

**[DISCUSSION DRAFT]**112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION**H. R.** \_\_\_\_\_

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

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## IN THE HOUSE OF REPRESENTATIVES

M\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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**A BILL**

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

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

3 **SECTION 1. SHORT TITLE.**

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

**1 SEC. 2. TABLE OF CONTENTS.****2** The table of contents of this Act is as follows:

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

**TITLE I—FEES RELATING TO DRUGS**

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

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

- Sec. 201. Short title; findings.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
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- Sec. 205. Savings clause.
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**TITLE III—FEES RELATING TO GENERIC DRUGS**

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

**TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS**

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

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

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

- Sec. 502. Government Accountability Office report.
- Sec. 503. Internal Committee for Review of Pediatric Plans, Assessments, Deferrals, Deferral Extensions, and Waivers.
- Sec. 504. Staff of Office of Pediatric Therapeutics.
- Sec. 505. Continuation of operation of Pediatric Advisory Committee.
- Sec. 506. Pediatric Subcommittee of the Oncologic Drugs Advisory Committee.

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

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

#### TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

##### Subtitle A—Premarket Predictability

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

##### Subtitle B—Patients Come First

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

##### Subtitle C—Novel Device Regulatory Relief

- Sec. 721. Modification of de novo application process.

##### Subtitle D—Keeping America Competitive Through Harmonization

- Sec. 731. Harmonization of device premarket review, inspection, and labeling symbols; report.
- Sec. 732. Participation in International Medical Device Regulators Forum.

##### Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

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

##### Subtitle G—Humanitarian Device Reform

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

#### TITLE VIII—DRUG REGULATORY IMPROVEMENTS

##### Subtitle A—Pharmaceutical Supply Chain

- Sec. 801. **【to be supplied】**.

## Subtitle B—Medical Gas Safety

Sec. 811. [to be supplied].

## Subtitle C—Generating Antibiotic Incentives Now

- Sec. 821. Extension of exclusivity period for drugs.  
Sec. 822. Additional extension of exclusivity period for qualified infectious disease products for which a qualified diagnostic test is cleared or approved.  
Sec. 823. Priority review.  
Sec. 824. Fast track product.  
Sec. 825. Study on incentives for qualified infectious disease biological products.  
Sec. 826. Clinical trials.

## Subtitle D—Accelerated Approval

- Sec. 831. Expedited approval of drugs for serious or life-threatening diseases or conditions.  
Sec. 832. Guidance; amended regulations.  
Sec. 833. Independent review.  
Sec. 834. Rule of construction.

## TITLE IX—DRUG SHORTAGES

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

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

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

1           **TITLE I—FEES RELATING TO**  
2   **DRUGS**

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

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

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

19   **SEC. 102. DEFINITIONS.**

20           Section 735(7) of the Federal Food, Drug, and Cos-  
21   metic Act is amended by striking “expenses incurred in  
22   connection with” and inserting “expenses in connection  
23   with”.

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

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

1 (1) in subsection (a)—

2 (A) in the matter preceding paragraph (1),  
3 by striking “fiscal year 2008” and inserting  
4 “fiscal year 2013”;

5 (B) in paragraph (1)(A)—

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

8 (ii) in clause (ii), by striking “(c)(5)”  
9 inserting “(c)(4)”;

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

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

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

22 (D) in paragraph (3)—

23 (i) in subparagraph (A)—

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

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

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

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

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

22 “(ii) the same product as another  
23 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”; and



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 percent change in  
14 the 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 percent change  
25 that occurred in the Consumer Price Index for

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

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

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

24 “(A) The adjustment shall be determined  
25 by the Secretary based on a weighted average

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

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

23 “(C) The Secretary shall contract with an  
24 independent accounting or consulting firm to  
25 periodically review the adequacy of the adjust-

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

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

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

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

22 “(5) LIMIT.—The total amount of fees charged,  
23 as adjusted under this subsection, for a fiscal year  
24 may not exceed the total costs for such fiscal year

1 for the resources allocated for the process for the re-  
2 view of human drug applications.”; and

3 (4) in subsection (g)—

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

7 (B) in paragraph (2)—

8 (i) in subparagraph (A)(i), by striking  
9 “shall be retained” and inserting “shall be  
10 collected and available”;

11 (ii) in subparagraph (A)(ii), by strik-  
12 ing “shall only be collected and available”  
13 and inserting “shall be available”; and

14 (iii) by adding at the end the fol-  
15 lowing 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—

24 “(A) the progress of the Food and Drug  
25 Administration in achieving the goals identified

1 in the letters described in section 101(b) of the  
2 Prescription Drug User Fee Amendments of  
3 2012 during such fiscal year and the future  
4 plans of the Food and Drug Administration for  
5 meeting the goals; and

6 **【“(B) the progress of each review division**  
7 **within the Center for Drug Evaluation and Re-**  
8 **search and the Center for Biologics Evaluation**  
9 **and Research in achieving the goals, and each**  
10 **such division’s future plans for meeting the**  
11 **goals, including—】**

12 **【“(i) the number of applications for**  
13 **approval of a new drug or new molecular**  
14 **entity under section 505(b) of this Act or**  
15 **section 351(a) of the Public Health Service**  
16 **Act filed per fiscal year by each review di-**  
17 **vision;】**

18 **【“(ii) the percentage of such applica-**  
19 **tions approved by each review division;】**

20 **【“(iii) the total number of review cy-**  
21 **cles per such approval and the average and**  
22 **median review cycles per such application**  
23 **by each review division;】**

1           【“(iv) the average and median review  
2           times per such application by each review  
3           division;】

4           【“(v) the percentage of applications  
5           that are considered pursuant to accelerated  
6           approval by each review division;】

7           【“(vi) the percentage of such applica-  
8           tions that are approved based on one clin-  
9           ical study by each review division; and】

10          【“(vii) the number of full-time equiva-  
11          lent positions and overall budget assigned  
12          to each review division.】

13          “(2) INCLUSION.—The report under this sub-  
14          section for a fiscal year shall include information on  
15          all previous cohorts for which the Secretary has not  
16          given a complete response on all human drug applica-  
17          tions and supplements in the cohort.”.

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

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

22   **【SEC. 105. SUNSET DATES.**

23          【(a) AUTHORIZATION.—Sections 735 and 736 of the  
24          Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;  
25          379h) shall cease to be effective October 1, 2017.】

1       **[(b) REPORTING REQUIREMENTS.—**Section 736B of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 379h–2) shall cease to be effective January 31, 2018.]

4       **[(c) PREVIOUS SUNSET PROVISION.—**The Prescrip-  
5 tion Drug User Fee Amendments of 2007 is amended by  
6 striking section 107.]

7       **[(d) TECHNICAL CORRECTION.—***[to be supplied?]*

8 **SEC. 106. EFFECTIVE DATE.**

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

16 **SEC. 107. SAVINGS CLAUSE.**

17       Notwithstanding section 106 of the Prescription  
18 Drug User Fee Amendments of 2007 (21 U.S.C. 379g  
19 note), and notwithstanding the amendments made by this  
20 title, part 2 of subchapter C of chapter VII of the Federal  
21 Food, Drug, and Cosmetic Act, as in effect on the day  
22 before the date of the enactment of this title, shall con-  
23 tinue to be in effect with respect to human drug applica-  
24 tions and supplements (as defined in such part as of such  
25 day) that on or after October 1, 2007, but before October

1 1, 2012, were accepted by the Food and Drug Administra-  
2 tion for filing with respect to assessing and collecting any  
3 fee required by such part for a fiscal year prior to fiscal  
4 year 2012.

## 5 **TITLE II—MEDICAL DEVICE** 6 **USER FEE AMENDMENTS OF 2012**

### 7 **SEC. 201. SHORT TITLE; FINDINGS.**

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

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

### 22 **SEC. 202. DEFINITIONS.**

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

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

3 (2) in paragraph (10), by striking “October  
4 2001” and inserting “October 2011”; and

5 (3) in paragraph (13), by striking “is required  
6 to register” and all that follows through the end of  
7 paragraph (13) and inserting the following: “is reg-  
8 istered (or is required to register) with the Secretary  
9 under section 510 because such establishment is en-  
10 gaged in the manufacture, preparation, propagation,  
11 compounding, or processing of a device.”.

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

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

16 (1) in paragraph (1), by striking “fiscal year  
17 2008” and inserting “fiscal year 2013”;

18 (2) in paragraph (2)(A)—

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

20 (i) by striking “subsections (d) and  
21 (e)” and inserting “subsections (d), (e),  
22 and (f)”;

23 (ii) by striking “October 1, 2002” and  
24 inserting “October 1, 2012”; and

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

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

5 (3) in paragraph (3)—

6 (A) in subparagraph (A), by inserting  
7 “and subsection (f)” after “subparagraph (B)”;  
8 and

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

12 “(i) the initial or annual registration  
13 (as applicable) of the establishment under  
14 section 510; or

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

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

22 “(b) FEE AMOUNTS.—

23 “(1) IN GENERAL.—Subject to subsections (c),  
24 (d), (e), (f), and (i), for each of fiscal years 2013  
25 through 2017, fees under subsection (a) shall be de-

1 rived from the base fee amounts specified in para-  
 2 graph (2), to generate the total revenue amounts  
 3 specified in paragraph (3).

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

“

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

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

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

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

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

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

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

15 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section  
 16 738(c) of the Federal Food, Drug, and Cosmetic Act (21  
 17 U.S.C. 379j(c)) is amended—

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

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

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



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

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

10 “(2) INFLATION ADJUSTMENTS.—

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

18 “(B) APPLICABLE INFLATION ADJUST-  
19 MENT TO TOTAL REVENUE AMOUNTS.—The ap-  
20 plicable inflation adjustment for a fiscal year  
21 is—

22 “(i) for fiscal year 2014, the base in-  
23 flation adjustment under subparagraph (C)  
24 for such fiscal year; and

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

3 “(I) the base inflation adjust-  
4 ment under subparagraph (C) for  
5 such fiscal year; and

6 “(II) the product of the base in-  
7 flation adjustment under subpara-  
8 graph (C) for each of the fiscal years  
9 preceding such fiscal year, beginning  
10 with fiscal year 2014.

11 “(C) BASE INFLATION ADJUSTMENT TO  
12 TOTAL REVENUE AMOUNTS.—

13 “(i) IN GENERAL.—Subject to further  
14 adjustment under clause (ii), the base in-  
15 flation adjustment for a fiscal year is the  
16 sum of one plus—

17 “(I) the average annual change  
18 in the cost, per full-time equivalent  
19 position of the Food and Drug Ad-  
20 ministration, of all personnel com-  
21 pensation and benefits paid with re-  
22 spect to such positions for the first 3  
23 years of the preceding 4 fiscal years,  
24 multiplied by 0.60; and

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

9                   “(ii) LIMITATIONS.—For purposes of  
10                  subparagraph (B), if the base inflation ad-  
11                  justment for a fiscal year under clause  
12                  (i)—

13                         “(I) is less than 1, such adjust-  
14                         ment shall be considered to be equal  
15                         to 1; or

16                         “(II) is greater than 1.04, such  
17                         adjustment shall be considered to be  
18                         equal to 1.04.

19                   “(D) ADJUSTMENT TO BASE FEE  
20                   AMOUNTS.—For each of fiscal years 2014  
21                   through 2017, the base fee amounts specified in  
22                   subsection (b)(2) shall be adjusted as needed,  
23                   on a uniform proportionate basis, to generate  
24                   the total revenue amounts under subsection

1 (b)(3), as adjusted for inflation under subpara-  
2 graph (A).

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

13 (d) FEE WAIVER OR REDUCTION.—Section 738 of  
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 379j) is amended by—

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

18 (2) by inserting after subsection (e) the fol-  
19 lowing new subsection (f):

20 “(f) FEE WAIVER OR REDUCTION.—

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

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

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

8           (e) CONDITIONS.—Section 738(h)(1)(A) of the Fed-  
9           eral Food, Drug, and Cosmetic Act (21 U.S.C.  
10          379j(h)(1)(A)), as redesignated by subsection (d)(1), is  
11          amended by striking “\$205,720,000” and inserting  
12          “\$280,587,000”.

13          (f) CREDITING AND AVAILABILITY OF FEES.—Sec-  
14          tion 738(i) of the Federal Food, Drug, and Cosmetic Act  
15          (21 U.S.C. 379j(i)), as redesignated by subsection (d)(1),  
16          is amended—

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

20                 (2) in paragraph (2)—

21                         (A) in subparagraph (A)—

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

1 (ii) in clause (ii)—

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

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

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

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

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

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

24 (4) in paragraph (4)—

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

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

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

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

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

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

15 (g) CONFORMING AMENDMENT.—Section  
16 515(c)(4)(A) of the Federal Food, Drug, and Cosmetic  
17 Act (21 U.S.C. 360e(c)(4)(A)) is amended by striking  
18 “738(g)” and inserting “738(h)”.

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

20 (a) REAUTHORIZATION.—Section 738A(b) of the  
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
22 1(b)) is amended—

23 (1) in paragraph (1), by striking “2012” and  
24 inserting “2017”; and

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

3           (b) PERFORMANCE REPORTS.—Section 738A(a) of  
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 379j–1(a)) is amended—

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

8           “(1) PERFORMANCE REPORT.—

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

24           “(B) TIMING.—



1           “(i) IN GENERAL.—In preparing re-  
2           ports under subparagraph (A), the Sec-  
3           retary shall submit categories of informa-  
4           tion on a quarterly or annual basis, as  
5           specified in the letters described in section  
6           201(b) of the Medical Device User Fee  
7           Amendments of 2012.

8           “(ii) QUARTERLY.—If the letters  
9           specify that information will be reported  
10          quarterly, the Secretary shall submit such  
11          information to the Committees specified in  
12          subparagraph (A) not later than 60 days  
13          after the end of the quarter to which such  
14          information applies.

15          “(iii) ANNUAL.—If the letters specify  
16          that information will be reported annually,  
17          the Secretary shall submit such informa-  
18          tion to the Committees specified in sub-  
19          paragraph (A) not later than 120 days  
20          after the end of the fiscal year to which  
21          such information applies.

22          “(C) UPDATES.—The Secretary shall in-  
23          clude in a report under subparagraph (A) for a  
24          quarter or fiscal year information on all pre-  
25          vious cohorts for which the Secretary has not

1 given a complete response on all required infor-  
2 mation (as specified in the letters) in the co-  
3 hort.”; and

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

6 **SEC. 205. SAVINGS CLAUSE.**

7 Notwithstanding section 217 of the Medical Device  
8 User Fee Amendments of 2007 (Public Law 110–85), and  
9 notwithstanding the amendments made by this title, part  
10 3 of subchapter C of chapter VII of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in  
12 effect on the day before the date of the enactment of this  
13 title, shall continue to be in effect with respect to pre-  
14 market applications, premarket reports, premarket notifi-  
15 cation submissions, and supplements (as defined in such  
16 part as of such day) that on or after October 1, 2007,  
17 but before October 1, 2012, were accepted by the Food  
18 and Drug Administration for filing with respect to assess-  
19 ing and collecting any fee required by such part for a fiscal  
20 year prior to fiscal year 2013.

21 **SEC. 206. EFFECTIVE DATE.**

22 The amendments made by this title shall take effect  
23 on October 1, 2012, or the date of the enactment of this  
24 Act, whichever is later, except that fees under part 3 of  
25 subchapter C of chapter VII of the Federal Food, Drug,

1 and Cosmetic Act shall be assessed for all premarket ap-  
2 plications, premarket reports, supplements, 30-day no-  
3 tices, and premarket notification submissions received on  
4 or after October 1, 2012, regardless of the date of the  
5 enactment of this Act.

6 **[SEC. 207. SUNSET CLAUSE.**

7 **[(a) IN GENERAL.—**Sections 737 and 738 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;  
9 739j) shall cease to be effective October 1, 2017. Section  
10 738A (21 U.S.C. 739j–1) of the Federal Food, Drug, and  
11 Cosmetic Act (regarding reauthorization and reporting re-  
12 quirements) ceases to be effective January 31, 2018.]

13 **[(b) PREVIOUS SUNSET PROVISION.—**The Prescrip-  
14 tion Drug User Fee Amendments of 2007 is amended by  
15 striking section 217.]

16 **[(c) TECHNICAL CORRECTION.—***[to be supplied?]***]**

17 **SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT**

18 **ACTIVITIES RELATED TO THE PROCESS FOR**

19 **THE REVIEW OF DEVICE APPLICATIONS.**

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

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

24 **“(a) IN GENERAL.—**In addition to any other per-  
25 sonnel authorities under other provisions of law, the Sec-

1   retary may, without regard to the provisions of title 5,  
2   United States Code, governing appointments in the com-  
3   petitive service, appoint employees to positions in the Food  
4   and Drug Administration to perform, administer, or sup-  
5   port activities described in subsection (b), if the Secretary  
6   determines that such appointments are needed to achieve  
7   the objectives specified in subsection (c).

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

12       “(c) OBJECTIVES SPECIFIED.—The objectives speci-  
13  fied in this subsection are with respect to the activities  
14  under subsection (b)(1), the goals referred to in section  
15  738A(a)(1).

16       “(d) INTERNAL CONTROLS.—The Secretary shall in-  
17  stitute appropriate internal controls for appointments  
18  under this section.

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

1     **TITLE III—FEES RELATING TO**  
2                     **GENERIC DRUGS**

3     **SEC. 301. SHORT TITLE.**

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

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

17     **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**  
18                     **NERIC DRUG FEES.**

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

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

22     **“SEC. 744A. DEFINITIONS.**

23             “For purposes of this part:

24                     “(1) The term ‘abbreviated new drug applica-  
25     tion’—

1           “(A) means an application submitted  
2           under section 505(j), an abbreviated application  
3           submitted under section 507 (as in effect on the  
4           day before the date of enactment of the Food  
5           and Drug Administration Modernization Act of  
6           1997), or an abbreviated new drug application  
7           submitted pursuant to regulations in effect  
8           prior to the implementation of the Drug Price  
9           Competition and Patent Term Restoration Act  
10          of 1984; and

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

13          “(2) The term ‘active pharmaceutical ingre-  
14          dient’ means—

15           “(A) a substance, or a mixture when the  
16           substance is unstable or cannot be transported  
17           on its own, intended—

18           “(i) to be used as a component of a  
19           drug; and

20           “(ii) to furnish pharmacological activ-  
21           ity or other direct effect in the diagnosis,  
22           cure, mitigation, treatment, or prevention  
23           of disease, or to affect the structure or any  
24           function of the human body; or

1           “(B) a substance intended for final crys-  
2 tallization, purification, or salt formation, or  
3 any combination of those activities, to become a  
4 substance or mixture described in subparagraph  
5 (A).

6           “(3) The term ‘adjustment factor’ means a fac-  
7 tor applicable to a fiscal year that is the Consumer  
8 Price Index for all urban consumers (all items;  
9 United States city average) for October of the pre-  
10 ceding fiscal year divided by such Index for October  
11 2011.

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

15           “(A) one business entity controls, or has  
16 the power to control, the other business entity;  
17 or

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

20           “(5)(A) The term ‘facility’—

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

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

24           “(II) at one geographic location or ad-  
25 dress engaged in manufacturing or proc-

1           essing an active pharmaceutical ingredient  
2           or a finished dosage form; and

3           “(ii) does not include a business or other  
4           entity whose only manufacturing or processing  
5           activities are one or more of the following: re-  
6           packaging, relabeling, or testing.

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

11           “(i) closely related to the same business  
12          enterprise;

13           “(ii) under the supervision of the same  
14          local management; and

15           “(iii) capable of being inspected by the  
16          Food and Drug Administration during a single  
17          inspection.

18          “(C) If a business or other entity would meet  
19          the definition of a facility under this paragraph but  
20          for being under multiple management, the business  
21          or other entity is deemed to constitute multiple fa-  
22          cilities, one per management entity, for purposes of  
23          this paragraph.

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



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

4           “(B) a drug product in a form in which re-  
5           constitution is necessary prior to administration  
6           to a patient, such as oral suspensions or  
7           lyophilized powders; or

8           “(C) any combination of an active pharma-  
9           ceutical ingredient with another component of a  
10          drug product for purposes of production of a  
11          drug product described in subparagraph (A) or  
12          (B).

13          “(7) The term ‘generic drug submission’ means  
14          an abbreviated new drug application, an amendment  
15          to an abbreviated new drug application, or a prior  
16          approval supplement to an abbreviated new drug ap-  
17          plication.

18          “(8) The term ‘human generic drug activities’  
19          means the following activities of the Secretary asso-  
20          ciated with generic drugs and inspection of facilities  
21          associated with generic drugs:

22                 “(A) The activities necessary for the re-  
23                 view of generic drug submissions, including re-  
24                 view of drug master files referenced in such  
25                 submissions.

1 “(B) The issuance of—

2 “(i) approval letters which approve  
3 abbreviated new drug applications or sup-  
4 plements to such applications; or

5 “(ii) complete response letters which  
6 set forth in detail the specific deficiencies  
7 in such applications and, where appro-  
8 priate, the actions necessary to place such  
9 applications in condition for approval.

10 “(C) The issuance of letters related to  
11 Type II active pharmaceutical drug master files  
12 which—

13 “(i) set forth in detail the specific de-  
14 ficiencies in such submissions, and where  
15 appropriate, the actions necessary to re-  
16 solve those deficiencies; or

17 “(ii) document that no deficiencies  
18 need to be addressed.

19 “(D) Inspections related to generic drugs.

20 “(E) Monitoring of research conducted in  
21 connection with the review of generic drug sub-  
22 missions and drug master files.

23 “(F) Postmarket safety activities with re-  
24 spect to drugs approved under abbreviated new

1 drug applications or supplements, including the  
2 following activities:

3 “(i) Collecting, developing, and re-  
4 viewing safety information on approved  
5 drugs, including adverse event reports.

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

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

13 “(iv) Implementing and enforcing sec-  
14 tion 505(o) (relating to postapproval stud-  
15 ies and clinical trials and labeling changes)  
16 and section 505(p) (relating to risk evalua-  
17 tion and mitigation strategies) insofar as  
18 those activities relate to abbreviated new  
19 drug applications.

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

23 “(G) Regulatory science activities related  
24 to generic drugs.

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

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

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

18           “(A) officers and employees of the Food  
19 and Drug Administration, contractors of the  
20 Food and Drug Administration, advisory com-  
21 mittees, and costs related to such officers and  
22 employees and to contracts with such contrac-  
23 tors;

1           “(B) management of information, and the  
2           acquisition, maintenance, and repair of com-  
3           puter resources;

4           “(C) leasing, maintenance, renovation, and  
5           repair of facilities and acquisition, maintenance,  
6           and repair of fixtures, furniture, scientific  
7           equipment, and other necessary materials and  
8           supplies; and

9           “(D) collecting fees under subsection (a)  
10          and accounting for resources allocated for the  
11          review of abbreviated new drug applications and  
12          supplements and inspection related to generic  
13          drugs.

14          “(12) The term ‘Type II active pharmaceutical  
15          ingredient drug master file’ means a submission of  
16          information to the Secretary by a person that in-  
17          tends to authorize the Food and Drug Administra-  
18          tion to reference the information to support approval  
19          of a generic drug submission without the submitter  
20          having to disclose the information to the generic  
21          drug submission applicant.

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

3 “(a) TYPES OF FEES.—Beginning in fiscal year  
4 2013, the Secretary shall assess and collect fees in accord-  
5 ance with this section as follows:

6 “(1) ONE-TIME BACKLOG FEE FOR ABBRE-  
7 VIATED NEW DRUG APPLICATIONS PENDING ON OC-  
8 TOBER 1, 2012.—

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

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

23 “(C) NOTICE.—Not later than October 31,  
24 2012, the Secretary shall cause to be published  
25 in the Federal Register a notice announcing the

1 amount of the fee required by subparagraph  
2 (A).

3 “(D) FEE DUE DATE.—The fee required  
4 by subparagraph (A) shall be due no later than  
5 30 calendar days after the date of the publica-  
6 tion of the notice specified in subparagraph (C).

7 “(2) DRUG MASTER FILE FEE.—

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

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

22 “(C) NOTICE.—

23 “(i) FISCAL YEAR 2013.—Not later  
24 than October 31, 2012, the Secretary shall  
25 cause to be published in the Federal Reg-

1           ister a notice announcing the amount of  
2           the drug master file fee for fiscal year  
3           2013.

4           “(ii) FISCAL YEAR 2014 THROUGH  
5           2017.—Not later than 60 days before the  
6           start of each of fiscal years 2014 through  
7           2017, the Secretary shall cause to be pub-  
8           lished in the Federal Register the amount  
9           of the drug master file fee established by  
10          this paragraph for such fiscal year.

11          “(D) AVAILABILITY FOR REFERENCE.—

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

18           “(ii) CONDITIONS.—A drug master  
19           file shall be deemed available for reference  
20           by the Secretary if—

21           “(I) the person that owns a Type  
22           II active pharmaceutical ingredient  
23           drug master file has paid the fee re-  
24           quired under subparagraph (A) within  
25           20 calendar days after the applicable



1 due date under subparagraph (E);  
2 and

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

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

17 “(E) FEE DUE DATE.—

18 “(i) IN GENERAL.—Subject to clause  
19 (ii), a drug master file fee shall be due no  
20 later than the date on which the first ge-  
21 neric drug submission is submitted that  
22 references the associated Type II active  
23 pharmaceutical ingredient drug master file.

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

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

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

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

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

22                               “(B) NOTICE.—

23                               “(i) FISCAL YEAR 2013.—Not later  
24                               than October 31, 2012, the Secretary shall  
25                               cause to be published in the Federal Reg-

1           ister a notice announcing the amount of  
2           the fees under subparagraph (A) for fiscal  
3           year 2013.

4           “(ii) FISCAL YEARS 2014 THROUGH  
5           2017.—Not later than 60 days before the  
6           start of each of fiscal years 2014 through  
7           2017, the Secretary shall cause to be pub-  
8           lished in the Federal Register the amount  
9           of the fees under subparagraph (A) for  
10          such fiscal year.

11          “(C) FEE DUE DATE.—

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

19          “(ii) SPECIAL RULE FOR 2013.—For  
20          fiscal year 2013, such fees shall be due on  
21          the later of—

22                  “(I) the date on which the fee is  
23                  due under clause (i);

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

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

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

23                  “(E) FEE FOR AN APPLICATION THE SEC-  
24                  RETARY CONSIDERS NOT TO HAVE BEEN RE-  
25                  CEIVED, OR THAT HAS BEEN WITHDRAWN.—An

1           abbreviated new drug application or prior ap-  
2           proval supplement that was submitted on or  
3           after October 1, 2012, and that the Secretary  
4           considers not to have been received, or that has  
5           been withdrawn, shall, upon resubmission of the  
6           application or a subsequent new submission fol-  
7           lowing the applicant's withdrawal of the appli-  
8           cation, be subject to a full fee under subpara-  
9           graph (A).

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

19           “(i) such submission contains infor-  
20           mation concerning the manufacture of an  
21           active pharmaceutical ingredient at a facil-  
22           ity by means other than reference by a let-  
23           ter of authorization to a Type II active  
24           pharmaceutical drug master file; and

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

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

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

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

22          “(ii) ACTIVE PHARMACEUTICAL IN-  
23          GREDIENT FACILITY.—Each person that  
24          owns a facility which produces, or which is  
25          pending review to produce, one or more ac-

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

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

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

24          “(C) NOTICE.—

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

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

14          “(D) FEE DUE DATE.—

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

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

21                  “(II) if an appropriations Act is  
22                  not enacted providing for the collec-  
23                  tion and obligation of fees under this  
24                  section by the date of the publication  
25                  of such notice, 30 days after the date



1 that such an appropriations Act is en-  
2 acted.

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

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

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

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

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

1           sion is not otherwise open for business shall be  
2           deemed to be submitted on the next day when  
3           that office is open for business; and

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

8           “(b) FEE REVENUE AMOUNTS.—

9           “(1) IN GENERAL.—

10           “(A) FISCAL YEAR 2013.—For fiscal year  
11           2013, fees under subsection (a) shall be estab-  
12           lished to generate a total estimated revenue  
13           amount under such subsection of \$299,000,000.  
14           Of that amount—

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

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

22           “(B) FISCAL YEARS 2014 THROUGH 2017.—  
23           For each of the fiscal years 2014 through 2017,  
24           fees under paragraphs (2) through (4) of sub-  
25           section (a) shall be established to generate a

1 total estimated revenue amount under such sub-  
2 section that is equal to \$299,000,000, as ad-  
3 justed pursuant to subsection (c).

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

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

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

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

1 er than the amount of the fee for a facility lo-  
2 cated in the United States and its territories  
3 and possessions, as determined by the Secretary  
4 on the basis of data concerning the difference  
5 in cost between inspections of facilities located  
6 in the United States, including its territories  
7 and possessions, and those located outside of  
8 the United States and its territories and posses-  
9 sions.

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

25 “(c) ADJUSTMENTS.—

1           “(1) INFLATION ADJUSTMENT.—For fiscal year  
2           2014 and subsequent fiscal years, the revenues es-  
3           tablished in subsection (b) shall be adjusted by the  
4           Secretary by notice, published in the Federal Reg-  
5           ister, for a fiscal year, by an amount equal to the  
6           sum of—

7                   “(A) one;

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

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

1           of human generic drug activities for the first 3  
2           years of the preceding 4 fiscal years.

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

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

23          “(d) ANNUAL FEE SETTING.—

24                 “(1) FISCAL YEAR 2013.—For fiscal year  
25                 2013—

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

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

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

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

8                   “(A) the sum of—

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

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

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

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

23           “(f) IDENTIFICATION OF FACILITIES.—

24                   “(1) PUBLICATION OF NOTICE; DEADLINE FOR  
25                   COMPLIANCE.—Not later than October 1, 2012, the



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

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

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

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

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

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

7                   “(B) whether the facility manufactures ac-  
8                   tive pharmaceutical ingredients or finished dos-  
9                   age forms, or both;

10                   “(C) whether or not the facility is located  
11                   within the United States and its territories and  
12                   possessions;

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

16                   “(E) whether the facility manufactures  
17                   drugs that are not generic drugs.

18           “(4) CERTAIN SITES AND ORGANIZATIONS.—

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

24                   “(B) SITES AND ORGANIZATIONS.—A site  
25                   or organization is described in this subpara-

1 graph if it is identified in a generic drug sub-  
2 mission and is—

3 “(i) a site in which a bioanalytical  
4 study is conducted;

5 “(ii) a clinical research organization;

6 “(iii) a contract analytical testing site;

7 or

8 “(iv) a contract repackager site.

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

16 “(D) INSPECTION AUTHORITY.—The Sec-  
17 retary’s inspection authority under section  
18 704(a)(1) shall extend to all such sites and or-  
19 ganizations.

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

21 “(1) GENERIC DRUG BACKLOG FEE.—Failure  
22 to pay the fee under subsection (a)(1) shall result in  
23 the Secretary placing the person that owns the ab-  
24 breviated new drug application subject to that fee on  
25 an arrears list, such that no new abbreviated new

1 drug applications or supplement submitted on or  
2 after October 1, 2012, from that person, or any af-  
3 filiate of that person, will be received within the  
4 meaning of section 505(j)(5)(A) until such out-  
5 standing fee is paid.

6 “(2) DRUG MASTER FILE FEE.—

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

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

22 “(ii) The condition specified in this clause  
23 is that the fee established under subsection  
24 (a)(2) has been paid within 20 calendar days of  
25 the Secretary providing the notification to the

1 sponsor of the abbreviated new drug application  
2 or supplement of the failure of the owner of the  
3 Type II active pharmaceutical ingredient drug  
4 master file to pay the drug master file fee as  
5 specified in subparagraph (C).

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

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

23 “(3) ABBREVIATED NEW DRUG APPLICATION  
24 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—  
25 Failure to pay a fee under subparagraph (A) or (F)

1 of subsection (a)(3) within 20 calendar days of the  
2 applicable due date under subparagraph (C) of such  
3 subsection shall result in the abbreviated new drug  
4 application or the prior approval supplement to an  
5 abbreviated new drug application not being received  
6 within the meaning of section 505(j)(5)(A) until  
7 such outstanding fee is paid.

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

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

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

23 “(ii) Any new generic drug submission  
24 submitted on or after October 1, 2012,  
25 that references such a facility shall not be

1 received, within the meaning of section  
2 505(j)(5)(A) if the outstanding facility fee  
3 is not paid within 20 calendar days of the  
4 Secretary providing the notification to the  
5 sponsor of the failure of the owner of the  
6 facility to pay the facility fee under sub-  
7 section (a)(4)(C).

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

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

18 “(C) NONRECEIVAL FOR NONPAYMENT.—

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

1 the sponsor of the generic drug submission  
2 of the failure of the owner of the facility  
3 to pay the facility fee.

4 “(ii) NONRECEIVAL.—If the facility  
5 fee is not paid within 20 calendar days of  
6 the Secretary providing the notification  
7 under clause (i), the abbreviated new drug  
8 application or supplement to an abbrevi-  
9 ated new drug application shall not be re-  
10 ceived within the meaning of section  
11 505(j)(5)(A).

12 “(h) LIMITATIONS.—

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



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

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

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

1           “(2) COLLECTIONS AND APPROPRIATION  
2 ACTS.—

3           “(A) IN GENERAL.—The fees authorized  
4 by this section—

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

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

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

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

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

24          “(3) AUTHORIZATION OF APPROPRIATIONS.—  
25          For each of the fiscal years 2013 through 2017,

1       there is authorized to be appropriated for fees under  
2       this section an amount equivalent to the total rev-  
3       enue amount determined under subsection (b) for  
4       the fiscal year, as adjusted under subsection (c), if  
5       applicable, or as otherwise affected under paragraph  
6       (2) of this subsection.

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

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

20      “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

21              “(1) EXEMPTION FROM FEES.—Submission of  
22      an application for a positron emission tomography  
23      drug or active pharmaceutical ingredient for a  
24      positron emission tomography drug shall not require  
25      the payment of any fee under this section. Facilities

1 that solely produce positron emission tomography  
2 drugs shall not be required to pay a facility fee as  
3 established in subsection (a)(4).

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

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

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

1 meaning of section 505(j)(5)(A) as of the date such appli-  
2 cable fee is received.”.

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

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

7 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**  
8 **MENTS.**

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

21 “(b) **FISCAL REPORT.**—Beginning with fiscal year  
22 2013, not later than 120 days after the end of each fiscal  
23 year for which fees are collected under this part, the Sec-  
24 retary shall prepare and submit to the Committee on En-  
25 ergy and Commerce of the House of Representatives and

1 the Committee on Health, Education, Labor, and Pen-  
2 sions of the Senate a report on the implementation of the  
3 authority for such fees during such fiscal year and the  
4 use, by the Food and Drug Administration, of the fees  
5 collected for such fiscal year.

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

10 “(d) REAUTHORIZATION.—

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

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

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

22 “(C) scientific and academic experts;

23 “(D) health care professionals;

24 “(E) representatives of patient and con-  
25 sumer advocacy groups; and

1                   “(F) the generic drug industry.

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

5                   “(A) publish a notice in the Federal Reg-  
6 ister requesting public input on the reauthoriza-  
7 tion;

8                   “(B) hold a public meeting at which the  
9 public may present its views on the reauthoriza-  
10 tion, including specific suggestions for changes  
11 to the goals referred to in subsection (a);

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

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

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



1           “(4) PUBLIC REVIEW OF RECOMMENDA-  
2           TIONS.—After negotiations with the generic drug in-  
3           dustry, the Secretary shall—

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

7                   “(B) publish such recommendations in the  
8                   Federal Register;

9                   “(C) provide for a period of 30 days for  
10                  the public to provide written comments on such  
11                  recommendations;

12                  “(D) hold a meeting at which the public  
13                  may present its views on such recommenda-  
14                  tions; and

15                  “(E) after consideration of such public  
16                  views and comments, revise such recommenda-  
17                  tions as necessary.

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

25           “(6) MINUTES OF NEGOTIATION MEETINGS.—

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

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

16 **SEC. 304. SUNSET DATES.**

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

19           (b) REPORTING REQUIREMENTS.—The amendments  
20           made by section 303 cease to be effective January 31,  
21           2018.

22 **SEC. 305. EFFECTIVE DATE.**

23           The amendments made by this title shall take effect  
24           on October 1, 2012, or the date of the enactment of this  
25           title, whichever is later, except that fees under section 302

1 shall be assessed for all human generic drug submissions  
2 and Type II active pharmaceutical drug master files re-  
3 ceived on or after October 1, 2012, regardless of the date  
4 of enactment of this title.

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

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

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

16 **SEC. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT**  
17 **ACTIVITIES RELATED TO HUMAN GENERIC**  
18 **DRUGS.**

19 Section 714 of the Federal Food, Drug, and Cosmetic  
20 Act, as added by section 208 of this Act, is amended—

21 (1) by amending subsection (b) to read as fol-  
22 lows:

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

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

4           “(2) activities under this Act related to human  
5 generic drug activities (as defined in section  
6 744A).”; and

7           (2) by amending subsection (c) to read as fol-  
8 lows:

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

11           “(1) with respect to the activities under sub-  
12 section (b)(1), the goals referred to in section  
13 738A(a)(1); and

14           “(2) with respect to the activities under sub-  
15 section (b)(2), the goals referred to in section  
16 744C(a).”.

## 17 **TITLE IV—FEES RELATING TO** 18 **BIOSIMILAR BIOLOGICAL** 19 **PRODUCTS**

### 20 **SEC. 401. SHORT TITLE; FINDING.**

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

23           (b) FINDING.—The Congress finds that the fees au-  
24 thorized by the amendments made in this title will be dedi-  
25 cated to expediting the process for the review of biosimilar

1 biological product applications, including postmarket safe-  
2 ty activities, as set forth in the goals identified for pur-  
3 poses of part 8 of subchapter C of chapter VII of the Fed-  
4 eral Food, Drug, and Cosmetic Act, in the letters from  
5 the Secretary of Health and Human Services to the Chair-  
6 man of the Committee on Health, Education, Labor, and  
7 Pensions of the Senate and the Chairman of the Com-  
8 mittee on Energy and Commerce of the House of Rep-  
9 resentatives, as set forth in the Congressional Record

10 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**  
11 **PRODUCTS.**

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

15 **“PART 8—FEES RELATING TO BIOSIMILAR**  
16 **BIOLOGICAL PRODUCTS**

17 **“SEC. 744G. DEFINITIONS.**

18 “For purposes of this part:

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

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

4                   “(A) one business entity controls, or has  
5           the power to control, the other business entity;  
6           or

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

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

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

17           “(B) Such term does not include—

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

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

1           “(iii) an application filed under section  
2           351(k) of the Public Health Service Act with  
3           respect to—

4                   “(I) whole blood or a blood component  
5                   for transfusion;

6                   “(II) an allergenic extract product;

7                   “(III) an in vitro diagnostic biological  
8                   product; or

9                   “(IV) a biological product for further  
10                  manufacturing use only; or

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

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

22                  “(6) The term ‘biosimilar biological product de-  
23                  velopment program’ means the program under this  
24                  part for expediting the process for the review of sub-

1 missions in connection with biosimilar biological  
2 product development.

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

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

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

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

14 “(8) The term ‘biosimilar initial advisory meet-  
15 ing’—

16 “(A) means a meeting, if requested, that is  
17 limited to—

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

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



1           “(B) does not include any meeting that in-  
2           volves substantive review of summary data or  
3           full study reports.

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

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

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

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

23          “(D) collecting fees under section 744H  
24          and accounting for resources allocated for the  
25          review of submissions in connection with bio-

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

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

9 “(11) The term ‘financial hold’—

10 “(A) means an order issued by the Sec-  
11 retary to prohibit the sponsor of a clinical in-  
12 vestigation from continuing the investigation if  
13 the Secretary determines that the investigation  
14 is intended to support a biosimilar biological  
15 product application and the sponsor has failed  
16 to pay any fee for the product required under  
17 subparagraph (A), (B), or (D) of section  
18 744H(a)(1); and

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

23 “(12) The term ‘person’ includes an affiliate of  
24 such person.

1           “(13) The term ‘process for the review of bio-  
2           similar biological product applications’ means the  
3           following activities of the Secretary with respect to  
4           the review of submissions in connection with bio-  
5           similar biological product development, biosimilar bi-  
6           ological product applications, and supplements:

7                   “(A) The activities necessary for the re-  
8                   view of submissions in connection with bio-  
9                   similar biological product development, bio-  
10                  similar biological product applications, and sup-  
11                  plements.

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

20                  “(C) The inspection of biosimilar biological  
21                  product establishments and other facilities un-  
22                  dertaken as part of the Secretary’s review of  
23                  pending biosimilar biological product applica-  
24                  tions and supplements.

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

4           “(E) Monitoring of research conducted in  
5 connection with the review of biosimilar biologi-  
6 cal product applications.

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

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

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

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

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

1 and section 505(p) (relating to risk evalua-  
2 tion and mitigation strategies).

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

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

14 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**  
15 **BIOLOGICAL PRODUCT FEES.**

16 “(a) TYPES OF FEES.—Beginning in fiscal year  
17 2013, the Secretary shall assess and collect fees in accord-  
18 ance with this section as follows:

19 “(1) BIOSIMILAR DEVELOPMENT PROGRAM  
20 FEES.—

21 “(A) INITIAL BIOSIMILAR BIOLOGICAL  
22 PRODUCT DEVELOPMENT FEE.—

23 “(i) IN GENERAL.—Each person that  
24 submits to the Secretary a meeting request  
25 described under clause (ii) or a clinical

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

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

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

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

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

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

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

21                   “(I) Not later than 60 days after  
22 the date of the enactment of the  
23 Biosimilars User Fee Act of 2012, if  
24 the Secretary determines that the in-  
25 vestigational new drug application de-

1 scribes an investigation that is in-  
2 tended to support a biosimilar biologi-  
3 cal product application.

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

8 “(B) ANNUAL BIOSIMILAR BIOLOGICAL  
9 PRODUCT DEVELOPMENT FEE.—

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

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



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

3 “(II) the first business day after  
4 the enactment of an appropriations  
5 Act providing for the collection and  
6 obligation of fees for such year under  
7 this section.

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

12 “(I) submitted a marketing appli-  
13 cation for the biological product that  
14 was accepted for filing; or

15 “(II) discontinued participation  
16 in the biosimilar biological product de-  
17 velopment program for the product  
18 under subparagraph (C).

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

1           “(i) if no investigational new drug ap-  
2           plication concerning the product has been  
3           submitted, submitting to the Secretary a  
4           written declaration that the person has no  
5           present intention of further developing the  
6           product as a biosimilar biological product;  
7           or

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

15          “(D) REACTIVATION FEE.—

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

23                         “(I) Not later than 5 days after  
24                         the Secretary grants a request for a  
25                         biosimilar biological product develop-

1                   ment meeting for the product (after  
2                   the date on which such participation  
3                   was discontinued).

4                   “(II) Upon the date of submis-  
5                   sion (after the date on which such  
6                   participation was discontinued) of an  
7                   investigational new drug application  
8                   describing an investigation that the  
9                   Secretary determines is intended to  
10                  support a biosimilar biological product  
11                  application for that product.

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

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

20                  “(i) NO BIOSIMILAR BIOLOGICAL  
21                  PRODUCT DEVELOPMENT MEETINGS.—If a  
22                  person has failed to pay an initial or an-  
23                  nual biosimilar biological product develop-  
24                  ment fee as required under subparagraph  
25                  (A) or (B), or a reactivation fee as re-

1           required under subparagraph (D), the Sec-  
2           retary shall not provide a biosimilar bio-  
3           logical product development meeting relat-  
4           ing to the product for which fees are owed.

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

11                   “(I) the Secretary determines  
12                   that the investigation is intended to  
13                   support a biosimilar biological product  
14                   application; and

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

22           “(iii) FINANCIAL HOLD.—Notwith-  
23           standing section 505(i)(2), except in ex-  
24           traordinary circumstances, the Secretary  
25           shall prohibit the sponsor of a clinical in-

1 investigation from continuing the investiga-  
2 tion if—

3 “(I) the Secretary determines  
4 that the investigation is intended to  
5 support a biosimilar biological product  
6 application; and

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

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

1 Secretary until all such fees owed by such  
2 person have been paid.

3 “(F) LIMITS REGARDING BIOSIMILAR DE-  
4 VELOPMENT PROGRAM FEES.—

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

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

19 “(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
20 CATION AND SUPPLEMENT FEE.—

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

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

3 “(I) the amount of the fee estab-  
4 lished under subsection (b)(1)(D) for  
5 a biosimilar biological product applica-  
6 tion; minus

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

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

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

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

1           “(iii) A fee for a supplement for which  
2           clinical data (other than comparative bio-  
3           availability studies) with respect to safety  
4           or effectiveness are required, that is equal  
5           to half of the amount of the fee established  
6           under subsection (b)(1)(D) for a biosimilar  
7           biological product application.

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

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



1           “(D) EXCEPTION FOR PREVIOUSLY FILED  
2           APPLICATION OR SUPPLEMENT.—If a biosimilar  
3           biological product application or supplement  
4           was submitted by a person that paid the fee for  
5           such application or supplement, was accepted  
6           for filing, and was not approved or was with-  
7           drawn (without a waiver), the submission of a  
8           biosimilar biological product application or a  
9           supplement for the same product by the same  
10          person (or the person’s licensee, assignee, or  
11          successor) shall not be subject to a fee under  
12          subparagraph (A).

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

20          “(F) FEES FOR APPLICATIONS PRE-  
21          VIOUSLY REFUSED FOR FILING OR WITHDRAWN  
22          BEFORE FILING.—A biosimilar biological prod-  
23          uct application or supplement that was sub-  
24          mitted but was refused for filing, or was with-  
25          drawn before being accepted or refused for fil-

1           ing, shall be subject to the full fee under sub-  
2           paragraph (A) upon being resubmitted or filed  
3           over protest, unless the fee is waived under sub-  
4           section (c).

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

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

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

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

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

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

9                   “(D) APPLICATION TO ESTABLISHMENT.—

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

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

1            biosimilar biological product fees under  
2            paragraph (4).

3            “(E) EXCEPTION FOR NEW PRODUCTS.—  
4            If, during the fiscal year, an applicant initiates  
5            or causes to be initiated the manufacture of a  
6            biosimilar biological product at an establish-  
7            ment listed in its biosimilar biological product  
8            application—

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

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

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

21            “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

22                    “(A) IN GENERAL.—Each person who is  
23                   named as the applicant in a biosimilar biologi-  
24                   cal product application shall pay for each such

1 biosimilar biological product the annual fee es-  
2 tablished under subsection (b)(1)(F).

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

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

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

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

16 “(b) FEE SETTING AND AMOUNTS.—

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

23 “(A) INITIAL BIOSIMILAR BIOLOGICAL  
24 PRODUCT DEVELOPMENT FEE.—The initial bio-  
25 similar biological product development fee under

1 subsection (a)(1)(A) for a fiscal year shall be  
2 equal to 10 percent of the amount established  
3 under section 736(c)(5) for a human drug ap-  
4 plication described in section 736(a)(1)(A)(i)  
5 for that fiscal year.

6 “(B) ANNUAL BIOSIMILAR BIOLOGICAL  
7 PRODUCT DEVELOPMENT FEE.—The annual  
8 biosimilar biological product development fee  
9 under subsection (a)(1)(B) for a fiscal year  
10 shall be equal to 10 percent of the amount es-  
11 tablished under section 736(c)(5) for a human  
12 drug application described in section  
13 736(a)(1)(A)(i) for that fiscal year.

14 “(C) REACTIVATION FEE.—The reactiva-  
15 tion fee under subsection (a)(1)(D) for a fiscal  
16 year shall be equal to 20 percent of the amount  
17 of the fee established under section 736(c)(5)  
18 for a human drug application described in sec-  
19 tion 736(a)(1)(A)(i) for that fiscal year.

20 “(D) BIOSIMILAR BIOLOGICAL PRODUCT  
21 APPLICATION FEE.—The biosimilar biological  
22 product application fee under subsection (a)(2)  
23 for a fiscal year shall be equal to the amount  
24 established under section 736(c)(5) for a

1 human drug application described in section  
2 736(a)(1)(A)(i) for that fiscal year.

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

10 “(F) BIOSIMILAR BIOLOGICAL PRODUCT  
11 FEE.—The biosimilar biological product fee  
12 under subsection (a)(4) for a fiscal year shall be  
13 equal to the amount established under section  
14 736(c)(5) for a prescription drug product for  
15 that fiscal year.

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

21 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-  
22 NESS.—

23 “(1) WAIVER OF APPLICATION FEE.—The Sec-  
24 retary shall grant to a person who is named in a bio-  
25 similar biological product application a waiver from

1 the application fee assessed to that person under  
2 subsection (a)(2)(A) for the first biosimilar biologi-  
3 cal product application that a small business or its  
4 affiliate submits to the Secretary for review. After a  
5 small business or its affiliate is granted such a waiv-  
6 er, the small business or its affiliate shall pay—

7 “(A) application fees for all subsequent  
8 biosimilar biological product applications sub-  
9 mitted to the Secretary for review in the same  
10 manner as an entity that is not a small busi-  
11 ness; and

12 “(B) all supplement fees for all supple-  
13 ments to biosimilar biological product applica-  
14 tions submitted to the Secretary for review in  
15 the same manner as an entity that is not a  
16 small business.

17 “(2) CONSIDERATIONS.—In determining wheth-  
18 er to grant a waiver of a fee under paragraph (1),  
19 the Secretary shall consider only the circumstances  
20 and assets of the applicant involved and any affiliate  
21 of the applicant.

22 “(3) SMALL BUSINESS DEFINED.—In this sub-  
23 section, the term ‘small business’ means an entity  
24 that has fewer than 500 employees, including em-  
25 ployees of affiliates, and does not have a drug prod-



1       uct that has been approved under a human drug ap-  
2       plication (as defined in section 735) or a biosimilar  
3       biological product application (as defined in section  
4       744G(4)) and introduced or delivered for introduc-  
5       tion into interstate commerce.

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

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

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

1           “(2) COLLECTIONS AND APPROPRIATION  
2 ACTS.—

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

10           “(B) USE OF FEES AND LIMITATION.—  
11 The fees authorized by this section shall be  
12 available for a fiscal year beginning after fiscal  
13 year 2012 to defray the costs of the process for  
14 the review of biosimilar biological product appli-  
15 cations (including such costs for an additional  
16 number of full-time equivalent positions in the  
17 Department of Health and Human Services to  
18 be engaged in such process), only if the Sec-  
19 retary allocates for such purpose an amount for  
20 such fiscal year (excluding amounts from fees  
21 collected under this section) no less than  
22 \$20,000,000, multiplied by the adjustment fac-  
23 tor applicable to the fiscal year involved.

24           “(C) FEE COLLECTION DURING FIRST  
25 PROGRAM YEAR.—Until the date of enactment

1 of an Act making appropriations through Sep-  
2 tember 30, 2013, for the salaries and expenses  
3 account of the Food and Drug Administration,  
4 fees authorized by this section for fiscal year  
5 2013 may be collected and shall be credited to  
6 such account and remain available until ex-  
7 pended.

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

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

20 “(f) COLLECTION OF UNPAID FEES.—In any case  
21 where the Secretary does not receive payment of a fee as-  
22 sessed under subsection (a) within 30 days after it is due,  
23 such fee shall be treated as a claim of the United States  
24 Government subject to subchapter II of chapter 37 of title  
25 31, United States Code.

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

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

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

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

19 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**  
20 **MENTS.**

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

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

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

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

1 “(d) STUDY.—

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

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

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

15 “(e) REAUTHORIZATION.—

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

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

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

3                   “(C) scientific and academic experts;

4                   “(D) health care professionals;

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

7                   “(F) the regulated industry.

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

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

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

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

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

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

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

8   **SEC. 404. SUNSET DATES.**

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

11          (b) REPORTING REQUIREMENTS.—The amendment  
12          made by section 403 shall cease to be effective January  
13          31, 2018.

14   **SEC. 405. EFFECTIVE DATE.**

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

18                 (1) October 1, 2012; or

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

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



1 **SEC. 406. SAVINGS CLAUSE.**

2 Notwithstanding section 106 of the Prescription  
3 Drug User Fee Amendments of 2007 (21 U.S.C. 379g  
4 note), and notwithstanding the amendments made by this  
5 title, part 2 of subchapter C of chapter VII of the Federal  
6 Food, Drug, and Cosmetic Act, as in effect on the day  
7 before the date of the enactment of this title, shall con-  
8 tinue to be in effect with respect to human drug applica-  
9 tions and supplements (as defined in such part as of such  
10 day) that were accepted by the Food and Drug Adminis-  
11 tration for filing on or after October 1, 2007, but before  
12 October 1, 2012, with respect to assessing and collecting  
13 any fee required by such part for a fiscal year prior to  
14 fiscal year 2013.

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

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

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

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

9 **[(a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—**  
10 Section 505A of the Federal Food, Drug, and Cosmetic  
11 Act (21 U.S.C. 355a) is amended—**]**

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

17 **[(2) by amending subsection (h) to read as fol-**  
18 **lows:]**

19 **[“(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-**  
20 **QUIREMENTS.—Exclusivity under this section shall only be**  
21 granted for the completion of a study or studies that are  
22 the subject of a written request and for which reports are  
23 submitted and accepted in accordance with subsection  
24 (d)(3). Written requests under this section may consist of  
25 a study or studies required under section 505B.”**];]**

1           **[(3) in subsection (k)(2), by striking “sub-**  
2           **section (f)(3)(F)” and inserting “subsection**  
3           **(f)(6)(F)”];]**

4           **[(4) in subsection (l)—]**

5           **[(A) in paragraph (1)—]**

6           **[(i) in the paragraph heading, by**  
7           **striking “YEAR ONE” and inserting “FIRST**  
8           **18-MONTH PERIOD”]; and]**

9           **[(ii) by striking “one-year” and in-**  
10          **serting “18-month”];]**

11          **[(B) in paragraph (2)—]**

12          **[(i) in the paragraph heading, by**  
13          **striking “YEARS” and inserting “PERI-**  
14          **ODS”]; and]**

15          **[(ii) by striking “one-year period”**  
16          **and inserting “18-month period”];]**

17          **[(C) by redesignating paragraph (3) as**  
18          **paragraph (4); and]**

19          **[(D) by inserting after paragraph (2) the**  
20          **following:]**

21          **[“(3) PRESERVATION OF AUTHORITY.—Noth-**  
22          **ing in this subsection shall prohibit the Office of Pe-**  
23          **diatric Therapeutics from providing for the review of**  
24          **adverse event reports by the Pediatric Advisory**  
25          **Committee prior to the 18-month period referred to**

1 in paragraph (1), if such review is necessary to en-  
2 sure safe use of a drug in a pediatric population.”;】

3 【(5) in subsection (n)—】

4 【(A) in the subsection heading, by striking  
5 “COMPLETED” and inserting “SUBMITTED”;  
6 and】

7 【(B) in paragraph (1)—】

8 【(i) in the text preceding subpara-  
9 graph (A), by striking “have not been com-  
10 pleted” and inserting “have not been sub-  
11 mitted by the date specified in the written  
12 request issued and agreed upon”; and】

13 【(ii) by revising subparagraphs (A)  
14 and (B) to read as follows:】

15 【“(A) For a drug for which there remains  
16 any listed patent or exclusivity protection, make  
17 a determination regarding whether an assess-  
18 ment shall be required to be submitted under  
19 section 505B(b).】

20 【“(B) For a drug that has no remaining  
21 listed patents or exclusivity protection, the Sec-  
22 retary shall refer the drug for inclusion on the  
23 list established under section 409I of the Public  
24 Health Service Act for the conduct of stud-  
25 ies.”;】

1           **[(6) in subsection (o)(2), by amending subpara-**  
2           **graph (B) to read as follows:]**

3           **["(B) a statement of any appropriate pedi-**  
4           **atric contraindications, warnings, precautions,**  
5           **or other information that the Secretary con-**  
6           **siders necessary to assure safe use."; and]**

7           **[(7) by striking subsection (q) (relating to a**  
8           **sunset).]**

9           **[(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS**  
10          **AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B**  
11          **of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.**  
12          **355e) is amended—]**

13           **[(1) in subsection (a)—]**

14           **[(A) in paragraph (1), in the matter be-**  
15           **fore subparagraph (A), by inserting “for a**  
16           **drug” after “(or supplement to an applica-**  
17           **tion)”;]**

18           **[(B) in paragraph (3)—]**

19           **[(i) by redesignating subparagraph**  
20           **(B) as subparagraph (D); and]**

21           **[(ii) by inserting after subparagraph**  
22           **(A) the following:]**

23           **["(B) DEFERRAL EXTENSION.—On the**  
24           **initiative of the Secretary or at the request of**  
25           **the applicant, the Secretary may grant an ex-**

1           tension of a deferral under subparagraph (A)  
2           if—】

3                   【“(i) the Secretary finds that the cri-  
4                   teria specified in subclause (II) or (III) of  
5                   subparagraph (A)(i) continue to be met;  
6                   and】

7                   【“(ii) the applicant submits the mate-  
8                   rials required under subparagraph (A)(ii).】

9                   【“(C) CONSIDERATION DURING DEFERRAL  
10                  PERIOD.—If the Secretary has under this para-  
11                  graph deferred the date by which an assessment  
12                  must be submitted, then until the date specified  
13                  in the deferral under subparagraph (A) (includ-  
14                  ing any extension of such date under subpara-  
15                  graph (B))—】

16                   【“(i) the assessment shall not be con-  
17                   sidered late or delayed;】

18                   【“(ii) the Secretary shall not classify  
19                   the assessment as late or delayed in any  
20                   report, database, or public posting.”; and】

21                   【“(iii) in subparagraph (D), as redesign-  
22                   ated, by amending clause (ii) to read as  
23                   follows:】

24                   【“(ii) PUBLIC AVAILABILITY.—Not  
25                   later than 60 days after the submission to

1 the Secretary of the information submitted  
2 through the annual review under clause (i),  
3 the Secretary shall make available to the  
4 public in an easily accessible manner, in-  
5 cluding through the Web site of the Food  
6 and Drug Administration—】

7 【“(I) such information;】

8 【“(II) the name of the applicant  
9 for the product subject to the assess-  
10 ment;】

11 【“(III) the date on which the  
12 product was approved; and】

13 【“(IV) the date of each deferral  
14 or deferral extension under this para-  
15 graph for the product.”; and】

16 【(C) in paragraph (4)(C)—】

17 【(i) in the first sentence, by inserting  
18 “partial” before “waiver is granted”; and】

19 【(ii) in the second sentence, by strik-  
20 ing “either a full or partial waiver” and in-  
21 serting “a partial waiver”;】

22 【(2) in subsection (b)(1), by striking “After  
23 providing notice in the form of a letter (that, for a  
24 drug approved under section 505, references a de-  
25 clined written request under section 505A for a la-

1 beled indication which written request is not referred  
2 under section 505A(n)(1)(A) to the Foundation of  
3 the National Institutes of Health for the pediatric  
4 studies), the Secretary” and inserting “The Sec-  
5 retary”];

6 [(3) by amending subsection (d) to read as fol-  
7 lows:]

8 [“(d) FAILURE TO MEET REQUIREMENTS.—If a  
9 person fails to submit a required assessment described in  
10 subsection (a)(2), fails to meet the applicable require-  
11 ments in subsection (a)(3), or fails to submit a request  
12 for approval of a pediatric formulation described in sub-  
13 section (a) or (b), in accordance with applicable provisions  
14 of subsections (a) and (b)—]

15 [“(1)(A) the Secretary shall issue a letter to  
16 such person informing such person of such failure;]

17 [“(B) not later than 30 calendar days after the  
18 issuance of a letter under subparagraph (A), the  
19 person who receives such letter shall submit to the  
20 Secretary a written response to such letter; and]

21 [“(C) not later than 45 calendar days after the  
22 issuance of a letter under subparagraph (A), the  
23 Secretary shall make such letter, and any response  
24 to such letter under subparagraph (B), available to  
25 the public on the Web site of the Food and Drug



1 Administration, with appropriate redactions made to  
2 protect trade secrets and confidential commercial in-  
3 formation, except that, if the Secretary determines  
4 that the letter under subparagraph (A) was issued  
5 in error, the requirements of this subparagraph shall  
6 not apply with respect to such letter; and】

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

15 【“(B) the failure to submit the required assess-  
16 ment, meet the applicable requirements in subsection  
17 (a)(3), or submit the required request for approval  
18 of a pediatric formulation shall not be the basis for  
19 a proceeding—】

20 【“(i) to withdraw approval for a drug  
21 under section 505(e); or】

22 【“(ii) to revoke the license for a biological  
23 product under section 351 of the Public Health  
24 Service Act.”;】

1           [(4) by amending subsection (e) to read as fol-  
2 lows:]

3           [“(e) INITIAL PEDIATRIC PLAN.—]

4           [“(1) IN GENERAL.—]

5           [“(A) SUBMISSION.—An applicant who is  
6 required to submit an assessment under sub-  
7 section (a)(1) shall submit an initial pediatric  
8 plan.]

9           [“(B) TIMING.—An applicant shall submit  
10 the initial pediatric plan under paragraph (1)—  
11 ]

12           [“(i) before the date on which the ap-  
13 plicant submits the assessments under sub-  
14 section (a)(2); and]

15           [“(ii) not later than—]

16           [“(I) 60 calendar days after the  
17 date of end-of-Phase 2 meeting (as  
18 such term is used in section 312.47 of  
19 title 21, Code of Federal Regulations,  
20 or successor regulations); or]

21           [“(II) such other time as may be  
22 agreed upon between the Secretary  
23 and the applicant.]

24           [Nothing in this section shall preclude the Sec-  
25 retary from accepting the submission of an ini-

1            tial pediatric plan earlier than the date other-  
2            wise applicable under this subparagraph.】

3            【“(C) CONTENTS.—The initial pediatric  
4            plan shall include—】

5            【“(i) an outline of the pediatric stud-  
6            ies that the applicant plans to conduct;】

7            【“(ii) any request for a deferral, par-  
8            tial waiver, or waiver under this section,  
9            along with supporting information; and】

10           【“(iii) other information the Secretary  
11           determines necessary, including any infor-  
12           mation specified in regulations under para-  
13           graph (5).】

14           【“(2) MEETING.—】

15           【“(A) IN GENERAL.—Subject to subpara-  
16           graph (B), not later than 60 calendar days  
17           after receiving an initial pediatric plan under  
18           paragraph (1), the Secretary shall meet with  
19           the applicant to discuss the plan.】

20           【“(B) WRITTEN RESPONSE.—If the Sec-  
21           retary determines that a written response to the  
22           initial pediatric plan is sufficient to commu-  
23           nicate comments on the initial pediatric plan,  
24           and that no meeting is necessary the Secretary

1 shall, not later than 60 days after receiving an  
2 initial pediatric plan under paragraph (1)—】

3 【“(i) notify the applicant of such de-  
4 termination; and】

5 【“(ii) provide to the applicant the  
6 Secretary’s written comments on the  
7 plan.】

8 【“(3) AGREED PEDIATRIC PLAN.—】

9 【“(A) SUBMISSION.—The applicant shall  
10 submit to the Secretary a document reflecting  
11 the agreement between the Secretary and the  
12 applicant on the initial pediatric plan (referred  
13 to in this subsection as an ‘agreed pediatric  
14 plan’).】

15 【“(B) CONFIRMATION.—Not later than 30  
16 days after receiving the agreed pediatric plan  
17 under subparagraph (A), the Secretary shall  
18 provide written confirmation to the applicant  
19 that such plan reflects the agreement of the  
20 Secretary.】

21 【“(C) DEFERRAL AND WAIVER.—If the  
22 agreed pediatric plan contains a request from  
23 the applicant for a deferral, partial waiver, or  
24 waiver under this section, the written confirma-  
25 tion under subparagraph (B) shall include a

1 recommendation from the Secretary as to  
2 whether such request meets the standards  
3 under paragraphs (3) or (4) of subsection (a).】

4 【“(D) AMENDMENTS TO THE PLAN.—At  
5 the initiative of the Secretary or the applicant,  
6 the agreed pediatric plan may be amended at  
7 any time. The requirements of paragraph (2)  
8 shall apply to any such proposed amendment in  
9 the same manner and to the same extent as  
10 such requirements apply to an initial pediatric  
11 plan under paragraph (1). The requirements of  
12 subparagraphs (A) through (C) of this para-  
13 graph shall apply to any agreement resulting  
14 from such proposed amendment in the same  
15 manner and to the same extent as such require-  
16 ments apply to an agreed pediatric plan.】

17 【“(4) INTERNAL COMMITTEE.—The Secretary  
18 shall consult the internal committee under section  
19 505C on the review of the initial pediatric plan,  
20 agreed pediatric plan, and any amendments to such  
21 plans.】

22 【“(5) MANDATORY RULEMAKING.—Not later  
23 than one year after the date of enactment of the  
24 BPCA and PREA Reauthorization Act of 2012, the  
25 Secretary shall promulgate proposed regulations and

1 guidance to implement the provisions of this sub-  
2 section.】

3 【“(6) EFFECTIVE DATE.—The provisions of  
4 this subsection shall take effect 180 calendar days  
5 after the date of enactment of the BPCA and PREA  
6 Reauthorization Act of 2012, irrespective of whether  
7 the Secretary has promulgated final regulations to  
8 carry out this subsection by such date.”;】

9 【(5) in subsection (f)—】

10 【(A) in the subsection heading, by insert-  
11 ing “DEFERRAL EXTENSIONS,” after “DEFER-  
12 RALS,”;】

13 【(B) in paragraph (4)—】

14 【(i) in the paragraph heading, by insert-  
15 ing “DEFERRAL EXTENSIONS,” after  
16 “DEFERRALS,”; and】

17 【(ii) in the second sentence, by insert-  
18 ing “, deferral extensions,” after “defer-  
19 rals”; and】

20 【(C) in paragraph (6)(D)—】

21 【(i) by inserting “and deferral exten-  
22 sions” before “requested and granted”;  
23 and】

1                    [(ii) by inserting “and deferral exten-  
2                    sions” after “the reasons for such defer-  
3                    rals”];]

4                    [(6) in subsection (g)—]

5                    [(A) in paragraph (1)(A), by striking  
6                    “after the date of the submission of the applica-  
7                    tion or supplement” and inserting “after the  
8                    date of the submission of an application or sup-  
9                    plement that receives a priority review or 330  
10                    days after the date of the submission of an ap-  
11                    plication or supplement that receives a standard  
12                    review”; and]

13                    [(B) in paragraph (2), by striking “the  
14                    label of such product” and inserting “the label-  
15                    ing of such product”];]

16                    [(7) in subsection (h)(1)—]

17                    [(A) by inserting “an application (or sup-  
18                    plement to an application) that contains” after  
19                    “date of submission of”; and]

20                    [(B) by inserting “if the application (or  
21                    supplement) receives a priority review, or not  
22                    later than 300 days after the date of submis-  
23                    sion of an application (or supplement to an ap-  
24                    plication) that contains a pediatric assessment  
25                    under this section, if the application (or supple-

1 ment) receives a standard review,” after “under  
2 this section.”;】

3 【(8) in subsection (i)—】

4 【(A) in paragraph (1)—】

5 【(i) in the paragraph heading, by  
6 striking “YEAR ONE” and inserting “FIRST  
7 18-MONTH PERIOD”; and】

8 【(ii) by striking “one-year” and in-  
9 serting “18-month”;】

10 【(B) in paragraph (2)—】

11 【(i) in the paragraph heading, by  
12 striking “YEARS” and inserting “PERI-  
13 ODS”; and】

14 【(ii) by striking “one-year period”  
15 and inserting “18-month period”;】

16 【(C) by redesignating paragraph (3) as  
17 paragraph (4); and】

18 【(D) by inserting after paragraph (2) the  
19 following:】

20 【“(3) PRESERVATION OF AUTHORITY.—Noth-  
21 ing in this subsection shall prohibit the Office of Pe-  
22 diatric Therapeutics from providing for the review of  
23 adverse event reports by the Pediatric Advisory  
24 Committee prior to the 18-month period referred to



1 in paragraph (1), if such review is necessary to en-  
2 sure safe use of a drug in a pediatric population.”;】

3 【(9) by striking subsection (m) (relating to in-  
4 tegration with other pediatric studies); and】

5 【(10) by redesignating subsection (n) as sub-  
6 section (m).】

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

12 【(d) APPLICATION; TRANSITION RULE.—】

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

23 【(2) TRANSITIONAL RULE FOR ADVERSE EVENT  
24 REPORTING.—With respect to a drug for which a la-  
25 beling change described under section 505A(l)(1) or

1 505B(i)(1) of the Federal Food, Drug, and Cosmetic  
2 Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved  
3 or made, respectively, during the one-year period  
4 that ends on the day before the date of enactment  
5 of this Act, the Secretary shall apply section 505A(l)  
6 and section 505B(i), as applicable, to such drug, as  
7 such sections were in effect on such day.】

8 【(e) CONFORMING AMENDMENT.—Section  
9 499(c)(1)(C) of the Public Health Service Act (42 U.S.C.  
10 290b(c)(1)(C)) is amended by striking “for which the Sec-  
11 retary issues a certification in the affirmative under sec-  
12 tion 505A(n)(1)(A) of the Federal Food, Drug, and Cos-  
13 metic Act”.】

14 **【SEC. 502. GOVERNMENT ACCOUNTABILITY OFFICE RE-**  
15 **PORT.**

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

1 pediatric populations and properly labeled for use in chil-  
2 dren.】

3 【(b) CONTENTS.—The report under subsection (a)  
4 shall include—】

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

11 【(2) a description of the importance for chil-  
12 dren, health care providers, parents, and others of  
13 labeling changes made as a result of such testing;】

14 【(3) the number and importance of drugs and  
15 biological products for children that are not being  
16 tested for their use in pediatric populations, notwith-  
17 standing the existence of such programs;】

18 【(4) the possible reasons for the lack of testing  
19 reported under paragraph (3);】

20 【(5) the number of drugs and biological prod-  
21 ucts for which testing is being done and labeling  
22 changes are required under the programs established  
23 by this Act, including—】

24 【(A) the date labeling changes are made;】

1           [(B) which labeling changes required the  
2           use of the dispute resolution process; and]

3           [(C) for labeling changes that required  
4           such dispute resolution process, a description  
5           of—]

6                   [(i) the disputes;]

7                   [(ii) the recommendations of the Pe-  
8                   diatric Advisory Committee; and]

9                   [(iii) the outcomes of such process;]

10           [(6) any recommendations for modifications to  
11           the programs established under sections 505A and  
12           505B of the Federal Food, Drug, and Cosmetic Act  
13           and section 409I of the Public Health Service Act  
14           that the Secretary determines to be appropriate, in-  
15           cluding a detailed rationale for each recommenda-  
16           tion;]

17           [(7)(A) the efforts made by the Secretary to in-  
18           crease the number of studies conducted in the  
19           neonate population (including efforts made to en-  
20           courage the conduct of appropriate studies in neo-  
21           nates by companies with products that have suffi-  
22           cient safety and other information to make the con-  
23           duct of the studies ethical and safe); and]

24                   [(B) the results of such efforts; and]

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

7           【(B) any recommendations for modifications to  
8           the programs under such sections that would lead to  
9           new and better therapies for children with cancer,  
10          including a detailed rationale for each recommenda-  
11          tion.】

12 **【SEC. 503. INTERNAL COMMITTEE FOR REVIEW OF PEDI-**  
13                   **ATRIC PLANS, ASSESSMENTS, DEFERRALS,**  
14                   **DEFERRAL EXTENSIONS, AND WAIVERS.**

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

17           【(1) in the section heading, by inserting “**DE-**  
18           **FERRAL EXTENSIONS,**” after “**DEFERRALS,**”;  
19           and】

20           【(2) by inserting “neonatology” after “pediatric  
21           ethics”.】

22 **【SEC. 504. STAFF OF OFFICE OF PEDIATRIC THERA-**  
23                   **PEUTICS.**

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



1 502(e) of the Food and Drug Administration Amendments  
2 Act of 2007 (Public Law 110–85), is amended—】

3 【(1) in paragraph (1)(D), by striking “section  
4 505B(f)” and inserting “section 505C”; and】

5 【(2) in paragraph (3), by striking “during the  
6 five-year period beginning on the date of the enact-  
7 ment of the Best Pharmaceuticals for Children Act  
8 of 2007” and inserting “to carry out the Sub-  
9 committee’s responsibilities under this section”.】

10 **TITLE VI—FOOD AND DRUG AD-**  
11 **MINISTRATION ADMINISTRATIVE REFORMS**  
12

13 **[SEC. 601. FDA’S MISSION.**

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

15 【(1) in paragraph (2), by striking “with respect  
16 to such products” and inserting “with respect to  
17 regulated products”;】

18 【(2) in paragraph (4), by striking “(1) through  
19 (3)” and inserting “(1) through (4)”；】

20 【(3) by redesignating paragraphs (2) through  
21 (4) as paragraphs (3) through (5); and】

22 【(4) by inserting after paragraph (1) the fol-  
23 lowing:】

24 【“(2) establish a regulatory system that—】

1           【“(A) advances medical innovation by in-  
2           corporating modern scientific tools, standards,  
3           and approaches to ensure the predictable, con-  
4           sistent, efficient, and reasonable review, clear-  
5           ance, approval, and licensing (as appropriate)  
6           of innovative products, including drugs, devices,  
7           and biological products;】

8           【“(B) protects the public health and en-  
9           ables patients to access novel products while  
10          promoting economic growth, innovation, com-  
11          petitiveness, and job creation among the indus-  
12          tries regulated by this Act;】

13          【“(C) is based on the best available  
14          science;】

15          【“(D) allows for public participation and  
16          an open exchange of ideas;】

17          【“(E) promotes predictability, allows flexi-  
18          bility, and reduces uncertainty;】

19          【“(F) identifies and uses the most innova-  
20          tive and least burdensome tools for achieving  
21          regulatory ends;】

22          【“(G) ensures that regulations are acces-  
23          sible, consistent, transparent, written in plain  
24          language, and easy to understand;】



1           【“(H) measures, and seeks to improve, the  
2           actual results of regulatory requirements; and】

3           【“(I) incorporates a patient-focused ben-  
4           efit-risk framework that accounts for varying  
5           degrees of risk tolerance, including for people  
6           living with a life-impacting chronic disease or  
7           disability;”.】

8 **【SEC. 602. PUBLIC PARTICIPATION IN ISSUANCE OF FDA**  
9 **GUIDANCE DOCUMENTS.**

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

12           【“(C) For any guidance document that  
13           sets forth initial interpretations of a statute or  
14           regulation, sets forth changes in interpretation  
15           or policy that are of more than a minor nature,  
16           includes complex scientific issues, or covers  
17           highly controversial issues—】

18                   【“(i) the Secretary shall—】

19                           【“(I) at least 3 months before  
20                           issuance of a draft of such guidance  
21                           document, publish notice in the Fed-  
22                           eral Register of the Secretary’s intent  
23                           to prepare such guidance document;  
24                           and】

1                   **【“(II) during preparation and**  
2                   before issuance of the draft of such  
3                   guidance document, meet with inter-  
4                   ested stakeholders and solicit public  
5                   comment;】

6                   **【“(ii) if the Secretary for good cause**  
7                   finds that, with respect to such guidance  
8                   document, compliance with clause (i) is im-  
9                   practicable, unnecessary, or contrary to the  
10                  public interest—】

11                  **【“(I) the Secretary shall publish**  
12                  such finding and a brief statement of  
13                  the reasons for such finding in the  
14                  Federal Register;】

15                  **【“(II) clause (i) shall not apply**  
16                  with respect to such guidance docu-  
17                  ment; and】

18                  **【“(III) during a 3-month period**  
19                  beginning not later than the date of  
20                  issuance of the draft of such guidance  
21                  document, the Secretary shall meet  
22                  with interested stakeholders and so-  
23                  licit public comment;】

1           **【**“(iii) upon issuance of a draft guid-  
2           ance document under clause (i) or (ii), the  
3           Secretary shall—**】**

4                   **【**“(I) designate the draft as pro-  
5                   posed or final; and**】**

6                   **【**“(II) not later than 12 months  
7                   after the date of issuance of a pro-  
8                   posed draft guidance document, issue  
9                   a final draft of such guidance docu-  
10                  ment in accordance with clauses (i)  
11                  and (ii);**】**

12                  **【**“(iv) if the Secretary issues a pro-  
13                  posed draft guidance document and fails to  
14                  finalize the draft by the deadline deter-  
15                  mined under clause (iii)(II), the Secretary  
16                  shall, beginning on the date of such dead-  
17                  line, treat the proposed draft as null and  
18                  void; and**】**

19                  **【**“(v) not less than every 5 years after  
20                  the issuance of a final guidance document  
21                  in accordance with clause (iii), the Sec-  
22                  retary shall—**】**

23                   **【**“(I) conduct a retrospective  
24                   analysis of such guidance document to  
25                   ensure it is not outmoded, ineffective,

1 insufficient, or excessively burden-  
2 some; and】

3 【“(II) based on such analysis,  
4 modify, streamline, expand, or repeal  
5 the guidance document in accordance  
6 with what has been learned.】

7 【“(D) A notice to industry guidance letter,  
8 a notice to industry advisory letter, and any  
9 similar notice that sets forth initial interpreta-  
10 tions of a statute or regulation, sets forth  
11 changes in interpretation or policy that are of  
12 more than a minor nature, includes complex sci-  
13 entific issues, or covers highly controversial  
14 issues shall be treated as a guidance document  
15 for purposes of subparagraph (C).”】

16 **【SEC. 603. CONFLICTS OF INTEREST.**

17 Chapter VII is amended by striking section 712 (21  
18 U.S.C. 379d-1).】

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

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

23 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

24 “(a) DRUGS AND BIOLOGICS.—

1           “(1) IN GENERAL.—Beginning no earlier than  
2           24 months after the issuance of a final guidance  
3           issued after public notice and opportunity for com-  
4           ment, submissions under subsection (b), (i), or (j) of  
5           section 505 of this Act or subsection (a) or (k) of  
6           section 351 of the Public Health Service Act shall  
7           be submitted in such electronic format as specified  
8           by the Secretary in such guidance.

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

11                 “(A) provide a timetable for establishment  
12                 by the Secretary of further standards for elec-  
13                 tronic submission as required by such para-  
14                 graph; and

15                 “(B) set forth criteria for waivers of and  
16                 exemptions from the requirements of this sub-  
17                 section.

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

20          “(b) DEVICES.—

21                 “(1) IN GENERAL.—Beginning after the  
22                 issuance of final guidance implementing this para-  
23                 graph, pre-submissions and submissions for devices  
24                 under section 510(k), 515(e), 515(d), 515(f),  
25                 520(g), 520(m), or 564 of this Act or section 351

1 of the Public Health Service Act, and any supple-  
2 ments to such pre-submissions or submissions, shall  
3 include an electronic copy of such pre-submissions or  
4 submissions.

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

7 “(A) provide standards for the electronic  
8 copy required under such paragraph; and

9 “(B) set forth criteria for waivers of and  
10 exemptions from the requirements of this sub-  
11 section.”.

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

13 **TITLE VII—MEDICAL DEVICE**  
14 **REGULATORY IMPROVEMENTS**  
15 **[Subtitle A—Premarket**  
16 **Predictability]**

17 **[SEC. 701. TRACKING AND REVIEW OF APPLICATIONS FOR**  
18 **INVESTIGATIONAL DEVICE EXEMPTIONS.**

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

21 【“(8)(A) Upon the submission of an application for  
22 an exemption for a device under this subsection, the sub-  
23 mission of a request to classify a device under section 513,  
24 or the submission of a report for a device under section

1 510(k), whichever occurs first, the Secretary shall assign  
2 a tracking number to the device.】

3 【“(B) The Secretary shall use such tracking number  
4 to record the following interactions between the Secretary  
5 and applicant with respect to the device:】

6 【“(i) Submission or approval of an application  
7 for an exemption under this subsection.】

8 【“(ii) Submission of a request to classify the  
9 device under section 513.】

10 【“(iii) Submission or clearance of a report  
11 under section 510(k).】

12 【“(iv) Any meeting or meeting request, includ-  
13 ing in anticipation of the submission of such an ap-  
14 plication or report.】

15 【“(v) Submission or approval of an application  
16 under section 515(c).】

17 【“(vi) Any formal or informal request by the  
18 Secretary for additional information.】

19 【“(vii) Any deficiency letter.】

20 【“(viii) Any response by the applicant to a re-  
21 quest described in clause (v) or a deficiency letter.】

22 【“(ix) Any written submission by the applicant  
23 to the Food and Drug Administration.】

24 【“(x) Any other matter, as determined appro-  
25 priate by the Secretary.】





1        requirement, relating to the approval or clearance of  
2        a device because the Secretary believes that a dif-  
3        ferent clinical testing design or plan could produce  
4        data more relevant to an approval or clearance deci-  
5        sion.”;】

6            【(4) in paragraph (7)(A), by striking “(7)(A)  
7        In the case” and all that follows through the end of  
8        paragraph (7)(A) and inserting the following:】

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

1           【“(I) whether there is a reasonable assur-  
2           ance of safety and effectiveness; or】

3           【“(II) whether the device is substantially  
4           equivalent to or is at least as safe and effective  
5           as a legally marketed device that is not subject  
6           to approval requirements under section 515.】

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

15           【(5) in paragraph (7)(B)(ii), by inserting “that  
16          has emerged since the date of the agreement and  
17          that is” after “substantial scientific issue”.】

18   **【SEC. 703. CLARIFICATION OF LEAST BURDENSOME STAND-**

19                           **ARD.**

20           【(a) PREMARKET APPROVAL.—Section 513(a)(3)(D)  
21   (21 U.S.C. 360e(a)(3)(D)) is amended—】

22           【(1) by redesignating clause (iii) as clause (iv);  
23          and】

24           【(2) by inserting after clause (ii) the fol-  
25          lowing:】

1                   **【“(iii) In carrying out clause (ii), the**  
2                   **Secretary—】**

3                   **【“(I) shall not request informa-**  
4                   **tion unrelated or irrelevant to a dem-**  
5                   **onstration of reasonable assurance of**  
6                   **device effectiveness;】**

7                   **【“(II) shall consider alternative**  
8                   **approaches to evaluating device effec-**  
9                   **tiveness in order to reduce the time,**  
10                   **effort, and cost of reaching proper**  
11                   **resolution of the issue;】**

12                   **【“(III) shall use all reasonable**  
13                   **mechanisms to lessen review times**  
14                   **and render regulatory decisions;】**

15                   **【“(IV) shall consider whether**  
16                   **pre-clinical data, such as well-designed**  
17                   **bench and animal testing, can meet**  
18                   **the statutory threshold for approval;**  
19                   **and】**

20                   **【“(V) if clinical data are needed,**  
21                   **shall consider alternatives to random-**  
22                   **ized, controlled clinical trials and the**  
23                   **use of surrogate endpoints.”.】**

1       **[(b) SUBSTANTIAL EQUIVALENCE DETERMINA-**  
2 **TION.—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is**  
3 **amended—]**

4               **[(1) by striking “(D) Whenever” and inserting**  
5 **“(D)(i) Whenever”; and]**

6               **[(2) by adding at the end the following:]**

7       **[(“(ii) For purposes of clause (i), the term ‘informa-**  
8 **tion that is necessary to making substantial equivalence**  
9 **determinations’ means information that—]**

10               **[(“(I) constitutes threshold evidence supporting**  
11 **a determination of substantial equivalence between a**  
12 **new device and the predicate device to which the**  
13 **premarket notification submitter claims substantial**  
14 **equivalence; and]**

15               **[(“(II) is relevant and directly related to the**  
16 **substantial equivalence determination.]**

17       **[(“(iii) Any request for additional information under**  
18 **clause (i) shall be a complete request for all of the addi-**  
19 **tional information that the Secretary determines would be**  
20 **necessary to support a determination of substantial**  
21 **equivalence.]**

22               **[(“(iv) The Secretary shall use all reasonable means**  
23 **to employ mechanisms to increase the efficiency of pre-**  
24 **market notification reviews and thereby reduce the time**

1 necessary to render appropriate classification determina-  
2 tions of substantial equivalence.”.]

3 **[SEC. 704. AGENCY DOCUMENTATION AND REVIEW OF SIG-**  
4 **NIFICANT DECISIONS.**

5 Chapter V is amended by inserting after section 517  
6 (21 U.S.C. 360g) the following:]

7 **[“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**  
8 **SIGNIFICANT DECISIONS REGARDING DE-**  
9 **VICES.**

10 **[“(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-**  
11 **CANT DECISIONS.—]**

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

22 **[“(2) PROVISION OF DOCUMENTATION.—**Upon  
23 request, the Secretary shall furnish such complete  
24 documentation to the person who is seeking to sub-

1 mit, or who has submitted, such report or applica-  
2 tion.】

3 【“(b) APPEAL RIGHTS AND PROCEDURES.—】

4 【“(1) APPEAL TO CENTER DIRECTOR.—Any  
5 person may, within 30 days after a significant deci-  
6 sion described in subsection (a)(1), appeal such deci-  
7 sion to the Director of the Center for Devices and  
8 Radiological Health (in this subsection referred to as  
9 the ‘Center Director’).】

10 【“(2) PETITION; PROCEDURES.—The Center  
11 Director—】

12 【“(A) may require that an appeal under  
13 paragraph (1) be in writing and set forth the  
14 decision being appealed and the grounds for the  
15 appeal; and】

16 【“(B) subject to paragraph (6), may pro-  
17 vide for such procedures as may be necessary  
18 with respect to such an appeal.】

19 【“(3) RESOLUTION BY CENTER DIRECTOR.—】

20 【“(A) MEETING.—The Center Director  
21 shall provide, upon the request of any person  
22 bringing an appeal under paragraph (1), for at  
23 least one meeting, to be held within 45 days  
24 after the filing of the appeal, to discuss the sig-  
25 nificant decision involved, the appeal of such

1 decision, and possible resolutions of the ap-  
2 peal.】

3 【“(B) FINAL DECISION.—The Center Di-  
4 rector shall issue a final written decision resolv-  
5 ing any appeal under paragraph (1), including  
6 the grounds for such decision, not later than 90  
7 days after the filing of the appeal.】

8 【“(4) APPEAL TO COMMISSIONER.—】

9 【“(A) IN GENERAL.—Any person who files  
10 an appeal under paragraph (1)—】

11 【“(i) within 30 days after receiving  
12 any decision of the Center Director resolv-  
13 ing the appeal, may appeal such decision  
14 to the Commissioner; or】

15 【“(ii) if the Center Director has not  
16 made a decision resolving the appeal under  
17 paragraph (1) within 90 days after the fil-  
18 ing of such appeal, may file directly with  
19 the Commissioner an appeal of the signifi-  
20 cant decision subject to such appeal under  
21 paragraph (1).】

22 【“(B) FINAL DECISION.—The Commis-  
23 sioner shall issue a final written decision resolv-  
24 ing any appeal under subparagraph (A), includ-  
25 ing the grounds for such decision, not later

1 than 30 days after the filing of such appeal  
2 under subparagraph (A).】

3 【“(5) REPORT.—The Commissioner shall issue  
4 a public report on at least an annual basis that sets  
5 forth—】

6 【“(A) the number of appeals under para-  
7 graph (1) and the disposition of those appeals;】

8 【“(B) for each appeal under paragraph  
9 (1), the number of days taken to reach a final  
10 decision under paragraph (3)(B);】

11 【“(C) the number of appeals to the Com-  
12 missioner under paragraph (4)(A), including  
13 the number of such appeals under paragraph  
14 (4)(A)(ii), and the disposition of those appeals;  
15 and】

16 【“(D) the number of appeals for which the  
17 Commissioner does not issue a final decision  
18 within 30 days as required by paragraph  
19 (4)(B).】

20 【“(6) AUTHORITY OF SECRETARY TO ESTAB-  
21 LISH APPEAL PROCEDURES AND TIMELINES.—】

22 【“(A) ESTABLISHMENT.—Subject to sub-  
23 paragraph (B), the Secretary may, by regula-  
24 tion or guidance, establish appeal procedures or



1           timelines applicable to appeals under paragraph  
2           (1) or (4).】

3           【“(B) LIMITATION.—No procedure or  
4           timeline established under subparagraph (A)  
5           may alter any requirement or extend or delay  
6           any timeline specified in any of paragraphs (1)  
7           through (5).”】

8   **【SEC. 705. TRANSPARENCY IN CLEARANCE PROCESS.**

9           【(a) PUBLICATION OF DETAILED DECISION SUM-  
10          MARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended  
11          by adding at the end the following:】

12          【“(5) Subject to subsection (c) and section 301(j),  
13          the Secretary shall regularly publish detailed decision  
14          summaries for each clearance of a device under section  
15          510(k).”】

16          【(b) APPLICATION.—The requirement of section  
17          520(h)(5) of the Federal Food, Drug, and Cosmetic Act,  
18          as added by subsection (a), applies only with respect to  
19          clearance of a device occurring after the date of the enact-  
20          ment of this Act.】

21   **【SEC. 706. NO 510(K) REPORT REQUIRED FOR CERTAIN**  
22          **MODIFICATIONS.**

23          【(a) IN GENERAL.—Section 510(n) (21 U.S.C.  
24          360(n)) is amended—】



1 Secretary of Health and Human Services shall establish  
2 the schedule referred to in section 515(i)(3) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).】

4 【(b) REGULATION.—Not later than one year after  
5 the date that the schedule is established under such sec-  
6 tion 515(i)(3) (as required by subsection (a)) the Sec-  
7 retary shall issue a final regulation under section 515(b)  
8 of such Act for each device that the Secretary requires  
9 to remain in class III through a determination under sec-  
10 tion 515(i)(2) of such Act.】

11 **【SEC. 712. PROGRAM TO IMPROVE THE DEVICE RECALL**  
12 **SYSTEM.**

13 Chapter V is amended by inserting after section 518  
14 (21 U.S.C. 360h) the following:】

15 **【“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**  
16 **SYSTEM.**

17 **【“(a) IN GENERAL.—The Secretary shall—】**

18 **【“(1) establish a program to routinely and sys-**  
19 **tematically assess information relating to device re-**  
20 **calls and use such information to proactively identify**  
21 **strategies for mitigating health risks presented by**  
22 **defective or unsafe devices;】**

23 **【“(2) clarify procedures for conducting device**  
24 **recall audit checks to improve the ability of inves-**

1        tigators to perform those checks in a consistent  
2        manner;】

3            【“(3) develop detailed criteria for assessing  
4        whether a person performing a device recall has per-  
5        formed an effective correction or action plan for the  
6        recall; and】

7            【“(4) document the basis for each termination  
8        by the Food and Drug Administration of a device re-  
9        call.】

10          【“(b) ASSESSMENT CONTENT.—The program estab-  
11        lished under subsection (a)(1) shall, at a minimum, iden-  
12        tify—】

13            【“(1) trends in the number and types of device  
14        recalls;】

15            【“(2) devices that are most frequently the sub-  
16        ject of a recall; and】

17            【“(3) underlying causes of device recalls.】

18          【“(c) DEFINITION.—In this section, the term ‘recall’  
19        means—】

20            【“(1) the removal from the market of a device  
21        pursuant to an order of the Secretary under sub-  
22        section (b) or (e) of section 518; or】

23            【“(2) the correction or removal from the mar-  
24        ket of a device at the initiative of the manufacturer

1 or importer of the device that is required to be re-  
2 ported to the Secretary under section 519(g).”.]

3 **[Subtitle C—Novel Device**  
4 **Regulatory Relief]**

5 **[SEC. 721. MODIFICATION OF DE NOVO APPLICATION**  
6 **PROCESS.]**

7 **[(a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.**  
8 **360c(f)(2)) is amended—]**

9 **[(1) by inserting “(i)” after “(2)(A)”;**

10 **[(2) by striking “under the criteria set forth”**  
11 **and all that follows and inserting a period; and]**

12 **[(3) by adding at the end of subparagraph (A)**  
13 **the following:]**

14 **[(“ii) In lieu of submitting a report under**  
15 **section 510(k) and submitting a request for**  
16 **classification under clause (i) for a device, if a**  
17 **person determines there is no legally marketed**  
18 **device upon which to base a determination of**  
19 **substantial equivalence (as defined in sub-**  
20 **section (i)), a person may submit a request**  
21 **under this clause for the Secretary to classify**  
22 **the device.]**

23 **[(“iii) Upon receipt of a request under**  
24 **clause (i) or (ii), the Secretary shall classify the**  
25 **device subject to the request under the criteria**

1 set forth in subparagraphs (A) through (C) of  
2 subsection (a)(1).】

3 【“(iv) Notwithstanding clause (iii), the  
4 Secretary may decline to undertake a classifica-  
5 tion of a device pursuant to a request under  
6 clause (ii) if the Secretary identifies a legally  
7 marketed device that would permit a substan-  
8 tial equivalence determination under paragraph  
9 (1) for the device.】

10 【“(v) A person submitting a request under  
11 clause (i) or (ii) may, in the request, rec-  
12 ommend to the Secretary a classification for the  
13 device. Any such request shall describe the de-  
14 vice and provide detailed information and rea-  
15 sons for the recommended classification.”.】

16 【(b) CONFORMING AMENDMENTS.—Section 513(f) of  
17 such Act (21 U.S.C. 360c(f)) is amended in paragraph  
18 (1)—】

19 【(1) in subparagraph (A), by striking “, or” at  
20 the end and inserting a semicolon;】

21 【(2) in subparagraph (B), by striking the pe-  
22 riod and inserting “; or”; and】

23 【(3) by inserting after subparagraph (B) the  
24 following:】

1                   【“(C) the device is classified pursuant to a  
2                   request submitted under paragraph (2).”】

3   **[Subtitle    D—Keeping    America**  
4           **Competitive Through Harmoni-**  
5           **zation]**

6   **[SEC. 731. HARMONIZATION OF DEVICE PREMARKET RE-**  
7                   **VIEW, INSPECTION, AND LABELING SYMBOLS;**  
8                   **REPORT.**

9           【(a) IN GENERAL.—Paragraph (4) of section 803(c)  
10 (21 U.S.C. 383(c)) is amended to read as follows:】

11           【“(4) With respect to devices, the Secretary shall, to  
12 the maximum extent practicable, enter into agreements  
13 with those countries identified in clauses (i) and (ii) of  
14 section 802(b)(1)(A) regarding methods and approaches  
15 to harmonizing regulatory requirements for inspections  
16 and common international labeling symbols.”】

17           【(b) REPORT.—Not later than 3 years after the date  
18 of enactment of this Act, the Secretary of Health and  
19 Human Services shall submit to the Committee on Health,  
20 Education, Labor, and Pensions of the Senate and the  
21 Committee on Energy and Commerce of the House of  
22 Representatives, a report listing the agreements entered  
23 into under section 803(c)(4) of the Federal Food, Drug,  
24 and Cosmetic Act (as amended by subsection (a)) and

1 itemizing the methods and approaches that have been har-  
2 monized pursuant to such section.】

3 **【SEC. 732. PARTICIPATION IN INTERNATIONAL MEDICAL**  
4 **DEVICE REGULATORS FORUM.**

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

7 **【(1) by striking “(3)” and inserting “(3)(A)”;**  
8 **and】**

9 **【(2) by adding at the end the following:】**

10 **【“(B) In carrying out subparagraph (A), the Sec-**  
11 **retary shall participate in the International Medical De-**  
12 **vice Regulators Forum and shall—】**

13 **【“(i) provide guidance to the Forum on strate-**  
14 **gies, policies, directions, membership, and other ac-**  
15 **tivities of the Forum;】**

16 **【“(ii) ensure that the representatives of the**  
17 **United States on the Forum are made up of an**  
18 **equal representation of international regulators and**  
19 **representatives from the device industry that are**  
20 **subject to regulation】**

21 **【“(iii) in providing guidance under clause (i),**  
22 **solicit, review, and consider comments from indus-**  
23 **try, academia, health care professionals, and patient**  
24 **groups; and】**



1           【“(iv) inform the public of the Secretary’s ac-  
2           tivities within the Forum and share with the public  
3           any documentation relating to the Forum’s strate-  
4           gies, policies, and other activities, including releasing  
5           the minutes that record Forum meetings and de-  
6           scribing Forum activities.”.】

7   **【Subtitle E—FDA Renewing Effi-  
8           ciency From Outside Reviewer  
9           Management】**

10 **【SEC. 741. PERSONS ACCREDITED TO REVIEW REPORTS  
11                    UNDER SECTION 510(k) AND MAKE REC-  
12                    COMMENDATIONS FOR INITIAL CLASSIFICA-  
13                    TION.**

14       **【(a) TIME PERIOD FOR REVIEW OF RECOMMENDA-  
15       TIONS OF ACCREDITED PERSONS.—Section 523(a) (21  
16       U.S.C. 360m(a)) is amended—】**

17           **【(1) in paragraph (1), by striking “reviewing  
18           reports” and inserting “reviewing, and making rec-  
19           ommendations to the Secretary regarding, reports”;  
20           and】**

21           **【(2) in paragraph (2), by amending subpara-  
22           graph (B) to read as follows:】**

23                   **【“(B) TIME PERIOD FOR REVIEW.—Not  
24                   later than 30 days after the date on which the  
25                   Secretary is notified under subparagraph (A) by**

1 an accredited person with respect to a rec-  
2 ommendation regarding a report submitted  
3 under section 510(k) or an initial classification  
4 of a device, the Secretary shall make a deter-  
5 mination with respect to the recommendation.  
6 If the Secretary fails to make such a determina-  
7 tion by the end of such 30-day period, the rec-  
8 ommendation is deemed to be accepted by the  
9 Secretary.”.]

10 [(b) ACCESS TO DEVICE INFORMATION.—Section  
11 523(a)(2) (21 U.S.C. 360m(a)(2)), as amended by sub-  
12 section (a)(2), is amended by adding at the end the fol-  
13 lowing:]

14 [(D) ACCESS TO DEVICE INFORMA-  
15 TION.—Subject to section 301(j), for the pur-  
16 pose of providing accredited persons with addi-  
17 tional information to review reports submitted  
18 under section 510(k) and make recommenda-  
19 tions regarding the initial classification of de-  
20 vices, the Secretary shall regularly publish—]

21 [(i) detailed decision summaries for  
22 each clearance of a device under section  
23 510(k), classification of a device under sec-  
24 tion 513, approval of an application for a  
25 device under section 515, or grant of an

1 exemption for a device under section  
2 520(m), occurring after the date of the en-  
3 actment of this subparagraph; and】

4 【“(ii) total product life cycles infor-  
5 mation for devices.”.】

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

9 【“(3) CERTAIN DEVICES.—】

10 【“(A) IN GENERAL.—An accredited person  
11 may be used to perform a review regarding any  
12 report submitted under section 510(k) except  
13 that an accredited person—】

14 【“(i) may not be used to perform a  
15 review of a class III device; and】

16 【“(ii) may be used to perform a re-  
17 view of a class II device which is intended  
18 to be permanently implantable or life sus-  
19 taining or supporting only if a notification  
20 is submitted under subparagraph (B).】

21 【“(B) NOTIFICATION OF INTENT TO PER-  
22 FORM A REVIEW.—Before performing a review  
23 of a report submitted under section 510(k) for  
24 a class II device which is intended to be perma-  
25 nently implantable or life sustaining or sup-

1           porting, an accredited person shall submit to  
2           the Secretary a notification of the person’s in-  
3           tent to perform the review. If the Secretary  
4           does not object within 60 days after receipt of  
5           such a notification, the Secretary is deemed to  
6           allow the accredited person to perform such re-  
7           view. If the Secretary objects to performance of  
8           the review by the accredited person, the Sec-  
9           retary shall specify in writing the basis for the  
10          objection, including any reasons why the ac-  
11          credited person is not capable of performing the  
12          review in a manner which provides a reasonable  
13          assurance of the safety and effectiveness of the  
14          device for its intended purpose.”.]

15          **[(d) ACCREDITATION.—Section 523(b) (21 U.S.C.**  
16 **360m(b)) is amended—]**

17                 **[(1) in paragraph (2)—]**

18                         **[(A) in the heading of subparagraph (C),**  
19                         **by inserting “AND TRAINING” after “AUDIT-**  
20                         **ING”];]**

21                         **[(B) in subparagraph (C)—]**

22                                 **[(i) in clause (i), by striking “and” at**  
23                                 **the end;]**

24                                 **[(ii) by redesignating clause (ii) as**  
25                                 **clause (iii); and]**

1           **[(iii) by inserting after clause (i) the**  
2           **following:]**

3           **["(ii) provide for the initial training**  
4           **and periodic updating of training of such**  
5           **person; and"; and]**

6           **[(C) by adding at the end the following:]**

7           **["(E) PERIODIC REACCREDITATION.—]**

8           **["(i) PERIOD.—Subject to suspension**  
9           **or withdrawal under subparagraph (B),**  
10           **any accreditation under this section shall**  
11           **be valid for a period of 3 years after its**  
12           **issuance.]**

13           **["(ii) RESPONSE TO REACCREDITA-**  
14           **TION REQUEST.—Upon the submission of a**  
15           **request by an accredited person for re-**  
16           **accreditation under this section, the Sec-**  
17           **retary shall approve or deny such request**  
18           **not later than 60 days after receipt of the**  
19           **request.]**

20           **["(iii) CRITERIA.—Not later than 120**  
21           **days after the date of the enactment of**  
22           **this subparagraph, the Secretary shall es-**  
23           **tablish and publish in the Federal Register**  
24           **criteria to reaccredit or deny reaccredita-**  
25           **tion to persons under this section. The re-**

1 accreditation of persons under this section  
2 shall specify the particular activities under  
3 subsection (a) for which such persons are  
4 reaccredited.”;】

5 【(2) in paragraph (3)—】

6 【(A) in subparagraph (A), by inserting “a  
7 sole practitioner or” after “may not be”;】

8 【(B) in subparagraph (B), by striking  
9 “such a manufacturer, supplier, or vendor” and  
10 inserting “a manufacturer, supplier, or vendor  
11 of devices of the type for which such person is  
12 accredited”; and】

13 【(C) in subparagraph (D), by striking “de-  
14 vices” and inserting “devices of the type for  
15 which such person is accredited”;】

16 【(3) by striking paragraph (4) (relating to se-  
17 lection of accredited persons); and】

18 【(4) by redesignating paragraph (5) as para-  
19 graph (4).】

20 【(e) DURATION OF AUTHORITY.—Section 523(c) (21  
21 U.S.C. 360m(c)) is amended by striking “October 1,  
22 2012” and inserting “October 1, 2017”.】

23 【(f) REPORT.—Section 523(d) (21 U.S.C. 360m(d))  
24 is amended by striking “January 10, 2007” and inserting  
25 “January 15, 2015”.】

1 **[SEC. 742. PERSONS ACCREDITED TO CONDUCT INSPEC-**  
2 **TIONS.**

3 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-  
4 ed by striking “October 1, 2012” and inserting “October  
5 1, 2017”.]

6 **[Subtitle G—Humanitarian Device**  
7 **Reform]**

8 **[SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DE-**  
9 **VICES.**

10 Section 520(m) (21 U.S.C. 360j(m)) is amended—  
11 **]**

12 **[(1) in paragraph (1), by striking “devices in-**  
13 **tended to benefit” and all that follows through the**  
14 **end of paragraph (1) and inserting the following:]**  
15 **“devices intended—**

16 **[(“A) to benefit patients in the treatment and**  
17 **diagnosis of diseases or conditions that affect fewer**  
18 **than 4,000 individuals in the United States annu-**  
19 **ally; or]**

20 **[(“B) to benefit patients in the treatment and**  
21 **diagnosis of diseases or conditions that affect great-**  
22 **er than 4,000 individuals in the United States annu-**  
23 **ally, if the person requesting the exemption dem-**  
24 **onstrates that the severity of the disease or condi-**  
25 **tion is such that public health requires a greater**

1 availability of the device to treat or diagnose such  
2 patients.”;】

3 【(2) in paragraph (2)—】

4 【(A) by amending subparagraph (A) to  
5 read as follows:】

6 【“(A)(i) the device is designed to treat or diag-  
7 nose a disease or condition that affects fewer than  
8 4,000 individuals in the United States annually, or】

9 【“(ii) the device is designed to treat or diag-  
10 nose a disease or condition that affects greater than  
11 4,000 individuals in the United States annually and  
12 the criteria in paragraph (1)(B) are met,”; and】

13 【(B) in the flush text at the end, by add-  
14 ing at the end the following: “Any order ap-  
15 proving an application for an exemption under  
16 this subsection shall not prohibit or in any way  
17 limit the number of devices that are medically  
18 necessary to treat, diagnose, or monitor individ-  
19 uals with diseases or conditions described in  
20 paragraph (1).”;】

21 【(3) by striking paragraphs (3) and (6);】

22 【(4) in paragraph (5), by striking “, if the Sec-  
23 retary has reason to believe that the requirements of  
24 paragraph (6) are no longer met,”;】



1           【(5) by amending paragraph (7) to read as fol-  
2 lows:】

3           【“(7)(A) The Secretary shall refer any report  
4 of an adverse event regarding a device described in  
5 subparagraph (B) to the Office of Pediatric Thera-  
6 peutics. In considering the report, the Director of  
7 the Office of Pediatric Therapeutics, in consultation  
8 with experts in the Center for Devices and Radio-  
9 logical Health, shall provide for periodic review of  
10 the report by the Pediatric Advisory Committee, in-  
11 cluding obtaining any recommendations of such  
12 Committee regarding whether the Secretary should  
13 take action under this Act in response to the re-  
14 port.】

15           【“(B) A device is described in this subpara-  
16 graph if—】

17           【“(i) an exemption is granted under para-  
18 graph (2) for the device for treatment or diag-  
19 nosis of a disease or condition that occurs in  
20 pediatric patients or in a pediatric subpopula-  
21 tion; and】

22           【“(ii) the device is labeled for use in pedi-  
23 atric patients or in a pediatric subpopulation in  
24 which the disease or condition occurs.】

25           【“(C) In this paragraph:】

1           【“(i) The term ‘pediatric patients’ means  
2 patients who are 21 years of age or younger at  
3 the time of the diagnosis or treatment.】

4           【“(ii) The term ‘pediatric subpopulation’  
5 means any of the following populations:】

6                   【“(I) Neonates.】

7                   【“(II) Infants.】

8                   【“(III) Children.】

9                   【“(IV) Adolescents.”;】

10           【(6) by amending paragraph (8) to read as fol-  
11 lows:】

12           【“(8) The Secretary, acting through the Office  
13 of Pediatric Therapeutics and the Center for Devices  
14 and Radiological Health, shall provide for an annual  
15 review by the Pediatric Advisory Committee of all  
16 devices described in paragraph (5)(B) to ensure that  
17 the exemption under paragraph (2) remains appro-  
18 priate for pediatric populations.”; and】

19           【(7) by redesignating paragraphs (4), (5), (7),  
20 and (8) as paragraphs (3), (4), (5) and (6), respec-  
21 tively.】

1                   **[TITLE VIII—DRUG**  
2   **REGULATORY IMPROVEMENTS]**  
3                   **[Subtitle A—Pharmaceutical**  
4                   **Supply Chain]**

5   **[SEC. 801. [TO BE SUPPLIED].**

6           **]**

7   **[Subtitle B—Medical Gas Safety]**

8   **[SEC. 811. [TO BE SUPPLIED].**

9   **[Subtitle C—Generating Antibiotic**  
10                   **Incentives Now]**

11   **[SEC. 821. EXTENSION OF EXCLUSIVITY PERIOD FOR**  
12                   **DRUGS.**

13           **[(a) IN GENERAL.—**The Federal Food, Drug, and  
14   Cosmetic Act is amended by inserting after section 505D  
15   (21 U.S.C. 355e) the following:**]**

16   **["SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR**  
17                   **NEW QUALIFIED INFECTIOUS DISEASE PROD-**  
18                   **UCTS.**

19           **["(a) EXTENSION.—**If the Secretary approves an ap-  
20   plication pursuant to section 505 for a drug that has been  
21   determined to be a qualified infectious disease product  
22   under subsection (d), then the four- and five-year periods  
23   described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of  
24   section 505, the three-year periods described in clauses  
25   (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and

1 (iv) of subsection (j)(5)(F) of section 505, or the seven  
2 year period described in section 527, as applicable, shall  
3 be extended by five 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  
9 to 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; or】

14 【“(2) a subsequent application filed by the  
15 same sponsor or manufacturer of a qualified infec-  
16 tious disease product described in paragraph (1) (or  
17 a licensor, predecessor in interest, or other related  
18 entity) for—】

19 【“(A) a change (not including a modifica-  
20 tion to the active moiety of the qualified infec-  
21 tious disease product) that results in a new in-  
22 dication, route of administration, dosing sched-  
23 ule, dosage form, delivery system, delivery de-  
24 vice, or strength; or】

1           【“(B) a modification to the active moiety  
2           of the qualified infectious disease product that  
3           does not result in a change in safety or effec-  
4           tiveness.】

5           【“(d) DETERMINATION.—The manufacturer or spon-  
6           sor of a drug may request that the Secretary designate  
7           a drug as a qualified infectious disease product at any  
8           time in the drug development process prior to the submis-  
9           sion of an application under section 505(b) for the drug,  
10          but not later than 45 days before the submission of such  
11          application. The Secretary shall, not later than 30 days  
12          after the submission of such request, determine whether  
13          the drug is a qualified infectious disease product.】

14          【“(e) REGULATIONS.—The Secretary shall promul-  
15          gate regulations for carrying out this section. The Sec-  
16          retary shall promulgate the initial regulations for carrying  
17          out this section not later than 12 months after the date  
18          of the enactment of this section.】

19          【“(f) DEFINITIONS.—In this section:】

20                 【“(1) QUALIFIED INFECTIOUS DISEASE PROD-  
21                 UCT.—The term ‘qualified infectious disease prod-  
22                 uct’ means an antibacterial drug for human use that  
23                 treats or prevents an infection caused by a quali-  
24                 fying pathogen.】

1           【“(2) QUALIFYING PATHOGEN.—The term  
2           ‘qualifying pathogen’ means—】

3           【“(A) resistant gram-positive pathogens,  
4           including methicillin-resistant *Staphylococcus*  
5           *aureus* (MRSA), vancomycin-resistant *Staphy-*  
6           *lococcus aureus* (VISA), and vancomycin-resist-  
7           ant *enterococcus* (VRE);】

8           【“(B) multidrug resistant gram-negative  
9           bacteria, including *Acinetobacter*, *Klebsiella*,  
10          *Pseudomonas*, and *E. coli* species;】

11          【“(C) multi-drug resistant tuberculosis;  
12          or】

13          【“(D) any other infectious pathogen iden-  
14          tified for purposes of this section by the Sec-  
15          retary.”.】

16          【(b) APPLICATION.—Section 505E of the Federal  
17          Food, Drug, and Cosmetic Act, as added by subsection  
18          (a), applies only with respect to a drug that is first ap-  
19          proved under section 505(c) of such Act (21 U.S.C.  
20          355(c)) on or after the date of the enactment of this Act.】

1 **[SEC. 822. ADDITIONAL EXTENSION OF EXCLUSIVITY PE-**  
2 **RIOD FOR QUALIFIED INFECTIOUS DISEASE**  
3 **PRODUCTS FOR WHICH A QUALIFIED DIAG-**  
4 **NOSTIC TEST IS CLEARED OR APPROVED.]**

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

8 **[“SEC. 505E-1. ADDITIONAL EXTENSION OF EXCLUSIVITY**  
9 **PERIOD FOR QUALIFIED INFECTIOUS DIS-**  
10 **EASE PRODUCTS FOR WHICH A QUALIFIED**  
11 **DIAGNOSTIC TEST IS CLEARED OR AP-**  
12 **PROVED.]**

13 **[“(a) IN GENERAL.—**If the sponsor or manufacturer  
14 of a qualified infectious disease product identifies in ac-  
15 cordance with subsection (b) a qualified diagnostic test de-  
16 scribed in subsection (c), any period extended under sec-  
17 tion 505E(a) with respect to such product shall be further  
18 extended by 6 months.】

19 **[“(b) IDENTIFICATION REQUIREMENTS.—**For pur-  
20 poses of subsection (a), the identification of a qualified  
21 diagnostic test shall—】

22 **[“(1) be made in such manner as the Secretary**  
23 **may require; and】**

24 **[“(2) occur before the expiration of the period**  
25 **to be extended under subsection (a), not counting**

1 any extension to such period under section 505E(a)  
2 or 505A.】

3 【“(c) QUALIFIED DIAGNOSTIC TEST.—For purposes  
4 of subsection (a), a device is a qualified diagnostic test  
5 with respect to a qualified infectious disease product if  
6 each of the following is met:】

7 【“(1) The device is determined by the Sec-  
8 retary under subsection (f) to be a test for diagnosis  
9 of a qualifying pathogen.】

10 【“(2) The qualified infectious disease product  
11 has been determined under section 505E(d) to be for  
12 treating, detecting, preventing, or identifying such  
13 qualifying pathogen.】

14 【“(3) The device is cleared under section  
15 510(k) or approved under section 515.】

16 【“(4) The sponsor or manufacturer, as applica-  
17 ble, of the qualified infectious disease product has  
18 the exclusive rights to submit an identification under  
19 subsection (a) with respect to the device.】

20 【“(d) RELATION TO PEDIATRIC EXCLUSIVITY.—Any  
21 extension under subsection (a) of a period with respect  
22 to a qualified infectious disease product shall be in addi-  
23 tion to any extension of the period under section 505A  
24 of this Act with respect to the product.】



1       **【“(e) LIMITATIONS.—**After the extension of any pe-  
2 riod under subsection (a) with respect to a qualified infec-  
3 tious disease product pursuant to the identification of a  
4 device as a qualified diagnostic test, subsection (a) does  
5 not authorize—**】**

6           **【“(1) any subsequent extension with respect to**  
7       such product; or**】**

8           **【“(2) any extension with respect to any other**  
9       product pursuant to identification of such device.**】**

10       **【“(f) DETERMINATION.—**The sponsor or manufac-  
11 turer of a drug may request the Secretary to determine  
12 that a device is a test for diagnosis of a qualifying patho-  
13 gen. Such a request shall be made at least 45 days before  
14 the submission of a notification under section 510(k) or  
15 an application under section 515 for such device. The Sec-  
16 retary shall, not later than 30 days after the submission  
17 of such request, determine whether the device is a test  
18 for diagnosis of a qualifying pathogen.**】**

19       **【“(g) DEFINITIONS.—**In this section:**】**

20           **【“(1) The term ‘qualified infectious disease**  
21       product’ means a drug that is determined to be a  
22       qualified infectious disease product under section  
23       505E.**】**

24           **【“(2) The term ‘qualifying pathogen’ has the**  
25       meaning given to such term in section 505E.”**】**

1 **[SEC. 823. PRIORITY REVIEW.**

2 **[(a) AMENDMENT.—**Chapter V is amended by insert-  
3 ing after section 524 (21 U.S.C. 360n) the following:**]**

4 **["SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFEC-**  
5 **TIOUS DISEASE PRODUCTS.**

6 **["(a) IN GENERAL.—**If the Secretary makes a deter-  
7 mination under section 505E(c) that a drug is a qualified  
8 infectious disease product, then the Secretary shall give  
9 priority review to any application submitted for approval  
10 for such drug under section 505(b).**]**

11 **["(b) DEFINITION.—**In this section, the term ‘pri-  
12 ority review’, with respect to an application described in  
13 subsection (a), means review and action by the Secretary  
14 on such application not later than 6 months after receipt  
15 by the Secretary of such application.”**]**

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) (21 U.S.C. 355(b)) on or  
20 after the date of the enactment of this Act.**]**

21 **[SEC. 824. FAST TRACK PRODUCT.**

22 Paragraph (1) of section 506(a) (21 U.S.C. 356(a)),  
23 as amended by section 831, is amended by inserting after  
24 “and it demonstrates the potential to address unmet med-  
25 ical needs for such a disease or condition” the following:

1 “or if the Secretary determines under section 505E that  
2 the drug is a qualified infectious disease product”.]

3 **[SEC. 825. STUDY ON INCENTIVES FOR QUALIFIED INFEC-**  
4 **TIOUS DISEASE BIOLOGICAL PRODUCTS.**

5 **[(a) IN GENERAL.—**The Comptroller General of the  
6 United States shall—**]**

7 **[(1)** conduct a study on the need for incentives  
8 to encourage research on and development and mar-  
9 keting of qualified infectious disease biological prod-  
10 ucts; and**]**

11 **[(2)** not later than 1 year after the date of the  
12 enactment of this Act, submit a report to the Con-  
13 gress on the results of such study, including any rec-  
14 ommendations of the Comptroller General on appro-  
15 priate incentives for addressing such need.**]**

16 **[(b) DEFINITIONS.—**In this section:**]**

17 **[(1)** The term “biological product” has the  
18 meaning given to such term in section 351 of the  
19 Public Health Service Act (42 U.S.C. 262).**]**

20 **[(2)** The term “qualified infectious disease bio-  
21 logical product” means a biological product for  
22 human use that treats or prevents an infection  
23 caused by a qualifying pathogen.**]**

24 **[(3)** The term “qualifying pathogen” has the  
25 meaning given to such term in section 505E of the

1 Federal Food, Drug, and Cosmetic Act, as added by  
2 section 821 of this Act.】

3 **【SEC. 826. CLINICAL TRIALS.**

4 **【(a) REVIEW AND REVISION OF GUIDELINES.—】**

5 **【(1) IN GENERAL.—**Not later than 1 year after  
6 the date of the enactment of this Act, and not later  
7 than 4 years thereafter, the Secretary shall—】

8 **【(A)** review the guidelines of the Food and  
9 Drug Administration for the conduct of clinical  
10 trials with respect to antibiotic drugs; and】

11 **【(B)** as appropriate, revise such guidelines  
12 to reflect developments in scientific and medical  
13 information and technology and to ensure clar-  
14 ity regarding the procedures and requirements  
15 for approval of an antibiotic drug under chapter  
16 V of the Federal Food, Drug, and Cosmetic Act  
17 (21 U.S.C. 351 et seq.).】

18 **【(2) ISSUES FOR REVIEW.—**At a minimum, the  
19 review under paragraph (1) shall address the appro-  
20 priate animal models of infection, in vitro tech-  
21 niques, valid microbiological surrogate markers, the  
22 use of noninferiority versus superiority trials, and  
23 appropriate delta values for noninferiority trials.】

24 **【(3) RULE OF CONSTRUCTION.—**Except to the  
25 extent to which the Secretary of Health and Human

1 Services makes revisions under paragraph (1)(B),  
2 nothing in this section shall be construed to repeal  
3 or otherwise affect the guidelines of the Food and  
4 Drug Administration.】

5 **【(b) RECOMMENDATIONS FOR INVESTIGATIONS.—】**

6 **【(1) REQUEST.—**The sponsor of a drug in-  
7 tended to be used to treat, detect, prevent, or iden-  
8 tify a qualifying pathogen may request that the Sec-  
9 retary provide written recommendations for nonclin-  
10 ical and clinical investigations which may be con-  
11 ducted with the drug before it may be approved for  
12 such use under section 505 of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 355).】

14 **【(2) RECOMMENDATIONS.—**If the Secretary  
15 has reason to believe that a drug for which a request  
16 is made under this subsection is a qualified infec-  
17 tious disease product, the Secretary shall provide the  
18 person making the request written recommendations  
19 for the nonclinical and clinical investigations which  
20 the Secretary believes, on the basis of information  
21 available to the Secretary at the time of the request,  
22 would be necessary for approval under section 505  
23 of the Federal Food, Drug, and Cosmetic Act (21  
24 U.S.C. 355) of such drug for the use described in  
25 paragraph (1).】

1 **[(c) DEFINITIONS.—In this section:]**

2 **[(1) The term “drug” has the meaning given to**  
3 **such term in section 201 of the Federal Food, Drug,**  
4 **and Cosmetic Act (21 U.S.C. 321).]**

5 **[(2) The term “qualified infectious disease**  
6 **product” has the meaning given to such term in sec-**  
7 **tion 505E of the Federal Food, Drug, and Cosmetic**  
8 **Act, as added by section 821 of this Act.]**

9 **[(3) The term “qualifying pathogen” has the**  
10 **meaning given to such term in section 505E of the**  
11 **Federal Food, Drug, and Cosmetic Act, as added by**  
12 **section 821 of this Act.]**

13 **[(4) The term “Secretary” means the Secretary**  
14 **of Health and Human Services, acting through the**  
15 **Commissioner of Food and Drugs.]**

16 **[Subtitle D—Accelerated**  
17 **Approval]**

18 **[SEC. 831. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**  
19 **OR LIFE-THREATENING DISEASES OR CONDI-**  
20 **TIONS.**

21 Section 506 of the Federal Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 356) is amended to read as follows:]

1 **["SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**  
2 **OR LIFE-THREATENING DISEASES OR CONDI-**  
3 **TIONS.**

4 **["(a) DESIGNATION OF DRUG AS A FAST TRACK**  
5 **PRODUCT.—]**

6 **["(1) IN GENERAL.—**The Secretary shall, at  
7 the request of the sponsor of a new drug, facilitate  
8 the development and expedite the review of such  
9 drug if it is intended, whether alone or in combina-  
10 tion with one or more other drugs, for the treatment  
11 of a serious or life-threatening disease or condition,  
12 and it demonstrates the potential to address unmet  
13 medical needs for such a disease or condition. (In  
14 this section, such a drug is referred to as a ‘fast  
15 track product’.)**]**

16 **["(2) REQUEST FOR DESIGNATION.—**The spon-  
17 sor of a new drug may request the Secretary to des-  
18 ignate the drug as a fast track product. A request  
19 for the designation may be made concurrently with,  
20 or at any time after, submission of an application  
21 for the investigation of the drug under section 505(i)  
22 of this Act or section 351(a)(3) of the Public Health  
23 Service Act.**]**

24 **["(3) DESIGNATION.—**Within 60 calendar days  
25 after the receipt of a request under paragraph (2),  
26 the Secretary shall determine whether the drug that

1 is the subject of the request meets the criteria de-  
2 scribed in paragraph (1). If the Secretary finds that  
3 the drug meets the criteria, the Secretary shall des-  
4 ignate the drug as a fast track product and shall  
5 take such actions as are appropriate to expedite the  
6 development and review of the application for ap-  
7 proval of such product.】

8 【“(b) ACCELERATED APPROVAL OF A DRUG FOR A  
9 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-  
10 TION, INCLUDING A FAST TRACK PRODUCT.—】

11 【“(1) IN GENERAL.—The Secretary may ap-  
12 prove an application for approval of a product for a  
13 serious or life-threatening disease or condition, in-  
14 cluding a fast track product, under section 505(c) of  
15 this Act or section 351(a) of the Public Health Serv-  
16 ice Act upon making a determination (taking into  
17 account the severity or rarity of the disease or condi-  
18 tion and the availability of alternative treatments)  
19 that the product has an effect on—】

20 【“(A) a surrogate endpoint that is reason-  
21 ably likely to predict clinical benefit; or】

22 【“(B) a clinical endpoint, including an  
23 endpoint that can be measured earlier than ir-  
24 reversible morbidity or mortality, that is reason-



1           ably likely to predict an effect on irreversible  
2           morbidity or mortality or other clinical benefit.】

3       【The evidence to support that an endpoint is reason-  
4       ably likely to predict clinical benefit may include epi-  
5       demiological, pathophysiologic, pharmacologic, thera-  
6       peutic or other evidence developed using, for exam-  
7       ple, biomarkers, or other scientific methods or  
8       tools.】

9           【“(2) LIMITATION.—Approval of a product  
10       under this subsection may, as determined by the  
11       Secretary, be subject to the following require-  
12       ments—】

13               【“(A) that the sponsor conduct appro-  
14       priate post-approval studies to verify and de-  
15       scribe the predicted effect of the product on ir-  
16       reversible morbidity or mortality or other clin-  
17       ical benefit; and】

18               【“(B) that the sponsor submit copies of all  
19       promotional materials related to the product, at  
20       least 30 days prior to dissemination of the ma-  
21       terials—】

22                       【“(i) during the preapproval review  
23                       period; and】

1                   【“(ii) following approval, for a period  
2                   that the Secretary determines to be appro-  
3                   priate.】

4                   【“(3) EXPEDITED WITHDRAWAL OF AP-  
5                   PROVAL.—The Secretary may withdraw approval of  
6                   a product approved pursuant to this subsection  
7                   using expedited procedures (as prescribed by the  
8                   Secretary in regulations, which shall include an op-  
9                   portunity for an informal hearing) if—】

10                  【“(A) the sponsor fails to conduct any re-  
11                  quired post-approval study of the product with  
12                  due diligence;】

13                  【“(B) a study required to verify and de-  
14                  scribe the predicted effect on irreversible mor-  
15                  bidity or mortality or other clinical benefit of  
16                  the product fails to verify and describe such ef-  
17                  fect or benefit;】

18                  【“(C) other evidence demonstrates that  
19                  the product is not safe or effective under the  
20                  conditions of use; or】

21                  【“(D) the sponsor disseminates false or  
22                  misleading promotional materials with respect  
23                  to the product.】

24                  【“(c) REVIEW OF INCOMPLETE APPLICATIONS FOR  
25                  APPROVAL OF A FAST TRACK PRODUCT.—】

1           【“(1) IN GENERAL.—If the Secretary deter-  
2           mines, after preliminary evaluation of clinical data  
3           submitted by the sponsor, that a fast track product  
4           may be effective, the Secretary shall evaluate for fil-  
5           ing, and may commence review of portions of, an ap-  
6           plication for the approval of the product before the  
7           sponsor submits a complete application. The Sec-  
8           retary shall commence such review only if the appli-  
9           cant—】

10                 【“(A) provides a schedule for submission  
11                 of information necessary to make the applica-  
12                 tion complete; and】

13                 【“(B) pays any fee that may be required  
14                 under section 736.】

15           【“(2) EXCEPTION.—Any time period for review  
16           of human drug applications that has been agreed to  
17           by the Secretary and that has been set forth in goals  
18           identified in letters of the Secretary (relating to the  
19           use of fees collected under section 736 to expedite  
20           the drug development process and the review of  
21           human drug applications) shall not apply to an ap-  
22           plication submitted under paragraph (1) until the  
23           date on which the application is complete.】

24           【“(d) AWARENESS EFFORTS.—The Secretary  
25           shall—】

1           【“(1) develop and disseminate to physicians,  
2           patient organizations, pharmaceutical and bio-  
3           technology companies, and other appropriate persons  
4           a description of the provisions of this section appli-  
5           cable to accelerated approval and fast track prod-  
6           ucts; and】

7           【“(2) establish a program to encourage the de-  
8           velopment of surrogate and clinical endpoints, in-  
9           cluding biomarkers, and other scientific methods and  
10          tools that can assist the Secretary in determining  
11          whether the evidence submitted in an application is  
12          reasonably likely to predict clinical benefit for seri-  
13          ous or life-threatening conditions for which there  
14          exist significant unmet medical needs.”.】

15 **【SEC. 832. GUIDANCE; AMENDED REGULATIONS.**

16          【(a) INITIAL GUIDANCE.—Not later than one year  
17          after the date of enactment of this Act, the Secretary of  
18          Health and Human Services (in this subtitle referred to  
19          as the “Secretary”) shall issue draft guidance to imple-  
20          ment the amendments made by section 831.】

21          【(b) FINAL GUIDANCE.—Not later than one year  
22          after the issuance of draft guidance under subsection (a),  
23          after an opportunity for public comment, the Secretary  
24          shall—】

1           【(1) issue final guidance to implement the  
2           amendments made by section 831; and】

3           【(2) amend the regulations governing acceler-  
4           ated approval in parts 314 and 601 of title 21, Code  
5           of Federal Regulations, as necessary to conform  
6           such regulations with the amendments made by sec-  
7           tion 831.】

8           【(c) CONSIDERATIONS.—In developing the guidance  
9           under subsections (a) and (b)(1) and the amendments  
10          under subsection (b)(2), the Secretary shall consider—】

11          【(1) issues arising under the accelerated ap-  
12          proval and fast track processes under section 506 of  
13          the Federal Food, Drug, and Cosmetic Act (as  
14          amended by section 831) for drugs designated for a  
15          rare disease or condition under section 526 of the  
16          Federal, Food, Drug, and Cosmetic Act; and】

17          【(2) how to incorporate novel approaches to the  
18          review of surrogate endpoints based on patho-  
19          physiologic and pharmacologic evidence in such guid-  
20          ance, especially in instances where the low preva-  
21          lence of a disease renders the existence or collection  
22          of other types of data unlikely or impractical.】

23          【(d) NO DELAY IN REVIEW OR APPROVAL.—The  
24          issuance (or non-issuance) of guidance or conforming reg-  
25          ulations implementing the amendments made by section

1 831 shall not preclude the review of, or action on, a re-  
2 quest for designation or an application for approval sub-  
3 mitted pursuant to section 506 of the Federal Food, Drug,  
4 and Cosmetic Act, as amended by section 831.】

5 **【SEC. 833. INDEPENDENT REVIEW.**

6 **【(a) IN GENERAL.—**The Secretary shall, in conjunc-  
7 tion with other planned reviews of the new drug review  
8 process, contract with an independent entity with expertise  
9 in assessing the quality and efficiency of biopharma-  
10 ceutical development and regulatory review programs, to  
11 evaluate the Food and Drug Administration’s application  
12 of the processes described in section 506 of the Federal  
13 Food, Drug, and Cosmetic Act, as amended by section  
14 831, and the impact of such processes on the development  
15 and timely availability of innovative treatments for pa-  
16 tients suffering from serious or life-threatening condi-  
17 tions.】

18 **【(b) CONSULTATION.—**Any evaluation under sub-  
19 section (a) shall include consultation with regulated indus-  
20 tries, patient advocacy and disease research foundations,  
21 and relevant academic medical centers.】

22 **【SEC. 834. RULE OF CONSTRUCTION.**

23 The amendments made to section 506(b) of the Fed-  
24 eral Food, Drug and Cosmetic Act by section 831 shall  
25 be construed in a manner that encourages the Secretary

1 to utilize innovative approaches for the assessment of  
2 products under accelerated approval while maintaining ap-  
3 propriate safety and effectiveness standards for such prod-  
4 ucts.]

## 5 **[TITLE IX—DRUG SHORTAGES]**

### 6 **[SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF** 7 **MANUFACTURING OF CERTAIN DRUGS.**

8 **[(a) IN GENERAL.—**Section 506C (21 U.S.C. 356e)  
9 is amended to read as follows:]

### 10 **["SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF** 11 **MANUFACTURING OF CERTAIN DRUGS.**

12 **["(a) IN GENERAL.—**A manufacturer of a drug sub-  
13 ject to section 503(b)(1)—]

14 **["(1) that is—]**

15 **["(A) life-supporting;]**

16 **["(B) life-sustaining; or]**

17 **["(C) intended for use in the prevention of**  
18 **a debilitating disease or condition; and]**

19 **["(2) that is not a radiopharmaceutical,]**

20 **[shall notify the Secretary of a discontinuance of the man-**  
21 **ufacture of the drug, or an interruption of the manufac-**  
22 **ture of the drug that is likely to lead to a meaningful dis-**  
23 **ruption in the manufacturer's supply of the drug, in ac-**  
24 **cordance with subsection (b).]**

1       **【“(b) TIMING.—**A notice required by subsection (a)  
2 shall be submitted to the Secretary—**】**

3           **【“(1) at least 6 months prior to the date of the**  
4       discontinuance or interruption; or**】**

5           **【“(2) if compliance with paragraph (1) is not**  
6       possible, as soon as practicable.**】**

7       **【“(c) DISTRIBUTION.—**To the maximum extent prac-  
8 ticable, the Secretary shall distribute information on the  
9 discontinuation or interruption of the manufacture of the  
10 drugs described in subsection (a) to appropriate organiza-  
11 tions, including physician and patient organizations, as de-  
12 scribed in section 506D.**】**

13       **【“(d) CONFIDENTIALITY.—**Nothing in this section  
14 shall be construed as authorizing the Secretary to disclose  
15 any information that is a trade secret or confidential infor-  
16 mation subject to section 552(b)(4) of title 5, United  
17 States Code, or section 1905 of title 18, United States  
18 Code.**】**

19       **【“(e) COORDINATION WITH ATTORNEY GENERAL.—**  
20 Not later than 30 days after the receipt of a notification  
21 described in subsection (a), the Secretary shall—**】**

22           **【“(1) determine whether the notification per-**  
23       tains to a controlled substance subject to a produc-  
24       tion quota under section 306 of the Controlled Sub-  
25       stances Act; and**】**



1           【“(2) if necessary, as determined by the Sec-  
2   retary—】

3           【“(A) notify the Attorney General that the  
4   Secretary has received such a notification;】

5           【“(B) request that the Attorney General  
6   increase the aggregate and individual produc-  
7   tion quotas under section 306 of the Controlled  
8   Substances Act applicable to such controlled  
9   substance and any ingredient therein to a level  
10   the Secretary deems necessary to address a  
11   shortage of a controlled substance based on the  
12   best available market data; and】

13          【“(C) if the Attorney General determines  
14   that the level requested is not necessary to ad-  
15   dress a shortage of a controlled substance, the  
16   Attorney General shall provide to the Secretary  
17   a written response detailing the basis for the  
18   Attorney General’s determination.】

19          【The Secretary shall make the written response pro-  
20   vided under subparagraph (C) available to the public  
21   on the Web site of the Food and Drug Administra-  
22   tion.】

23          【“(f) FAILURE TO MEET REQUIREMENTS.—If a per-  
24   son fails to submit information required under subsection  
25   (a) in accordance with subsection (b)—】

1           【“(1) the Secretary shall issue a letter to such  
2 person informing such person of such failure;】

3           【“(2) not later than 30 calendar days after the  
4 issuance of a letter under paragraph (1), the person  
5 who receives such letter shall submit to the Sec-  
6 retary a written response to such letter setting forth  
7 the basis for noncompliance and providing informa-  
8 tion required under subsection (a); and】

9           【“(3) not later than 45 calendar days after the  
10 issuance of a letter under paragraph (1), the Sec-  
11 retary shall make such letter and any response to  
12 such letter under paragraph (2) available to the pub-  
13 lic on the Web site of the Food and Drug Adminis-  
14 tration, with appropriate redactions made to protect  
15 information described in subsection (d), except that,  
16 if the Secretary determines that the letter under  
17 paragraph (1) was issued in error or, after review of  
18 such response, the person had a reasonable basis for  
19 not notifying as required under subsection (a), the  
20 requirements of this paragraph shall not apply.”.】

21       【(b) REGULATIONS.—】

22           【(1) IN GENERAL.—Not later than 18 months  
23 after the date of the enactment of this Act, the Sec-  
24 retary of Health and Human Services, after issuing  
25 a notice of proposed rule and holding a public hear-

1       ing, shall promulgate final regulations that imple-  
2       ment the amendment made by subsection (a).】

3           【(2) CONTENTS.—Such regulations shall, for  
4       purposes of section 506C of the Federal Food,  
5       Drug, and Cosmetic Act (21 U.S.C. 356c)—】

6           【(A) define the terms “life-supporting”,  
7       “life-sustaining”, and “intended for use in the  
8       prevention of a debilitating disease or condi-  
9       tion”; and】

10          【(B) define the term “interruption of the  
11       manufacture of the drug that is likely to lead  
12       to a meaningful disruption in the supply of the  
13       manufacturer’s drug” to mean a change in pro-  
14       duction that is highly likely to lead to more  
15       than a negligible reduction in the supply of the  
16       drug and affects the ability of the manufacturer  
17       to meet demand for such drug, but not to in-  
18       clude a change in production due to matters  
19       such as routine maintenance or insignificant  
20       changes in manufacturing so long as the manu-  
21       facturer expects to resume operations in a short  
22       period of time.】

23   **【SEC. 902. DRUG SHORTAGE LIST.**

24       Title V (21 U.S.C. 351 et seq.) is amended by insert-  
25       ing after section 506C the following new section:】

1 **["SEC. 506D. DRUG SHORTAGE LIST.**

2 **["(a) ESTABLISHMENT.—**The Secretary shall main-  
3 tain an up-to-date list of drugs that are determined by  
4 the Secretary to be in shortage in the United States.]

5 **["(b) CONTENTS.—**For each drug on such list, the  
6 Secretary shall include the following information:]

7 **["(1) The name of the drug in shortage.]**

8 **["(2) The name of each manufacturer of such**  
9 **drug.]**

10 **["(3) The reason for the shortage, as deter-**  
11 **mined by the Secretary, selecting from the following**  
12 **categories:]**

13 **["(A) Requirements related to complying**  
14 **with good manufacturing practices.]**

15 **["(B) Regulatory delay.]**

16 **["(C) Shortage of an active ingredient.]**

17 **["(D) Shortage of an inactive ingredient**  
18 **component.]**

19 **["(E) Discontinuation of the manufacture**  
20 **of the drug.]**

21 **["(F) Delay in shipping of the drug.]**

22 **["(G) Demand increase for the drug.]**

23 **["(4) The estimated duration of the shortage**  
24 **as determined by the Secretary.]**

25 **["(c) PUBLIC AVAILABILITY.—**

1           【“(1) IN GENERAL.—Subject to paragraphs (2)  
2           and (3), the Secretary shall make the information in  
3           such list publicly available.】

4           【“(2) TRADE SECRETS AND CONFIDENTIAL IN-  
5           FORMATION.—Nothing in this section alters or  
6           amends section 1905 of title 18, United States Code,  
7           or section 552(b)(4) of title 5 of such Code.】

8           【“(3) PUBLIC HEALTH EXCEPTION.—The Sec-  
9           retary may choose not to make information collected  
10          under this section publicly available under paragraph  
11          (1) if the Secretary determines that disclosure of  
12          such information would adversely affect the public  
13          health (such as by increasing the possibility of  
14          hoarding or other disruption of the availability of  
15          drug products to patients).”】

16 **【SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

17          Section 306 of the Controlled Substances Act (21  
18          U.S.C. 826) is amended by adding at the end the fol-  
19          lowing:】

20          【“(h)(1) Not later than 30 days after the receipt of  
21          a request described in paragraph (2), the Attorney Gen-  
22          eral shall—】

23                 【“(A) complete review of such request; and】

24                 【“(B)(i) as necessary to address a shortage of  
25          a controlled substance, increase the aggregate and

1 individual production quotas under this section ap-  
2 plicable to such controlled substance and any ingre-  
3 dient therein to the level requested; or】

4 【“(ii) if the Attorney General determines that  
5 the level requested is not necessary to address a  
6 shortage of a controlled substance, the Attorney  
7 General shall provide a written response detailing  
8 the basis for the Attorney General’s determination.】

9 The Secretary shall make the written response pro-  
10 vided under subparagraph (B)(ii) available to the  
11 public on the Web site of the Food and Drug Ad-  
12 ministration.

13 【“(2) A request is described in this paragraph if—  
14 】

15 【“(A) the request pertains to a controlled sub-  
16 stance on the list of drugs in shortage maintained  
17 under section 506D of the Federal Food, Drug, and  
18 Cosmetic Act;】

19 【“(B) the request is submitted by the manufac-  
20 turer of the controlled substance; and】

21 【“(C) the controlled substance is in schedule  
22 II.”.】

1 **[SEC. 904. EXPEDITED REVIEW OF MAJOR MANUFAC-**  
2 **TURING CHANGES FOR POTENTIAL AND**  
3 **VERIFIED SHORTAGES OF DRUGS THAT ARE**  
4 **LIFE-SUPPORTING, LIFE-SUSTAINING, OR IN-**  
5 **TENDED FOR USE IN THE PREVENTION OF A**  
6 **DEBILITATING DISEASE OR CONDITION.**

7 Subsection (c) of section 506A (21 U.S.C. 356a) is  
8 amended by adding at the end the following new para-  
9 graph:】

10 **【“(3) CHANGES ADDRESSING A DRUG SHORT-**  
11 **AGE.—】**

12 **【“(A) CERTIFICATION.—】**

13 **【“(i) DESCRIPTION.—**A certification  
14 is described in this subparagraph if the  
15 holder of the approved application or li-  
16 cense for the drug involved certifies (in  
17 such certification) that the major manufac-  
18 turing change for which approval is being  
19 sought may prevent or alleviate a verified  
20 or anticipated shortage of a drug described  
21 in section 506C(a)(1).】

22 **【“(ii) BAD FAITH EXCEPTION.—**Sub-  
23 paragraphs (B) and (C) do not apply in  
24 the case of a certification which the Sec-  
25 retary determines to be made in bad  
26 faith.】

1           **【“(B) EXPEDITED REVIEW.—**If a certifi-  
2           cation described in subparagraph (A) is sub-  
3           mitted in connection with a supplemental appli-  
4           cation for a major manufacturing change, the  
5           Secretary shall—**】**

6                   **【“(i) expedite any technical review or**  
7                   inspection necessary for consideration of  
8                   the supplemental application;**】**

9                   **【“(ii) provide any technical assistance**  
10                  necessary to facilitate approval of the sup-  
11                  plemental application; and**】**

12                  **【“(iii) not later than 60 days after re-**  
13                  ceipt of the certification, complete review  
14                  of the supplemental application.**】**

15           **【“(C) GOOD MANUFACTURING PRAC-**  
16           **TICE.—**In approving a major manufacturing  
17           change for which a certification described in  
18           subparagraph (A) is submitted, the Secretary  
19           may, for the purpose of preventing or alle-  
20           viating the shortage addressed by the certifi-  
21           cation, deem the change to be in compliance  
22           with the requirements of this Act for current  
23           good manufacturing practice (within the mean-  
24           ing of section 501(a)(1)(B)) if the manufac-  
25           turing facilities involved—**】**



1           【“(i) have a plan to achieve full com-  
2           pliance with such requirements, as in effect  
3           at the time of the Secretary’s determina-  
4           tion;】

5           【“(ii) have sufficient resources to  
6           achieve, and demonstrate adequate  
7           progress in achieving, such full compliance;  
8           and】

9           【“(iii) are implementing adequate in-  
10          terim controls, as determined by the Sec-  
11          retary, in order to ensure the quality of the  
12          drug.”.】

13 **【SEC. 905. STUDY ON DRUG SHORTAGES.**

14          【(a) STUDY.—The Comptroller General of the United  
15          States shall conduct a study to examine the cause of drug  
16          shortages and formulate recommendations on how to pre-  
17          vent or alleviate such shortages.】

18          【(b) CONSIDERATION.—In conducting the study  
19          under this section, the Comptroller General shall consider  
20          the following questions:】

21                 【(1) What are the dominant characteristics of  
22                 drugs that have gone into actual shortage over the  
23                 preceding three years?】

24                 【(2) Are there systemic high-risk factors (such  
25                 as drug pricing structure, including Federal reim-

1 bursements, or the number of manufacturers pro-  
2 ducing a drug product) that have led to the con-  
3 centration of drug shortages in certain drug prod-  
4 ucts that have made such products vulnerable to  
5 drug shortages?】

6 【(3) Is there a reason why drug shortages have  
7 occurred primarily in the sterile injectable market  
8 and in certain therapeutic areas?】

9 【(4) How have regulations, guidance docu-  
10 ments, regulatory practices, and other actions of  
11 Federal departments and agencies (including the ef-  
12 fectiveness of interagency and intraagency coordina-  
13 tion, communication, strategic planning, and deci-  
14 sion-making) affected drug shortages?】

15 【(5) How does hoarding affect drug short-  
16 ages?】

17 【(6) How would incentives alleviate or prevent  
18 drug shortages?】

19 【(c) CONSULTATION WITH STAKEHOLDERS.—In  
20 conducting the study under this section, the Comptroller  
21 General shall consult with relevant stakeholders, including  
22 physicians, pharmacists, hospitals, patients, and drug  
23 manufacturers.】

24 【(d) REPORT.—Note later than 18 months after the  
25 date of the enactment of this Act, the Comptroller General

1 shall submit a report to the Committee on Energy and  
2 Commerce of the House of Representatives and the Com-  
3 mittee on Health, Education, Labor, and Pensions of the  
4 Senate on the results of the study under this section.】

5 **【SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.**

6 Not later than 18 months after the date of the enact-  
7 ment of this Act, and annually thereafter, the Secretary  
8 of Health and Human Services shall submit to the Com-  
9 mittee on Energy and Commerce of the House of Rep-  
10 resentatives and the Committee on Health, Education,  
11 Labor, and Pensions of the Senate a report on drug short-  
12 ages that—】

13 **【(1) describes the communication between the**  
14 **field investigators of the Food and Drug Administra-**  
15 **tion and the staff of the Center for Drug Evaluation**  
16 **and Research’s Office of Compliance and Drug**  
17 **Shortage Program, including the Food and Drug**  
18 **Administration’s procedures for enabling and ensur-**  
19 **ing such communication;】**

20 **【(2) describes the Food and Drug Administra-**  
21 **tion’s efforts to expedite the review of new manufac-**  
22 **turing sites, new suppliers, and specification changes**  
23 **to prevent or alleviate a drug shortage;】**

24 **【(3) describes the coordination between the**  
25 **Food and Drug Administration and the Drug En-**

1       forcement Administration on efforts to prevent or al-  
2       leviate drug shortages;】

3           【(4) identifies the number of, and describes  
4       the, instances in which the Food and Drug Adminis-  
5       tration exercised regulatory flexibility and discretion  
6       to prevent or alleviate a drug shortage;】

7           【(5) identifies the number of instances in which  
8       the Food and Drug Administration asked firms to  
9       increase production to prevent or alleviate a short-  
10      age;】

11          【(6) identifies the number of notifications sub-  
12      mitted to the Secretary under section 506C of the  
13      Federal Food, Drug, and Cosmetic Act, as amended  
14      by section 901 of this Act, including the percentage  
15      of such notifications for a drug that is a sterile  
16      injectable;】

17          【(7) describes the Food and Drug Administra-  
18      tion’s implementation of section 506D of the Fed-  
19      eral Food, Drug, and Cosmetic Act (relating to a  
20      drug shortage list), as added by section 902 of this  
21      Act, and identifies—】

22           【(A) the name of each drug on the list  
23           under such section 506D at any point during  
24           the period covered by the report;】

1           **[(B) the name of each manufacturer of**  
2           **each such drug;]**

3           **[(C) the reason for the shortage of each**  
4           **such drug; and]**

5           **[(D) the anticipated or, if known, actual**  
6           **duration of the shortage of each such drug;]**

7           **[(8) identifies whether, and how, the Food and**  
8           **Drug Administration expedited the review of regu-**  
9           **latory submissions to prevent or alleviate shortages,**  
10          **including how the Administration utilized the au-**  
11          **thority in section 506A(c)(3) of the Federal Food,**  
12          **Drug, and Cosmetic Act, as added by section 904 of**  
13          **this Act;]**

14          **[(9) identifies the number of certifications sub-**  
15          **mitted under such section 506A(c)(3) and, for each**  
16          **such certification, whether the Food and Drug Ad-**  
17          **ministration completed expedited review within 60**  
18          **days as required by subparagraph (B) of such sec-**  
19          **tion 506A(c)(3);]**

20          **[(10) describes the Secretary's public engage-**  
21          **ment on drug shortages with stakeholders, including**  
22          **physicians, pharmacists, patients, hospitals, and**  
23          **drug manufacturers; and]**

24          **[(11) contains the Secretary's plan for address-**  
25          **ing drug shortages in the upcoming year, including**

1 with respect to the issues described in paragraphs  
2 (1) through (10).】

3 **【SEC. 907. ATTORNEY GENERAL REPORT ON DRUG SHORT-**  
4 **AGES.**

5 Not later than 6 months after the date of the enact-  
6 ment of this Act, and annually thereafter, the Attorney  
7 General shall submit to the Committee on Energy and  
8 Commerce of the House of Representatives and the Com-  
9 mittee on the Judiciary of the Senate a report on drug  
10 shortages that—】

11 【(1) identifies the number of requests received  
12 under section 306(h) of the Controlled Substances  
13 Act (as added by section 903 of this Act), the aver-  
14 age review time for such requests, the number of re-  
15 quests granted and denied under such section, and,  
16 for each of the requests denied under such section,  
17 the basis for such denial;】

18 【(2) describes the coordination between the  
19 Drug Enforcement Administration and Food and  
20 Drug Administration on efforts to prevent or allevi-  
21 ate drug shortages; and】

22 【(3) identifies drugs containing a controlled  
23 substance subject to section 306 of the Controlled  
24 Substances Act when such a drug is determined by

1 the Secretary of Health and Human Services to be  
2 in shortage.】