend-
22 ments made by this section to section 506(a) of
23 the Federal Food, Drug, and Cosmetic Act, the
24 Secretary shall amend such regulations not

1 later than 2 years after the date of enactment
2 of this Act.

3 (2) REQUIREMENTS.—Guidance issued under
4 this section shall—

5 (A) specify the process and criteria by
6 which the Secretary makes a designation under
7 section 506(a)(3) of the Federal Food, Drug,
8 and Cosmetic Act; and

9 (B) specify the actions the Secretary shall
10 take to expedite the development and review of
11 a breakthrough therapy pursuant to such des-
12 ignation under such section 506(a)(3), includ-
13 ing updating good review management practices
14 to reflect breakthrough therapies.

15 (c) INDEPENDENT REVIEW.—Not later than 3 years
16 after the date of enactment of this Act, the Comptroller
17 General of the United States, in consultation with appro-
18 priate experts, shall assess the manner by which the Food
19 and Drug Administration has applied the processes de-
20 scribed in section 506(a) of the Federal Food, Drug, and
21 Cosmetic Act, as amended by this section, and the impact
22 of such processes on the development and timely avail-
23 ability of innovative treatments for patients affected by se-
24 rious or life-threatening conditions. Such assessment shall
25 be made publicly available upon completion.

1 (d) CONFORMING AMENDMENTS.—Section 506B(e)
2 (21 U.S.C. 356b) is amended by striking “section
3 506(b)(2)(A)” each place such term appears and inserting
4 “section 506(c)(2)(A)”.

5 **SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON**
6 **RARE DISEASES, TARGETED THERAPIES, AND**
7 **GENETIC TARGETING OF TREATMENTS.**

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

10 **“SEC. 568. CONSULTATION WITH EXTERNAL EXPERTS ON**
11 **RARE DISEASES, TARGETED THERAPIES, AND**
12 **GENETIC TARGETING OF TREATMENTS.**

13 “(a) IN GENERAL.—For the purpose of promoting
14 the efficiency of and informing the review by the Food
15 and Drug Administration of new drugs and biological
16 products for rare diseases and drugs and biologic products
17 that are genetically targeted, the following shall apply:

18 “(1) CONSULTATION WITH STAKEHOLDERS.—
19 Consistent with sections X.C and IX.E.4 of the
20 PDUFA Reauthorization Performance Goals and
21 Procedures Fiscal Years 2013 through 2017, as ref-
22 erenced in the letters described in section 101(b) of
23 the Prescription Drug User Fee Amendments of
24 2012, the Secretary shall ensure that opportunities
25 exist, at a time the Secretary determines appro-

1 piate, for consultations with stakeholders on the
2 topics described in subsection (c).

3 “(2) CONSULTATION WITH EXTERNAL EX-
4 PERTS.—The Secretary shall develop and maintain a
5 list of external experts who, because of their special
6 expertise, are qualified to provide advice on rare dis-
7 ease issues, including topics described in subsection
8 (c). The Secretary may, when appropriate to address
9 a specific regulatory question, consult such external
10 experts, or other experts as appropriate, on any
11 topic, including the topics described in subsection
12 (c), when such consultation is necessary because the
13 Secretary lacks specific scientific, medical, or tech-
14 nical expertise necessary for the performance of its
15 regulatory responsibilities and the necessary exper-
16 tise can be provided by the external experts.

17 “(b) EXTERNAL EXPERTS.—For purposes of sub-
18 section (a)(2), external experts are those who possess sci-
19 entific or medical training that the Secretary lacks with
20 respect to one or more rare diseases.

21 “(c) TOPICS FOR CONSULTATION.—Topics for con-
22 sultation pursuant to this section may include—

23 “(1) rare diseases;

24 “(2) the severity of rare diseases;

1 “(3) the unmet medical need associated with
2 rare diseases;

3 “(4) the willingness and ability of individuals
4 with a rare disease to participate in clinical trials;

5 “(5) an assessment of the risk-benefit tolerance
6 of patients with rare diseases;

7 “(6) the general design of clinical trials for rare
8 disease populations and subpopulations; and

9 “(7) demographics and the clinical description
10 of patient populations.

11 “(d) CLASSIFICATION AS SPECIAL GOVERNMENT EM-
12 PLOYEES.—The external experts who are consulted under
13 this section may be considered special government employ-
14 ees, as defined under section 202 of title 18, United States
15 Code.

16 “(e) PROTECTION OF PROPRIETARY INFORMA-
17 TION.—Nothing in this section shall be construed to alter
18 the protections offered by laws, regulations, and policies
19 governing disclosure of confidential commercial or trade
20 secret information, and any other information exempt
21 from disclosure pursuant to section 552(b) of title 5,
22 United States Code, as such provisions would be applied
23 to consultation with individuals and organizations prior to
24 the date of enactment of this section.

1 drug container labels for individuals who are blind
2 or visually impaired.

3 (2) MEMBERS.—The working group shall be
4 comprised of representatives of national organiza-
5 tions representing blind and visually-impaired indi-
6 viduals, national organizations representing the el-
7 derly, and industry groups representing stake-
8 holders, including retail, mail order, and independent
9 community pharmacies, who would be impacted by
10 such best practices. Representation within the work-
11 ing group shall be divided equally between consumer
12 and industry advocates.

13 (3) BEST PRACTICES.—

14 (A) IN GENERAL.—The working group
15 shall develop, not later than 1 year after the
16 date of the enactment of this Act, best practices
17 for pharmacies to ensure that blind and vis-
18 ually-impaired individuals have safe, consistent,
19 reliable, and independent access to the informa-
20 tion on prescription drug container labels.

21 (B) PUBLIC AVAILABILITY.—The best
22 practices developed under subparagraph (A)
23 may be made publicly available, including
24 through the Internet Web sites of the working
25 group participant organizations, and through

1 other means, in a manner that provides access
2 to interested individuals, including individuals
3 with disabilities.

4 (C) LIMITATIONS.—The best practices de-
5 veloped under subparagraph (A) shall not be
6 construed as accessibility guidelines or stand-
7 ards of the Access Board, and shall not confer
8 any rights or impose any obligations on working
9 group participants or other persons. Nothing in
10 this section shall be construed to limit or condi-
11 tion any right, obligation, or remedy available
12 under the Americans with Disabilities Act of
13 1990 (42 U.S.C. 12101 et seq.) or any other
14 Federal or State law requiring effective commu-
15 nication, barrier removal, or nondiscrimination
16 on the basis of disability.

17 (4) CONSIDERATIONS.—In developing and
18 issuing the best practices under paragraph (3)(A),
19 the working group shall consider—

20 (A) the use of—

21 (i) Braille;

22 (ii) auditory means, such as—

23 (I) “talking bottles” that provide
24 audible container label information;

1 (II) digital voice recorders at-
2 tached to the prescription drug con-
3 tainer; and

4 (III) radio frequency identifica-
5 tion tags;

6 (iii) enhanced visual means, such as—

7 (I) large font labels or large font
8 “duplicate” labels that are affixed or
9 matched to a prescription drug con-
10 tainer;

11 (II) high-contrast printing; and

12 (III) sans-serif font; and

13 (iv) other relevant alternatives as de-
14 termined by the working group;

15 (B) whether there are technical, financial,
16 manpower, or other factors unique to phar-
17 macies with 20 or fewer retail locations which
18 may pose significant challenges to the adoption
19 of the best practices; and

20 (C) such other factors as the working
21 group determines to be appropriate.

22 (5) INFORMATION CAMPAIGN.—Upon comple-
23 tion of development of the best practices under sub-
24 section (a)(3), the National Council on Disability, in
25 consultation with the working group, shall conduct

1 an informational and educational campaign designed
2 to inform individuals with disabilities, pharmacists,
3 and the public about such best practices.

4 (6) FACA WAIVER.—The Federal Advisory
5 Committee Act (5 U.S.C. App.) shall not apply to
6 the working group.

7 (b) GAO STUDY.—

8 (1) IN GENERAL.—Beginning 18 months after
9 the completion of the development of best practices
10 under subsection (a)(3)(A), the Comptroller General
11 of the United States shall conduct a review of the
12 extent to which pharmacies are utilizing such best
13 practices, and the extent to which barriers to acces-
14 sible information on prescription drug container la-
15 bels for blind and visually-impaired individuals con-
16 tinue.

17 (2) REPORT.—Not later than September 30,
18 2016, the Comptroller General of the United States
19 shall submit to Congress a report on the review con-
20 ducted under paragraph (1). Such report shall in-
21 clude recommendations about how best to reduce the
22 barriers experienced by blind and visually-impaired
23 individuals to independently accessing information
24 on prescription drug container labels.

25 (c) DEFINITIONS.—In this section—

1 (1) the term “pharmacy” includes a pharmacy
2 that receives prescriptions and dispenses prescription
3 drugs through an Internet Web site or by mail;

4 (2) the term “prescription drug” means a drug
5 subject to section 503(b)(1) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

7 (3) the term “prescription drug container label”
8 means the label with the directions for use that is
9 affixed to the prescription drug container by the
10 pharmacist and dispensed to the consumer.

11 **TITLE X—DRUG SHORTAGES**

12 **SEC. 1001. DRUG SHORTAGES.**

13 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)
14 is amended to read as follows:

15 **“SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE** 16 **PRODUCTION OF LIFE-SAVING DRUGS.**

17 “(a) IN GENERAL.—A manufacturer of a drug—

18 “(1) that is—

19 “(A) life-supporting;

20 “(B) life-sustaining;

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

23 “(D) a sterile injectable product; or

24 “(E) used in emergency medical care or
25 during surgery; and

1 “(2) that is not a radio pharmaceutical drug
2 product, a human tissue replaced by a recombinant
3 product, a product derived from human plasma pro-
4 tein, or any other product as designated by the Sec-
5 retary,

6 shall notify the Secretary, in accordance with subsection
7 (b), of a permanent discontinuance in the manufacture of
8 the drug or an interruption of the manufacture of the drug
9 that could lead to a meaningful disruption in the supply
10 of that drug in the United States.

11 “(b) TIMING.—A notice required under subsection (a)
12 shall be submitted to the Secretary—

13 “(1) at least 6 months prior to the date of the
14 discontinuance or interruption; or

15 “(2) if compliance with paragraph (1) is impos-
16 sible, as soon as practicable.

17 “(c) EXPEDITED INSPECTIONS AND REVIEWS.—If,
18 based on notifications described in subsection (a) or any
19 other relevant information, the Secretary concludes that
20 there is, or is likely to be, a drug shortage of a drug de-
21 scribed in subsection (a), the Secretary may—

22 “(1) expedite the review of a supplement to a
23 new drug application submitted under section
24 505(b), an abbreviated new drug application sub-
25 mitted under section 505(j), or a supplement to such

1 an application submitted under section 505(j) that
2 could help mitigate or prevent such shortage; or

3 “(2) expedite an inspection or reinspection of
4 an establishment that could help mitigate or prevent
5 such drug shortage.

6 “(d) COORDINATION.—

7 “(1) TASK FORCE AND STRATEGIC PLAN.—

8 “(A) IN GENERAL.—

9 “(i) TASK FORCE.—As soon as prac-
10 ticable after the date of enactment of the
11 Food and Drug Administration Safety and
12 Innovation Act, the Secretary shall estab-
13 lish a Task Force to develop and imple-
14 ment a strategic plan for enhancing the
15 Secretary’s response to preventing and
16 mitigating drug shortages.

17 “(ii) STRATEGIC PLAN.—The strategic
18 plan described in clause (i) shall include—

19 “(I) plans for enhanced inter-
20 agency and intraagency coordination,
21 communication, and decisionmaking;

22 “(II) plans for ensuring that
23 drug shortages are considered when
24 the Secretary initiates a regulatory
25 action that could precipitate a drug

1 shortage or exacerbate an existing
2 drug shortage;

3 “(III) plans for effective commu-
4 nication with outside stakeholders, in-
5 cluding who the Secretary should alert
6 about potential or actual drug short-
7 ages, how the communication should
8 occur, and what types of information
9 should be shared; and

10 “(IV) plans for considering the
11 impact of drug shortages on research
12 and clinical trials.

13 “(iii) CONSULTATION.—In carrying
14 out this subparagraph, the Task Force
15 shall ensure consultation with the appro-
16 priate offices within the Food and Drug
17 Administration, including the Office of the
18 Commissioner, the Center for Drug Eval-
19 uation and Research, the Office of Regu-
20 latory Affairs, and employees within the
21 Department of Health and Human Serv-
22 ices with expertise regarding drug short-
23 ages. The Secretary shall engage external
24 stakeholders and experts as appropriate.

1 “(B) TIMING.—Not later than 1 year after
2 the date of enactment Food and Drug Adminis-
3 tration Safety and Innovation Act, the Task
4 Force shall—

5 “(i) publish the strategic plan de-
6 scribed in subparagraph (A); and

7 “(ii) submit such plan to Congress.

8 “(2) COMMUNICATION.—The Secretary shall
9 ensure that, prior to any enforcement action or
10 issuance of a warning letter that the Secretary de-
11 termines could reasonably be anticipated to lead to
12 a meaningful disruption in the supply in the United
13 States of a drug described under subsection (a),
14 there is communication with the appropriate office
15 of the Food and Drug Administration with expertise
16 regarding drug shortages regarding whether the ac-
17 tion or letter could cause, or exacerbate, a shortage
18 of the drug.

19 “(3) ACTION.—If the Secretary determines,
20 after the communication described in paragraph (2),
21 that an enforcement action or a warning letter could
22 reasonably cause or exacerbate a shortage of a drug
23 described under subsection (a), then the Secretary
24 shall evaluate the risks associated with the impact of
25 such shortage upon patients and those risks associ-

1 ated with the violation involved before taking such
2 action or issuing such letter, unless there is immi-
3 nent risk of serious adverse health consequences or
4 death to humans.

5 “(4) REPORTING BY OTHER ENTITIES.—The
6 Secretary shall identify or establish a mechanism by
7 which healthcare providers and other third-party or-
8 ganizations may report to the Secretary evidence of
9 a drug shortage.

10 “(5) REVIEW AND CONSTRUCTION.—No deter-
11 mination, finding, action, or omission of the Sec-
12 retary under this subsection shall—

13 “(A) be subject to judicial review; or

14 “(B) be construed to establish a defense to
15 an enforcement action by the Secretary.

16 “(e) RECORDKEEPING AND REPORTING.—

17 “(1) RECORDKEEPING.—The Secretary shall
18 maintain records related to drug shortages, includ-
19 ing with respect to each of the following:

20 “(A) The number of manufacturers that
21 submitted a notification to the Secretary under
22 subsection (a) in each calendar year.

23 “(B) The number of drug shortages that
24 occurred in each calendar year and a list of

1 drug names, drug types, and classes that were
2 the subject of such shortages.

3 “(C) A list of the known factors contrib-
4 uting to the drug shortages described in sub-
5 paragraph (B).

6 “(D)(i) A list of major actions taken by
7 the Secretary to prevent or mitigate the drug
8 shortages described in subparagraph (B).

9 “(ii) The Secretary shall include in the list
10 under clause (i) the following:

11 “(I) The number of applications for
12 which the Secretary expedited review under
13 subsection (c)(1) in each calendar year.

14 “(II) The number of expedited estab-
15 lishment inspections or reinspections that
16 the Secretary expedited under subsection
17 (c)(2) in each calendar year.

18 “(E) The number of notifications sub-
19 mitted to the Secretary under subsection (a) in
20 each calendar year.

21 “(F) The names of manufacturers that the
22 Secretary has learned did not comply with the
23 notification requirement under subsection (a) in
24 each calendar year.

1 “(G) The number of times in each cal-
2 endar year that the Secretary determined under
3 subsection (d)(3) that an enforcement action or
4 a warning letter could reasonably cause or exac-
5 erbate a shortage of a drug described under
6 subsection (a), but did not evaluate the risks
7 associated with the impact of such shortage
8 upon patients and those risks associated with
9 the violation involved before taking such action
10 or issuing such letter on the grounds that there
11 was imminent risk of serious adverse health
12 consequences or death to humans, and a sum-
13 mary of the determinations.

14 “(H) A summary of the communications
15 made and actions taken under subsection (d) in
16 each calendar year.

17 “(I) Any other information the Secretary
18 deems appropriate to better prevent and miti-
19 gate drug shortages.

20 “(2) TREND ANALYSIS.—The Secretary is au-
21 thorized to retain a third party to conduct a study,
22 if the Secretary believes such a study would help
23 clarify the causes, trends, or solutions related to
24 drug shortages.

1 “(3) ANNUAL SUMMARY.—Not later than 18
2 months after the date of enactment of the Food and
3 Drug Administration Safety and Innovation Act, and
4 annually thereafter, the Secretary shall submit to
5 the Committee on Health, Education, Labor, and
6 Pensions of the Senate and the Committee on En-
7 ergy and Commerce of the House of Representatives
8 a report summarizing, with respect to the 1-year pe-
9 riod preceding such report, the findings described in
10 paragraph (1). Such report shall not include any in-
11 formation that is exempt from disclosure under sec-
12 tion 552 of title 5, United States Code, by reason
13 of subsection (b)(4) of such section.

14 “(f) DEFINITIONS.—For purposes of this section—

15 “(1) the term ‘drug’—

16 “(A) means a drug (as defined in section
17 201(g)) that is intended for human use; and

18 “(B) does not include biological products
19 (as defined in section 351 of the Public Health
20 Service Act), unless otherwise provided by the
21 Secretary in the regulations promulgated under
22 subsection (h);

23 “(2) the term ‘drug shortage’ or ‘shortage’,
24 with respect to a drug, means a period of time when
25 the demand or projected demand for the drug within

1 the United States exceeds the supply of the drug;
2 and

3 “(3) the term ‘meaningful disruption’—

4 “(A) means a change in production that is
5 reasonably likely to lead to a reduction in the
6 supply of a drug by a manufacturer that is
7 more than negligible and impacts the ability of
8 the manufacturer to fill orders or meet expected
9 demand for its product; and

10 “(B) does not include interruptions in
11 manufacturing due to matters such as routine
12 maintenance or insignificant changes in manu-
13 facturing so long as the manufacturer expects
14 to resume operations in a short period of time.

15 “(g) DISTRIBUTION.—To the maximum extent prac-
16 ticable, the Secretary may distribute information on drug
17 shortages and on the permanent discontinuation of the
18 drugs described in this section to appropriate provider and
19 patient organizations, except that any such distribution
20 shall not include any information that is exempt from dis-
21 closure under section 552 of title 5, United States Code,
22 by reason of subsection (b)(4) of such section.

23 “(h) REGULATIONS.—

24 “(1) IN GENERAL.—Not later than 18 months
25 after the date of enactment of the Food and Drug

1 Administration Safety and Innovation Act, the Sec-
2 retary shall adopt a final regulation implementing
3 this section.

4 “(2) INCLUSION OF BIOLOGICAL PRODUCTS.—

5 “(A) IN GENERAL.—The Secretary may by
6 regulation apply this section to biological prod-
7 ucts (as defined in section 351 of the Public
8 Health Service Act) if the Secretary determines
9 such inclusion would benefit the public health.

10 “(B) RULE FOR VACCINES.—If the Sec-
11 retary applies this section to vaccines pursuant
12 to subparagraph (A), the Secretary shall—

13 “(i) consider whether the notification
14 requirement under subsection (a) may be
15 satisfied by submitting a notification to the
16 Centers for Disease Control and Preven-
17 tion under the vaccine shortage notification
18 program of such Centers; and

19 “(ii) explain the determination made
20 by the Secretary under clause (i) in the
21 regulation.

22 “(3) PROCEDURE.—In promulgating a regula-
23 tion implementing this section, the Secretary shall—

24 “(A) issue a notice of proposed rulemaking
25 that includes a copy of the proposed regulation;

1 “(B) provide a period of not less than 60
2 days for comments on the proposed regulation;
3 and

4 “(C) publish the final regulation not less
5 than 30 days before the regulation’s effective
6 date.

7 “(4) RESTRICTIONS.—Notwithstanding any
8 other provision of Federal law, in implementing this
9 section, the Secretary shall only promulgate regula-
10 tions as described in paragraph (3).”.

11 (b) EFFECT OF NOTIFICATION.—The submission of
12 a notification to the Secretary of Health and Human Serv-
13 ices (referred to in this section as the “Secretary”) for
14 purposes of complying with the requirement in section
15 506C(a) of the Federal Food, Drug, and Cosmetic Act (as
16 amended by subsection (a)) shall not be construed—

17 (1) as an admission that any product that is
18 the subject of such notification violates any provision
19 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 301 et seq.); or

21 (2) as evidence of an intention to promote or
22 market the product for an indication or use for
23 which the product has not been approved by the Sec-
24 retary.

1 (c) INTERNAL REVIEW.—Not later than 2 years after
2 the date of enactment of this Act, the Secretary shall—

3 (1) analyze and review the regulations promul-
4 gated under the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 301 et seq.), the guidances or poli-
6 cies issued under such Act related to drugs intended
7 for human use, and the practices of the Food and
8 Drug Administration regarding enforcing such Act
9 related to manufacturing of such drugs, to identify
10 any such regulations, guidances, policies, or prac-
11 tices that cause, exacerbate, prevent, or mitigate
12 drug shortages (as defined in section 506C of the
13 Federal Food, Drug, and Cosmetic Act (as amended
14 by subsection (a))); and

15 (2) determine how regulations, guidances, poli-
16 cies, or practices identified under paragraph (1)
17 should be modified, streamlined, expanded, or dis-
18 continued in order to reduce or prevent such drug
19 shortages, taking into consideration the effect of any
20 changes on the public health.

21 (d) STUDY ON MARKET FACTORS CONTRIBUTING TO
22 DRUG SHORTAGES AND STOCKPILING.—

23 (1) IN GENERAL.—Not later than 1 year after
24 the date of enactment of this Act, the Comptroller
25 General of the United States, in consultation with

1 the Secretary, the Department of Health and
2 Human Services Office of the Inspector General, the
3 Attorney General, and Chairman of the Federal
4 Trade Commission, shall publish a report reviewing
5 any findings that drug shortages (as so defined)
6 have led market participants to stockpile affected
7 drugs or sell them at significantly increased prices,
8 the impact of such activities on Federal revenue, and
9 any economic factors that have exacerbated or cre-
10 ated a market for such actions.

11 (2) CONTENT.—The report under paragraph
12 (1) shall include—

13 (A) an analysis of the incidence of any of
14 the activities described in paragraph (1) and
15 the effect of such activities on the public health;

16 (B) an evaluation of whether in such cases
17 there is a correlation between drugs in shortage
18 and—

19 (i) the number of manufacturers pro-
20 ducing such drugs;

21 (ii) the pricing structure, including
22 Federal reimbursements, for such drugs
23 before such drugs were in shortage, and to
24 the extent possible, revenue received by
25 each such manufacturer of such drugs;

1 (iii) pricing structure and revenue, to
2 the extent possible, for the same drugs
3 when sold under the conditions described
4 in paragraph (1); and

5 (iv) the impact of contracting prac-
6 tices by market participants (including
7 manufacturers, distributors, group pur-
8 chasing organizations, and providers) on
9 competition, access to drugs, and pricing
10 of drugs;

11 (C) whether the activities described in
12 paragraph (1) are consistent with applicable
13 law; and

14 (D) recommendations to Congress on what,
15 if any, additional reporting or enforcement ac-
16 tions are necessary.

17 (e) TRADE SECRET AND CONFIDENTIAL INFORMA-
18 TION.—Nothing in this section alters or amends section
19 1905 of title 18, United States Code, or section 552(b)(4)
20 of title 5, United States Code.

21 **TITLE XI—OTHER PROVISIONS**

22 **SEC. 1101. GUIDANCE DOCUMENT REGARDING PRODUCT** 23 **PROMOTION USING THE INTERNET.**

24 Not later than 2 years after the date of enactment
25 this Act, the Secretary of Health and Human Services

1 shall issue a guidance document that describes the policy
2 of the Food and Drug Administration regarding the pro-
3 motion, using the Internet (including social media), of
4 medical products that are regulated by such Administra-
5 tion.

6 **SEC. 1102. REAUTHORIZATION OF PROVISION RELATING TO**
7 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
8 **TAINING SINGLE ENANTIOMERS.**

9 Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended
10 by striking “2012” and inserting “2017”.

11 **SEC. 1103. REAUTHORIZATION OF THE CRITICAL PATH**
12 **PUBLIC-PRIVATE PARTNERSHIPS.**

13 Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended
14 by striking “2012” and inserting “2017”.

15 **SEC. 1104. ELECTRONIC SUBMISSION OF APPLICATIONS.**

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

19 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

20 **“(a) DRUGS AND BIOLOGICS.—**

21 **“(1) IN GENERAL.—**Beginning no earlier than
22 24 months after the issuance of a final guidance
23 issued after public notice and opportunity for com-
24 ment, submissions under subsection (b), (i), or (j) of
25 section 505 of this Act or subsection (a) or (k) of

1 section 351 of the Public Health Service Act shall
2 be submitted in such electronic format as specified
3 by the Secretary in such guidance.

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

6 “(A) provide a timetable for establishment
7 by the Secretary of further standards for elec-
8 tronic submission as required by such para-
9 graph; and

10 “(B) set forth criteria for waivers of and
11 exemptions from the requirements of this sub-
12 section.

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

15 “(b) DEVICES.—

16 “(1) IN GENERAL.—Beginning after the
17 issuance of final guidance implementing this para-
18 graph, pre-submissions and submissions for devices
19 under section 510(k), 513(f)(2)(A)(ii), 515(c),
20 515(d), 515(f), 520(g), 520(m), or 564 of this Act
21 or section 351 of the Public Health Service Act, and
22 any supplements to such pre-submissions or submis-
23 sions, shall include an electronic copy of such pre-
24 submissions or submissions.

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

3 “(A) provide standards for the electronic
4 copy required under such paragraph; and

5 “(B) set forth criteria for waivers of and
6 exemptions from the requirements of this sub-
7 section.”.