

In the House of Representatives, U. S.,

June 20, 2012.

Resolved, That the bill from the Senate (S. 3187) entitled “An Act to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.”, do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

1 ***SECTION 1. SHORT TITLE.***

2 *This Act may be cited as the “Food and Drug Admin-*
3 *istration Safety and Innovation Act”.*

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

5 *(a) TABLE OF CONTENTS.—The table of contents of*
6 *this Act is as follows:*

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Sunset dates.

Sec. 106. Effective date.

Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

Sec. 201. Short title; findings.

Sec. 202. Definitions.

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

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title.*
- Sec. 302. Authority to assess and use human generic drug fees.*
- Sec. 303. Reauthorization; reporting requirements.*
- Sec. 304. Sunset dates.*
- Sec. 305. Effective date.*
- Sec. 306. Amendment with respect to misbranding.*
- Sec. 307. Streamlined hiring authority to support activities related to human generic drugs.*
- Sec. 308. Additional reporting requirements.*

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.*
- Sec. 408. Additional reporting requirements.*

TITLE V—PEDIATRIC DRUGS AND DEVICES

- Sec. 501. Permanence.*
- Sec. 502. Written requests.*
- Sec. 503. Communication with Pediatric Review Committee.*
- Sec. 504. Access to data.*
- Sec. 505. Ensuring the completion of pediatric studies.*
- Sec. 506. Pediatric study plans.*
- Sec. 507. Reauthorizations.*
- Sec. 508. Report.*
- Sec. 509. Technical amendments.*
- Sec. 510. Pediatric rare diseases.*
- Sec. 511. Staff of Office of Pediatric Therapeutics.*

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

- Sec. 601. Investigational device exemptions.*
- Sec. 602. Clarification of least burdensome standard.*
- Sec. 603. Agency documentation and review of significant decisions.*
- Sec. 604. Device modifications requiring premarket notification prior to marketing.*
- Sec. 605. Program to improve the device recall system.*
- Sec. 606. Clinical holds on investigational device exemptions.*
- Sec. 607. Modification of de novo application process.*
- Sec. 608. Reclassification procedures.*

- Sec. 609. Harmonization of device premarket review, inspection, and labeling symbols.*
- Sec. 610. Participation in international fora.*
- Sec. 611. Reauthorization of third-party review.*
- Sec. 612. Reauthorization of third-party inspection.*
- Sec. 613. Humanitarian device exemptions.*
- Sec. 614. Unique device identifier.*
- Sec. 615. Sentinel.*
- Sec. 616. Postmarket surveillance.*
- Sec. 617. Custom devices.*
- Sec. 618. Health information technology.*
- Sec. 619. Good guidance practices relating to devices.*
- Sec. 620. Pediatric device consortia.*

TITLE VII—DRUG SUPPLY CHAIN

- Sec. 701. Registration of domestic drug establishments.*
- Sec. 702. Registration of foreign establishments.*
- Sec. 703. Identification of drug excipient information with product listing.*
- Sec. 704. Electronic system for registration and listing.*
- Sec. 705. Risk-based inspection frequency.*
- Sec. 706. Records for inspection.*
- Sec. 707. Prohibition against delaying, denying, limiting, or refusing inspection.*
- Sec. 708. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.*
- Sec. 709. Administrative detention.*
- Sec. 710. Exchange of information.*
- Sec. 711. Enhancing the safety and quality of the drug supply.*
- Sec. 712. Recognition of foreign government inspections.*
- Sec. 713. Standards for admission of imported drugs.*
- Sec. 714. Registration of commercial importers.*
- Sec. 715. Notification.*
- Sec. 716. Protection against intentional adulteration.*
- Sec. 717. Penalties for counterfeiting drugs.*
- Sec. 718. Extraterritorial jurisdiction.*

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

- Sec. 801. Extension of exclusivity period for drugs.*
- Sec. 802. Priority review.*
- Sec. 803. Fast track product.*
- Sec. 804. Clinical trials.*
- Sec. 805. Reassessment of qualified infectious disease product incentives in 5 years.*
- Sec. 806. Guidance on pathogen-focused antibacterial drug development.*

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

- Sec. 901. Enhancement of accelerated patient access to new medical treatments.*
- Sec. 902. Breakthrough therapies.*
- Sec. 903. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.*
- Sec. 904. Accessibility of information on prescription drug container labels by visually impaired and blind consumers.*
- Sec. 905. Risk-benefit framework.*
- Sec. 906. Grants and Contracts for the Development of Orphan Drugs.*

- Sec. 907. Reporting of inclusion of demographic subgroups in clinical trials and data analysis in applications for drugs, biologics, and devices.*
- Sec. 908. Rare pediatric disease priority review voucher incentive program.*

TITLE X—DRUG SHORTAGES

- Sec. 1001. Discontinuance or interruption in the production of life-saving drugs.*
- Sec. 1002. Annual reporting on drug shortages.*
- Sec. 1003. Coordination; task force and strategic plan.*
- Sec. 1004. Drug shortage list.*
- Sec. 1005. Quotas applicable to drugs in shortage.*
- Sec. 1006. Attorney General report on drug shortages.*
- Sec. 1007. Hospital repackaging of drugs in shortage.*
- Sec. 1008. Study on drug shortages.*

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

- Sec. 1101. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.*
- Sec. 1102. Reauthorization of the critical path public-private partnerships.*

Subtitle B—Medical Gas Product Regulation

- Sec. 1111. Regulation of medical gases.*
- Sec. 1112. Changes to regulations.*
- Sec. 1113. Rules of construction.*

Subtitle C—Miscellaneous Provisions

- Sec. 1121. Guidance document regarding product promotion using the Internet.*
- Sec. 1122. Combating prescription drug abuse.*
- Sec. 1123. Optimizing global clinical trials.*
- Sec. 1124. Advancing regulatory science to promote public health innovation.*
- Sec. 1125. Information technology.*
- Sec. 1126. Nanotechnology.*
- Sec. 1127. Online pharmacy report to Congress.*
- Sec. 1128. Report on small businesses.*
- Sec. 1129. Protections for the commissioned corps of the public health service act.*
- Sec. 1130. Compliance date for rule relating to sunscreen drug products for over-the-counter human use.*
- Sec. 1131. Strategic integrated management plan.*
- Sec. 1132. Assessment and modification of REMS.*
- Sec. 1133. Extension of period for first applicant to obtain tentative approval without forfeiting 180-day-exclusivity period.*
- Sec. 1134. Deadline for determination on certain petitions.*
- Sec. 1135. Final agency action relating to petitions and civil actions.*
- Sec. 1136. Electronic submission of applications.*
- Sec. 1137. Patient participation in medical product discussions.*
- Sec. 1138. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups.*
- Sec. 1139. Scheduling of hydrocodone.*
- Sec. 1140. Study on Drug Labeling by Electronic Means.*
- Sec. 1141. Recommendations on interoperability standards.*
- Sec. 1142. Conflicts of interest.*

Sec. 1143. Notification of FDA intent to regulate laboratory-developed tests.

Subtitle D—Synthetic Drugs

Sec. 1151. Short title.

Sec. 1152. Addition of synthetic drugs to schedule I of the Controlled Substances Act.

Sec. 1153. Temporary scheduling to avoid imminent hazards to public safety expansion.

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

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

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

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

11 **(b) FINDING.**—*The Congress finds that the fees author-*
 12 *ized by the amendments made in this title will be dedicated*
 13 *toward expediting the drug development process and the*
 14 *process for the review of human drug applications, includ-*
 15 *ing postmarket drug safety activities, as set forth in the*
 16 *goals identified for purposes of part 2 of subchapter C of*
 17 *chapter VII of the Federal Food, Drug, and Cosmetic Act,*
 18 *in the letters from the Secretary of Health and Human*
 19 *Services to the Chairman of the Committee on Health, Edu-*
 20 *cation, Labor, and Pensions of the Senate and the Chair-*
 21 *man of the Committee on Energy and Commerce of the*

1 *House of Representatives, as set forth in the Congressional*
 2 *Record.*

3 **SEC. 102. DEFINITIONS.**

4 *Section 735(7) (21 U.S.C. 379g) is amended by strik-*
 5 *ing “expenses incurred in connection with” and inserting*
 6 *“expenses in connection with”.*

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

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

9 *(1) in subsection (a)—*

10 *(A) in the matter preceding paragraph (1),*
 11 *by striking “fiscal year 2008” and inserting “fis-*
 12 *cal year 2013”;*

13 *(B) in paragraph (1)(A)—*

14 *(i) in clause (i), by striking “(c)(5)”*
 15 *and inserting “(c)(4)”;* and

16 *(ii) in clause (ii), by striking “(c)(5)”*
 17 *and inserting “(c)(4)”;*

18 *(C) in the matter following clause (ii) in*
 19 *paragraph (2)(A)—*

20 *(i) by striking “(c)(5)” and inserting*
 21 *“(c)(4)”;* and

22 *(ii) by striking “payable on or before*
 23 *October 1 of each year” and inserting “due*
 24 *on the later of the first business day on or*
 25 *after October 1 of each fiscal year or the*

1 *first business day after the enactment of an*
 2 *appropriations Act providing for the collec-*
 3 *tion and obligation of fees for such fiscal*
 4 *year under this section”;*

5 *(D) in paragraph (3)—*

6 *(i) in subparagraph (A)—*

7 *(I) by striking “subsection (c)(5)”*

8 *and inserting “subsection (c)(4)”;* and

9 *(II) by striking “payable on or*

10 *before October 1 of each year.” and in-*

11 *serting “due on the later of the first*

12 *business day on or after October 1 of*

13 *each fiscal year or the first business*

14 *day after the enactment of an appro-*

15 *priations Act providing for the collec-*

16 *tion and obligation of fees for such fis-*

17 *cal year under this section.”; and*

18 *(ii) by amending subparagraph (B) to*

19 *read as follows:*

20 *“(B) EXCEPTION.—A prescription drug*

21 *product shall not be assessed a fee under sub-*

22 *paragraph (A) if such product is—*

23 *“(i) identified on the list compiled*

24 *under section 505(j)(7) with a potency de-*

25 *scribed in terms of per 100 mL;*

1 “(ii) the same product as another
2 product that—

3 “(I) was approved under an ap-
4 plication filed under section 505(b) or
5 505(j); and

6 “(II) is not in the list of discon-
7 tinued products compiled under section
8 505(j)(7);

9 “(iii) the same product as another
10 product that was approved under an abbrev-
11 iated application filed under section 507
12 (as in effect on the day before the date of en-
13 actment of the Food and Drug Administra-
14 tion Modernization Act of 1997); or

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

21 (2) in subsection (b)—

22 (A) in paragraph (1)—

23 (i) in the matter preceding subpara-
24 graph (A), by striking “fiscal years 2008

1 *through 2012” and inserting “fiscal years*
 2 *2013 through 2017”;*

3 *(ii) in subparagraph (A), by striking*
 4 *“\$392,783,000; and” and inserting*
 5 *“\$693,099,000.”; and*

6 *(iii) by striking subparagraph (B) and*
 7 *inserting the following:*

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

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

14 *(B) by striking paragraphs (3) and (4) and*
 15 *inserting the following:*

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

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

24 *“(i) \$652,709,000 multiplied by the re-*
 25 *sult of an inflation adjustment calculation*

determined using the methodology described
in subsection (c)(1)(B); and

“(ii) \$652,709,000 multiplied by the
result of an inflation adjustment calculation
determined using the methodology described
in subsection (c)(1)(C).

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

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

“(ii) the amount (if any) by which a
percentage workload adjustment for fiscal
year 2013, as determined using the method-
ology described in subsection (c)(2)(A),
would exceed the percentage workload ad-
justment (as so determined) for fiscal year
2012, if both such adjustment percentages
were calculated using the 5-year base period
consisting of fiscal years 2003 through
2007.

“(C) *LIMITATION*.—Under no circumstances
shall the adjustment under subparagraph (B) re-
sult in fee revenues for fiscal year 2013 that are

1 *less than the sum of the amount under para-*
 2 *graph (1)(A) and the amount under paragraph*
 3 *(1)(B).”;*

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

6 “(c) *ADJUSTMENTS.*—

7 “(1) *INFLATION ADJUSTMENT.*—*For fiscal year*
 8 *2014 and subsequent fiscal years, the revenues estab-*
 9 *lished in subsection (b) shall be adjusted by the Sec-*
 10 *retary by notice, published in the Federal Register,*
 11 *for a fiscal year by the amount equal to the 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 costs*
 20 *to total costs of the process for the review of*
 21 *human drug applications (as defined in section*
 22 *735(6)) for the first 3 years of the preceding 4*
 23 *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 items;*
 3 *Annual Index) for the first 3 years of the pre-*
 4 *ceding 4 years of available data multiplied by*
 5 *the proportion of all costs other than personnel*
 6 *compensation and benefits costs to total costs of*
 7 *the process for the review of human drug appli-*
 8 *cations (as defined in section 735(6)) for the first*
 9 *3 years of the preceding 4 fiscal years.*

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

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

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

1 *plications (adjusted for changes in review activi-*
2 *ties, as described in the notice that the Secretary*
3 *is required to publish in the Federal Register*
4 *under this subparagraph), efficacy supplements,*
5 *and manufacturing supplements submitted to the*
6 *Secretary, and the change in the total number of*
7 *active commercial investigational new drug ap-*
8 *plications (adjusted for changes in review activi-*
9 *ties, as so described) during the most recent 12-*
10 *month period for which data on such submis-*
11 *sions is available. The Secretary shall publish in*
12 *the Federal Register the fee revenues and fees re-*
13 *sulting from the adjustment and the supporting*
14 *methodologies.*

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

21 *“(C) The Secretary shall contract with an*
22 *independent accounting or consulting firm to pe-*
23 *riodically review the adequacy of the adjustment*
24 *and publish the results of those reviews. The first*
25 *review shall be conducted and published by the*

1 *end of fiscal year 2013 (to examine the perform-*
2 *ance of the adjustment since fiscal year 2009),*
3 *and the second review shall be conducted and*
4 *published by the end of fiscal year 2015 (to ex-*
5 *amine the continued performance of the adjust-*
6 *ment). The reports shall evaluate whether the ad-*
7 *justment reasonably represents actual changes in*
8 *workload volume and complexity and present op-*
9 *tions to discontinue, retain, or modify any ele-*
10 *ments of the adjustment. The reports shall be*
11 *published for public comment. After review of the*
12 *reports and receipt of public comments, the Sec-*
13 *retary shall, if warranted, adopt appropriate*
14 *changes to the methodology. If the Secretary*
15 *adopts changes to the methodology based on the*
16 *first report, the changes shall be effective for the*
17 *first fiscal year for which fees are set after the*
18 *Secretary adopts such changes and each subse-*
19 *quent fiscal year.*

20 “(3) *FINAL YEAR ADJUSTMENT.*—*For fiscal year*
21 *2017, the Secretary may, in addition to adjustments*
22 *under this paragraph and paragraphs (1) and (2),*
23 *further increase the fee revenues and fees established*
24 *in subsection (b) if such an adjustment is necessary*
25 *to provide for not more than 3 months of operating*

1 reserves of carryover user fees for the process for the
 2 review of human drug applications for the first 3
 3 months of fiscal year 2018. If such an adjustment is
 4 necessary, the rationale for the amount of the increase
 5 shall be contained in the annual notice establishing
 6 fee revenues and fees for fiscal year 2017. If the Sec-
 7 retary has carryover balances for such process in ex-
 8 cess of 3 months of such operating reserves, the adjust-
 9 ment under this paragraph shall not be made.

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

17 “(5) LIMIT.—The total amount of fees charged,
 18 as adjusted under this subsection, for a fiscal year
 19 may not exceed the total costs for such fiscal year for
 20 the resources allocated for the process for the review
 21 of human drug applications.”; and

22 (4) in subsection (g)—

23 (A) in paragraph (1), by striking “Fees au-
 24 thorized” and inserting “Subject to paragraph
 25 (2)(C), fees authorized”;

1 (B) in paragraph (2)—

2 (i) in subparagraph (A)(i), by striking
3 “shall be retained” and inserting “subject to
4 subparagraph (C), shall be collected and
5 available”;

6 (ii) in subparagraph (A)(ii), by strik-
7 ing “shall only be collected and available”
8 and inserting “shall be available”; and

9 (iii) by adding at the end the following
10 new subparagraph:

11 “(C) *PROVISION FOR EARLY PAYMENTS.—*
12 *Payment of fees authorized under this section for*
13 *a fiscal year, prior to the due date for such fees,*
14 *may be accepted by the Secretary in accordance*
15 *with authority provided in advance in a prior*
16 *year appropriations Act.”;*

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

20 (D) in paragraph (4)—

21 (i) by striking “fiscal years 2008
22 through 2010” and inserting “fiscal years
23 2013 through 2015”;

24 (ii) by striking “fiscal year 2011” and
25 inserting “fiscal year 2016”;

1 (iii) by striking “fiscal years 2008
 2 through 2011” and inserting “fiscal years
 3 2013 through 2016”; and
 4 (iv) by striking “fiscal year 2012” and
 5 inserting “fiscal year 2017”.

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

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

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

10 “(a) *PERFORMANCE REPORT.*—

11 “(1) *IN GENERAL.*—Beginning with fiscal year
 12 2013, not later than 120 days after the end of each
 13 fiscal year for which fees are collected under this part,
 14 the Secretary shall prepare and submit to the Com-
 15 mittee on Energy and Commerce of the House of Rep-
 16 resentatives and the Committee on Health, Education,
 17 Labor, and Pensions of the Senate a report con-
 18 cerning—

19 “(A) the progress of the Food and Drug Ad-
 20 ministration in achieving the goals identified in
 21 the letters described in section 101(b) of the Pre-
 22 scription Drug User Fee Amendments of 2012
 23 during such fiscal year and the future plans of
 24 the Food and Drug Administration for meeting

1 *the goals, including the status of the independent*
2 *assessment described in such letters; and*

3 *“(B) the progress of the Center for Drug*
4 *Evaluation and Research and the Center for Bio-*
5 *logics Evaluation and Research in achieving the*
6 *goals, and future plans for meeting the goals, in-*
7 *cluding, for each review division—*

8 *“(i) the number of original standard*
9 *new drug applications and biologics license*
10 *applications filed per fiscal year for each*
11 *review division;*

12 *“(ii) the number of original priority*
13 *new drug applications and biologics license*
14 *applications filed per fiscal year for each*
15 *review division;*

16 *“(iii) the number of standard efficacy*
17 *supplements filed per fiscal year for each re-*
18 *view division;*

19 *“(iv) the number of priority efficacy*
20 *supplements filed per fiscal year for each re-*
21 *view division;*

22 *“(v) the number of applications filed*
23 *for review under accelerated approval per*
24 *fiscal year for each review division;*

1 “(vi) the number of applications filed
2 for review as fast track products per fiscal
3 year for each review division;

4 “(vii) the number of applications filed
5 for orphan-designated products per fiscal
6 year for each review division; and

7 “(viii) the number of breakthrough des-
8 ignations for a fiscal year for each review
9 division.

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

15 (2) in subsection (b), by striking “2008” and in-
16 serting “2013”; and

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

19 **SEC. 105. SUNSET DATES.**

20 (a) *AUTHORIZATION.*—Sections 735 and 736 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
22 379h) shall cease to be effective October 1, 2017.

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

1 (c) *PREVIOUS SUNSET PROVISION.*—

2 (1) *IN GENERAL.*—*Section 106 of the Food and*
 3 *Drug Administration Amendments Act of 2007 (Pub-*
 4 *lic Law 110–85) is repealed.*

5 (2) *CONFORMING AMENDMENT.*—*The Food and*
 6 *Drug Administration Amendments Act of 2007 (Pub-*
 7 *lic Law 110–85) is amended in the table of contents*
 8 *in section 2, by striking the item relating to section*
 9 *106.*

10 (d) *TECHNICAL CLARIFICATIONS.*—

11 (1) *Effective September 30, 2007—*

12 (A) *section 509 of the Prescription Drug*
 13 *User Fee Amendments Act of 2002 (Title V of*
 14 *Public Law 107–188) is repealed; and*

15 (B) *the Public Health Security and Bioter-*
 16 *rorism Preparedness and Response Act of 2002*
 17 *(Public Law 107–188) is amended in the table*
 18 *of contents in section 1(b), by striking the item*
 19 *relating to section 509.*

20 (2) *Effective September 30, 2002—*

21 (A) *section 107 of the Food and Drug Ad-*
 22 *ministration Modernization Act of 1997 (Public*
 23 *Law 105–115) is repealed; and*

1 (B) the table of contents in section 1(c) of
2 such Act is amended by striking the item related
3 to section 107.

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

7 **SEC. 106. EFFECTIVE DATE.**

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

15 **SEC. 107. SAVINGS CLAUSE.**

16 Notwithstanding the amendments made by this title,
17 part 2 of subchapter C of chapter VII of the Federal Food,
18 Drug, and Cosmetic Act, as in effect on the day before the
19 date of the enactment of this title, shall continue to be in
20 effect with respect to human drug applications and supple-
21 ments (as defined in such part as of such day) that on or
22 after October 1, 2007, but before October 1, 2012, were ac-
23 cepted by the Food and Drug Administration for filing with
24 respect to assessing and collecting any fee required by such
25 part for a fiscal year prior to fiscal year 2012.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

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

(b) *FINDINGS.*—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

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

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

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

(3) in paragraph (13), by striking “is required to register” and all that follows through the end of

1 *paragraph (13) and inserting the following: “is reg-*
 2 *istered (or is required to register) with the Secretary*
 3 *under section 510 because such establishment is en-*
 4 *gaged in the manufacture, preparation, propagation,*
 5 *compounding, or processing of a device.”.*

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

7 *(a) TYPES OF FEES.—Section 738(a) (21 U.S.C.*
 8 *379j(a)) is amended—*

9 *(1) in paragraph (1), by striking “fiscal year*
 10 *2008” and inserting “fiscal year 2013”;*

11 *(2) in paragraph (2)(A)—*

12 *(A) in the matter preceding clause (i)—*

13 *(i) by striking “subsections (d) and*
 14 *(e)” and inserting “subsections (d), (e), and*
 15 *(f)”;*

16 *(ii) by striking “October 1, 2002” and*
 17 *inserting “October 1, 2012”; and*

18 *(iii) by striking “subsection (c)(1)”*
 19 *and inserting “subsection (c)”;* and

20 *(B) in clause (viii), by striking “1.84” and*
 21 *inserting “2”; and*

22 *(3) in paragraph (3)—*

23 *(A) in subparagraph (A), by inserting “and*
 24 *subsection (f)” after “subparagraph (B)”;* and

(B) in subparagraph (C), by striking “initial registration” and all that follows through “section 510.” and inserting “later of—

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

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

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

“(b) *FEE AMOUNTS.*—

“(1) *IN GENERAL.*—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

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

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

1 “(3) *TOTAL REVENUE AMOUNTS SPECIFIED.*—

2 *For purposes of paragraph (1), the total revenue*
 3 *amounts specified in this paragraph are as follows:*

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

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

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

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

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

9 (c) *ANNUAL FEE SETTING; ADJUSTMENTS.*—Section
 10 738(c) (21 U.S.C. 379j(c)) is amended—

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

13 (2) *by striking paragraphs (1) and (2);*

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

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

18 “(1) *IN GENERAL.*—*The Secretary shall, 60 days*
 19 *before the start of each fiscal year after September 30,*
 20 *2012, establish fees under subsection (a), based on*
 21 *amounts specified under subsection (b) and the ad-*
 22 *justments provided under this subsection, and publish*
 23 *such fees, and the rationale for any adjustments to*
 24 *such fees, in the Federal Register.*

25 “(2) *INFLATION ADJUSTMENTS.*—

1 “(A) *ADJUSTMENT TO TOTAL REVENUE*
 2 *AMOUNTS.—For fiscal year 2014 and each subse-*
 3 *quent fiscal year, the Secretary shall adjust the*
 4 *total revenue amount specified in subsection*
 5 *(b)(3) for such fiscal year by multiplying such*
 6 *amount by the applicable inflation adjustment*
 7 *under subparagraph (B) for such year.*

8 “(B) *APPLICABLE INFLATION ADJUSTMENT*
 9 *TO TOTAL REVENUE AMOUNTS.—The applicable*
 10 *inflation adjustment for a fiscal year is—*

11 “(i) *for fiscal year 2014, the base infla-*
 12 *tion adjustment under subparagraph (C) for*
 13 *such fiscal year; and*

14 “(ii) *for fiscal year 2015 and each sub-*
 15 *sequent fiscal year, the product of—*

16 “(I) *the base inflation adjustment*
 17 *under subparagraph (C) for such fiscal*
 18 *year; and*

19 “(II) *the product of the base infla-*
 20 *tion adjustment under subparagraph*
 21 *(C) for each of the fiscal years pre-*
 22 *ceding such fiscal year, beginning with*
 23 *fiscal year 2014.*

24 “(C) *BASE INFLATION ADJUSTMENT TO*
 25 *TOTAL REVENUE AMOUNTS.—*

1 “(i) *IN GENERAL.*—Subject to further
 2 adjustment under clause (ii), the base infla-
 3 tion adjustment for a fiscal year is the sum
 4 of one plus—

5 “(I) the average annual percent
 6 change in the cost, per full-time equiv-
 7 alent position of the Food and Drug
 8 Administration, of all personnel com-
 9 pensation and benefits paid with re-
 10 spect to such positions for the first 3
 11 years of the preceding 4 fiscal years,
 12 multiplied by 0.60; and

13 “(II) the average annual percent
 14 change that occurred in the Consumer
 15 Price Index for urban consumers
 16 (Washington-Baltimore, DC–MD–VA–
 17 WV; Not Seasonally Adjusted; All
 18 items; Annual Index) for the first 3
 19 years of the preceding 4 years of avail-
 20 able data multiplied by 0.40.

21 “(ii) *LIMITATIONS.*—For purposes of
 22 subparagraph (B), if the base inflation ad-
 23 justment for a fiscal year under clause (i)—

1 “(I) is less than 1, such adjust-
 2 ment shall be considered to be equal to
 3 1; or

4 “(II) is greater than 1.04, such
 5 adjustment shall be considered to be
 6 equal to 1.04.

7 “(D) ADJUSTMENT TO BASE FEE
 8 AMOUNTS.—For each of fiscal years 2014
 9 through 2017, the base fee amounts specified in
 10 subsection (b)(2) shall be adjusted as needed, on
 11 a uniform proportionate basis, to generate the
 12 total revenue amounts under subsection (b)(3), as
 13 adjusted for inflation under subparagraph (A).

14 “(3) VOLUME-BASED ADJUSTMENTS TO ESTAB-
 15 LISHMENT REGISTRATION BASE FEES.—For each of
 16 fiscal years 2014 through 2017, after the base fee
 17 amounts specified in subsection (b)(2) are adjusted
 18 under paragraph (2)(D), the base establishment reg-
 19 istration fee amounts specified in such subsection
 20 shall be further adjusted, as the Secretary estimates is
 21 necessary in order for total fee collections for such fis-
 22 cal year to generate the total revenue amounts, as ad-
 23 justed under paragraph (2).”.

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

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

3 (2) by inserting after subsection (e) the following
4 new subsection:

5 “(f) *FEE WAIVER OR REDUCTION.*—

6 “(1) *IN GENERAL.*—The Secretary may, at the
7 Secretary’s sole discretion, grant a waiver or reduc-
8 tion of fees under subsection (a)(2) or (a)(3) if the
9 Secretary finds that such waiver or reduction is in
10 the interest of public health.

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

16 “(3) *DURATION.*—The authority provided by this
17 subsection terminates October 1, 2017.”.

18 (e) *CONDITIONS.*—Section 738(h)(1)(A) (21 U.S.C.
19 379j(h)(1)(A)), as redesignated by subsection (d)(1), is
20 amended by striking “\$205,720,000” and inserting
21 “\$280,587,000”.

22 (f) *CREDITING AND AVAILABILITY OF FEES.*—Section
23 738(i) (21 U.S.C. 379j(i)), as redesignated by subsection
24 (d)(1), is amended—

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

4 (2) in paragraph (2)—

5 (A) in subparagraph (A)—

6 (i) in clause (i), by striking “shall be
 7 retained” and inserting “subject to subpara-
 8 graph (C), shall be collected and available”;
 9 and

10 (ii) in clause (ii)—

11 (I) by striking “collected and”
 12 after “shall only be”; and

13 (II) by striking “fiscal year 2002”
 14 and inserting “fiscal year 2009”; and

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

16 “(C) *PROVISION FOR EARLY PAYMENTS.*—

17 *Payment of fees authorized under this section for*
 18 *a fiscal year, prior to the due date for such fees,*
 19 *may be accepted by the Secretary in accordance*
 20 *with authority provided in advance in a prior*
 21 *year appropriations Act.”;*

22 (3) by amending paragraph (3) to read as fol-
 23 lows:

24 “(3) *AUTHORIZATIONS OF APPROPRIATIONS.*—

25 *For each of the fiscal years 2013 through 2017, there*

1 *is authorized to be appropriated for fees under this*
 2 *section an amount equal to the total revenue amount*
 3 *specified under subsection (b)(3) for the fiscal year, as*
 4 *adjusted under subsection (c) and, for fiscal year*
 5 *2017 only, as further adjusted under paragraph (4).”;*
 6 *and*

7 *(4) in paragraph (4)—*

8 *(A) by striking “fiscal years 2008, 2009,*
 9 *and 2010” and inserting “fiscal years 2013,*
 10 *2014, and 2015”;*

11 *(B) by striking “fiscal year 2011” and in-*
 12 *serting “fiscal year 2016”;*

13 *(C) by striking “June 30, 2011” and insert-*
 14 *ing “June 30, 2016”;*

15 *(D) by striking “the amount of fees specified*
 16 *in aggregate in” and inserting “the cumulative*
 17 *amount appropriated pursuant to”;*

18 *(E) by striking “aggregate amount in” be-*
 19 *fore “excess shall be credited”; and*

20 *(F) by striking “fiscal year 2012” and in-*
 21 *serting “fiscal year 2017”.*

22 *(g) CONFORMING AMENDMENT.—Section 515(c)(4)(A)*
 23 *(21 U.S.C. 360e(c)(4)(A)) is amended by striking “738(g)”*
 24 *and inserting “738(h)”.*

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

2 (a) *REAUTHORIZATION.*—Section 738A(b) (21 U.S.C.
3 379j–1(b)) is amended—

4 (1) in paragraph (1), by striking “2012” and in-
5 serting “2017”; and

6 (2) in paragraph (5), by striking “2012” and in-
7 serting “2017”.

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

10 (1) by striking paragraph (1) and inserting the
11 following:

12 “(1) *PERFORMANCE REPORT.*—

13 “(A) *IN GENERAL.*—Beginning with fiscal
14 year 2013, for each fiscal year for which fees are
15 collected under this part, the Secretary shall pre-
16 pare and submit to the Committee on Health,
17 Education, Labor, and Pensions of the Senate
18 and the Committee on Energy and Commerce of
19 the House of Representatives annual reports con-
20 cerning the progress of the Food and Drug Ad-
21 ministration in achieving the goals identified in
22 the letters described in section 201(b) of the Med-
23 ical Device User Fee Amendments of 2012 dur-
24 ing such fiscal year and the future plans of the
25 Food and Drug Administration for meeting the
26 goals.

1 “(B) *PUBLICATION.*—With regard to infor-
 2 mation to be reported by the Food and Drug Ad-
 3 ministration to industry on a quarterly and an-
 4 nual basis pursuant to the letters described in
 5 section 201(b) of the Medical Device User Fee
 6 Amendments Act of 2012, the Secretary shall
 7 make such information publicly available on the
 8 Internet Web site of the Food and Drug Admin-
 9 istration not later than 60 days after the end of
 10 each quarter or 120 days after the end of each
 11 fiscal year, respectively, to which such informa-
 12 tion applies. This information shall include the
 13 status of the independent assessment identified
 14 in the letters described in such section 201(b).

15 “(C) *UPDATES.*—The Secretary shall in-
 16 clude in each report under subparagraph (A) in-
 17 formation on all previous cohorts for which the
 18 Secretary has not given a complete response on
 19 all device premarket applications and reports,
 20 supplements, and premarket notifications in the
 21 cohort.”; and

22 (2) in paragraph (2), by striking “2008 through
 23 2012” and inserting “2013 through 2017”.

1 **SEC. 205. SAVINGS CLAUSE.**

2 *Notwithstanding the amendments made by this title,*
 3 *part 3 of subchapter C of chapter VII of the Federal Food,*
 4 *Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect*
 5 *on the day before the date of the enactment of this title,*
 6 *shall continue to be in effect with respect to the submissions*
 7 *listed in section 738(a)(2)(A) of such Act (in effect as of*
 8 *such day) that on or after October 1, 2007, but before Octo-*
 9 *ber 1, 2012, were accepted by the Food and Drug Adminis-*
 10 *tration for filing with respect to assessing and collecting*
 11 *any fee required by such part for a fiscal year prior to fiscal*
 12 *year 2013.*

13 **SEC. 206. EFFECTIVE DATE.**

14 *The amendments made by this title shall take effect*
 15 *on October 1, 2012, or the date of the enactment of this*
 16 *Act, whichever is later, except that fees under part 3 of sub-*
 17 *chapter C of chapter VII of the Federal Food, Drug, and*
 18 *Cosmetic Act shall be assessed for all submissions listed in*
 19 *section 738(a)(2)(A) of such Act received on or after October*
 20 *1, 2012, regardless of the date of the enactment of this Act.*

21 **SEC. 207. SUNSET CLAUSE.**

22 (a) *IN GENERAL.*—*Sections 737 and 738 of the Federal*
 23 *Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j) shall*
 24 *cease to be effective October 1, 2017. Section 738A (21*
 25 *U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic*

1 *Act (regarding reauthorization and reporting requirements)*
 2 *shall cease to be effective January 31, 2018.*

3 *(b) PREVIOUS SUNSET PROVISION.—*

4 *(1) IN GENERAL.—Section 217 of the Food and*
 5 *Drug Administration Amendments Act of 2007 (Title*
 6 *II of Public Law 110–85) is repealed.*

7 *(2) CONFORMING AMENDMENT.—The Food and*
 8 *Drug Administration Amendments Act of 2007 (Pub-*
 9 *lic Law 110–85) is amended in the table of contents*
 10 *in section 2, by striking the item relating to section*
 11 *217.*

12 *(c) TECHNICAL CLARIFICATION.—Effective September*
 13 *30, 2007—*

14 *(1) section 107 of the Medical Device User Fee*
 15 *and Modernization Act of 2002 (Public Law 107–*
 16 *250) is repealed; and*

17 *(2) the table of contents in section 1(b) of such*
 18 *Act is amended by striking the item related to section*
 19 *107.*

20 **SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT**
 21 **ACTIVITIES RELATED TO THE PROCESS FOR**
 22 **THE REVIEW OF DEVICE APPLICATIONS.**

23 *Subchapter A of chapter VII (21 U.S.C. 371 et seq.)*
 24 *is amended by inserting after section 713 the following new*
 25 *section:*

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

2 “(a) *IN GENERAL.*—*In addition to any other personnel*
 3 *authorities under other provisions of law, the Secretary*
 4 *may, without regard to the provisions of title 5, United*
 5 *States Code, governing appointments in the competitive*
 6 *service, appoint employees to positions in the Food and*
 7 *Drug Administration to perform, administer, or support*
 8 *activities described in subsection (b), if the Secretary deter-*
 9 *mines that such appointments are needed to achieve the ob-*
 10 *jectives specified in subsection (c).*

11 “(b) *ACTIVITIES DESCRIBED.*—*The activities described*
 12 *in this subsection are activities under this Act related to*
 13 *the process for the review of device applications (as defined*
 14 *in section 737(8)).*

15 “(c) *OBJECTIVES SPECIFIED.*—*The objectives specified*
 16 *in this subsection are with respect to the activities under*
 17 *subsection (b), the goals referred to in section 738A(a)(1).*

18 “(d) *INTERNAL CONTROLS.*—*The Secretary shall insti-*
 19 *tute appropriate internal controls for appointments under*
 20 *this section.*

21 “(e) *SUNSET.*—*The authority to appoint employees*
 22 *under this section shall terminate on the date that is 3 years*
 23 *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 “Ge-
 5 neric Drug User Fee Amendments of 2012”.

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

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

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

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

21 **“SEC. 744A. DEFINITIONS.**

22 “For purposes of this part:

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

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

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

13 “(2) The term ‘active pharmaceutical ingredient’
 14 means—

15 “(A) a substance, or a mixture when the
 16 substance is unstable or cannot be transported on
 17 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 of
 23 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 factor
 7 applicable to a fiscal year that is the Consumer Price
 8 Index for all urban consumers (all items; United
 9 States city average) for October of the preceding fiscal
 10 year divided by such Index for October 2011.

11 “(4) The term ‘affiliate’ means a business entity
 12 that has a relationship with a second business entity
 13 if, directly or indirectly—

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

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

18 “(5)(A) The term ‘facility’—

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

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

22 “(II) at one geographic location or ad-
 23 dress engaged in manufacturing or proc-
 24 essing an active pharmaceutical ingredient
 25 or a finished dosage form; and

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

5 “(B) For purposes of subparagraph (A), separate
6 buildings within close proximity are considered to be
7 at one geographic location or address if the activities
8 in them are—

9 “(i) closely related to the same business en-
10 terprise;

11 “(ii) under the supervision of the same local
12 management; and

13 “(iii) capable of being inspected by the Food
14 and Drug Administration during a single in-
15 spection.

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

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

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

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

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

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

15 “(8) The term ‘human generic drug activities’
16 means the following activities of the Secretary associ-
17 ated with generic drugs and inspection of facilities
18 associated with generic drugs:

19 “(A) The activities necessary for the review
20 of generic drug submissions, including review of
21 drug master files referenced in such submissions.

22 “(B) The issuance of—

23 “(i) approval letters which approve ab-
24 breviated new drug applications or supple-
25 ments to such applications; or

1 “(ii) complete response letters which set
 2 forth in detail the specific deficiencies in
 3 such applications and, where appropriate,
 4 the actions necessary to place such applica-
 5 tions in condition for approval.

6 “(C) The issuance of letters related to Type
 7 II active pharmaceutical drug master files
 8 which—

9 “(i) set forth in detail the specific defi-
 10 ciencies in such submissions, and where ap-
 11 propriate, the actions necessary to resolve
 12 those deficiencies; or

13 “(ii) document that no deficiencies
 14 need to be addressed.

15 “(D) Inspections related to generic drugs.

16 “(E) Monitoring of research conducted in
 17 connection with the review of generic drug sub-
 18 missions and drug master files.

19 “(F) Postmarket safety activities with re-
 20 spect to drugs approved under abbreviated new
 21 drug applications or supplements, including the
 22 following activities:

23 “(i) Collecting, developing, and review-
 24 ing safety information on approved drugs,
 25 including adverse event reports.

1 “(ii) *Developing and using improved*
2 *adverse-event data-collection systems, in-*
3 *cluding information technology systems.*

4 “(iii) *Developing and using improved*
5 *analytical tools to assess potential safety*
6 *problems, including access to external data*
7 *bases.*

8 “(iv) *Implementing and enforcing sec-*
9 *tion 505(o) (relating to postapproval studies*
10 *and clinical trials and labeling changes)*
11 *and section 505(p) (relating to risk evalua-*
12 *tion and mitigation strategies) insofar as*
13 *those activities relate to abbreviated new*
14 *drug applications.*

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

18 “(G) *Regulatory science activities related to*
19 *generic drugs.*

20 “(9) *The term ‘positron emission tomography*
21 *drug’ has the meaning given to the term ‘compounded*
22 *positron emission tomography drug’ in section*
23 *201(ii), except that paragraph (1)(B) of such section*
24 *shall not apply.*

1 “(10) The term ‘prior approval supplement’
2 means a request to the Secretary to approve a change
3 in the drug substance, drug product, production proc-
4 ess, quality controls, equipment, or facilities covered
5 by an approved abbreviated new drug application
6 when that change has a substantial potential to have
7 an adverse effect on the identity, strength, quality,
8 purity, or potency of the drug product as these factors
9 may relate to the safety or effectiveness of the drug
10 product.

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

13 “(A) officers and employees of the Food and
14 Drug Administration, contractors of the Food
15 and Drug Administration, advisory committees,
16 and costs related to such officers and employees
17 and to contracts with such contractors;

18 “(B) management of information, and the
19 acquisition, maintenance, and repair of com-
20 puter resources;

21 “(C) leasing, maintenance, renovation, and
22 repair of facilities and acquisition, maintenance,
23 and repair of fixtures, furniture, scientific equip-
24 ment, and other necessary materials and sup-
25 plies; and

1 “(D) collecting fees under subsection (a) and
 2 accounting for resources allocated for the review
 3 of abbreviated new drug applications and sup-
 4 plements and inspection related to generic drugs.

5 “(12) The term ‘Type II active pharmaceutical
 6 ingredient drug master file’ means a submission of
 7 information to the Secretary by a person that intends
 8 to authorize the Food and Drug Administration to
 9 reference the information to support approval of a ge-
 10 neric drug submission without the submitter having
 11 to disclose the information to the generic drug submis-
 12 sion applicant.

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

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

18 “(1) *ONE-TIME BACKLOG FEE FOR ABBREVIATED*
 19 *NEW DRUG APPLICATIONS PENDING ON OCTOBER 1,*
 20 *2012.*—

21 “(A) *IN GENERAL.*—Each person that owns
 22 an abbreviated new drug application that is
 23 pending on October 1, 2012, and that has not re-
 24 ceived a tentative approval prior to that date,

1 *shall be subject to a fee for each such application,*
 2 *as calculated under subparagraph (B).*

3 “(B) *METHOD OF FEE AMOUNT CALCULA-*
 4 *TION.—The amount of each one-time backlog fee*
 5 *shall be calculated by dividing \$50,000,000 by*
 6 *the total number of abbreviated new drug appli-*
 7 *cations pending on October 1, 2012, that have*
 8 *not received a tentative approval as of that date.*

9 “(C) *NOTICE.—Not later than October 31,*
 10 *2012, the Secretary shall publish in the Federal*
 11 *Register a notice announcing the amount of the*
 12 *fee required by subparagraph (A).*

13 “(D) *FEE DUE DATE.—The fee required by*
 14 *subparagraph (A) shall be due no later than 30*
 15 *calendar days after the date of the publication of*
 16 *the notice specified in subparagraph (C).*

17 “(2) *DRUG MASTER FILE FEE.—*

18 “(A) *IN GENERAL.—Each person that owns*
 19 *a Type II active pharmaceutical ingredient drug*
 20 *master file that is referenced on or after October*
 21 *1, 2012, in a generic drug submission by any*
 22 *initial letter of authorization shall be subject to*
 23 *a drug master file fee.*

24 “(B) *ONE-TIME PAYMENT.—If a person has*
 25 *paid a drug master file fee for a Type II active*

1 *pharmaceutical ingredient drug master file, the*
 2 *person shall not be required to pay a subsequent*
 3 *drug master file fee when that Type II active*
 4 *pharmaceutical ingredient drug master file is*
 5 *subsequently referenced in generic drug submis-*
 6 *sions.*

7 *“(C) NOTICE.—*

8 *“(i) FISCAL YEAR 2013.—Not later than*
 9 *October 31, 2012, the Secretary shall pub-*
 10 *lish in the Federal Register a notice an-*
 11 *nouncing the amount of the drug master file*
 12 *fee for fiscal year 2013.*

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

20 *“(D) AVAILABILITY FOR REFERENCE.—*

21 *“(i) IN GENERAL.—Subject to sub-*
 22 *section (g)(2)(C), for a generic drug submis-*
 23 *sion to reference a Type II active pharma-*
 24 *ceutical ingredient drug master file, the*

1 *drug master file must be deemed available*
2 *for reference by the Secretary.*

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

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

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

17 “(iii) *LIST.—The Secretary shall make*
18 *publicly available on the Internet Web site*
19 *of the Food and Drug Administration a list*
20 *of the drug master file numbers that cor-*
21 *respond to drug master files that have suc-*
22 *cessfully undergone an initial completeness*
23 *assessment, in accordance with criteria to*
24 *be published by the Secretary, and are*
25 *available for reference.*

1 “(E) *FEE DUE DATE.*—

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

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

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

15 “(II) *30 calendar days after the*
 16 *date of enactment of an appropriations*
 17 *Act providing for the collection and ob-*
 18 *ligation of fees under this section.*

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

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

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

3 “(B) NOTICE.—

4 “(i) FISCAL YEAR 2013.—Not later than
5 October 31, 2012, the Secretary shall pub-
6 lish in the Federal Register a notice an-
7 nouncing the amount of the fees under sub-
8 paragraph (A) for fiscal year 2013.

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

16 “(C) FEE DUE DATE.—

17 “(i) IN GENERAL.—Except as provided
18 in clause (ii), the fees required by subpara-
19 graphs (A) and (F) shall be due no later
20 than the date of submission of the abbre-
21 viated new drug application or prior ap-
22 proval supplement for which such fee ap-
23 plies.

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

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

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

9 “(III) *if an appropriations Act is*
10 *not enacted providing for the collection*
11 *and obligation of fees under this sec-*
12 *tion by the date of submission of the*
13 *application or prior approval supple-*
14 *ment for which the fees under subpara-*
15 *graphs (A) and (F) apply, 30 calendar*
16 *days after the date that such an appro-*
17 *priations Act is enacted.*

18 “(D) *REFUND OF FEE IF ABBREVIATED NEW*
19 *DRUG APPLICATION IS NOT CONSIDERED TO*
20 *HAVE BEEN RECEIVED.*—*The Secretary shall re-*
21 *fund 75 percent of the fee paid under subpara-*
22 *graph (A) for any abbreviated new drug applica-*
23 *tion or prior approval supplement to an abbrev-*
24 *iated new drug application that the Secretary*
25 *considers not to have been received within the*

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

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

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

24 “(i) *such submission contains informa-*
 25 *tion concerning the manufacture of an ac-*

1 *tive pharmaceutical ingredient at a facility*
 2 *by means other than reference by a letter of*
 3 *authorization to a Type II active pharma-*
 4 *ceutical drug master file; and*

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

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

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

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

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

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

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

4 “(C) *NOTICE.*—

5 “(i) *FISCAL YEAR 2013.*—*For fiscal*
 6 *year 2013, the Secretary shall publish in*
 7 *the Federal Register a notice announcing*
 8 *the amount of the fees provided for in sub-*
 9 *paragraph (A) within the timeframe speci-*
 10 *fied in subsection (d)(1)(B).*

11 “(ii) *FISCAL YEARS 2014 THROUGH*
 12 *2017.*—*Within the timeframe specified in*
 13 *subsection (d)(2), the Secretary shall pub-*
 14 *lish in the Federal Register the amount of*
 15 *the fees under subparagraph (A) for such*
 16 *fiscal year.*

17 “(D) *FEE DUE DATE.*—

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

21 “(I) *not later than 45 days after*
 22 *the publication of the notice under sub-*
 23 *paragraph (B); or*

24 “(II) *if an appropriations Act is*
 25 *not enacted providing for the collection*

1 *and obligation of fees under this sec-*
 2 *tion by the date of the publication of*
 3 *such notice, 30 days after the date that*
 4 *such an appropriations Act is enacted.*

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

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

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

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

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

or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

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

“(b) *FEE REVENUE AMOUNTS.*—

“(1) *IN GENERAL.*—

“(A) *FISCAL YEAR 2013.*—For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of \$299,000,000. Of that amount—

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

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

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

For each of the fiscal years 2014 through 2017,

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

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

13 *“(A) Six percent shall be derived from fees*
 14 *under subsection (a)(2) (relating to drug master*
 15 *files).*

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

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

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

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

1 “(c) *ADJUSTMENTS.*—

2 “(1) *INFLATION ADJUSTMENT.*—*For fiscal year*
 3 *2014 and subsequent fiscal years, the revenues estab-*
 4 *lished in subsection (b) shall be adjusted by the Sec-*
 5 *retary by notice, published in the Federal Register,*
 6 *for a fiscal year, by an amount equal to the sum of—*

7 “(A) *one;*

8 “(B) *the average annual percent change in*
 9 *the 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 costs*
 15 *to total costs of human generic drug activities for*
 16 *the first 3 years of the preceding 4 fiscal years;*
 17 *and*

18 “(C) *the average annual percent change*
 19 *that occurred in the Consumer Price Index for*
 20 *urban consumers (Washington-Baltimore, DC–*
 21 *MD–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 of*

1 *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 sub-*
 4 *section shall be added on a compounded basis to the*
 5 *sum of all adjustments made each fiscal year after fis-*
 6 *cal year 2013 under this subsection.*

7 “(2) *FINAL YEAR ADJUSTMENT.*—*For fiscal year*
 8 *2017, the Secretary may, in addition to adjustments*
 9 *under paragraph (1), further increase the fee revenues*
 10 *and fees established in subsection (b) if such an ad-*
 11 *justment is necessary to provide for not more than 3*
 12 *months of operating reserves of carryover user fees for*
 13 *human generic drug activities for the first 3 months*
 14 *of fiscal year 2018. Such fees may only be used in fis-*
 15 *cal year 2018. If such an adjustment is necessary, the*
 16 *rationale for the amount of the increase shall be con-*
 17 *tained in the annual notice establishing fee revenues*
 18 *and fees for fiscal year 2017. If the Secretary has car-*
 19 *ryover balances for such activities in excess of 3*
 20 *months of such operating reserves, the adjustment*
 21 *under this subparagraph shall not be made.*

22 “(d) *ANNUAL FEE SETTING.*—

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

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

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

7 *“(B) the Secretary shall establish, not later*
 8 *than 45 days after the date to comply with the*
 9 *requirement for identification of facilities in sub-*
 10 *section (f)(2), the generic drug facility fee and*
 11 *active pharmaceutical ingredient facility fee*
 12 *under subsection (a) based on the revenue*
 13 *amounts established under subsection (b).*

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

24 *“(3) FEE FOR ACTIVE PHARMACEUTICAL INGRE-*
 25 *DIENT INFORMATION NOT INCLUDED BY REFERENCE*

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

6 *“(A) the sum of—*

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

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

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

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

21 *“(f) IDENTIFICATION OF FACILITIES.—*

22 *“(1) PUBLICATION OF NOTICE; DEADLINE FOR*
 23 *COMPLIANCE.—Not later than October 1, 2012, the*
 24 *Secretary shall publish in the Federal Register a no-*
 25 *tice requiring each person that owns a facility de-*

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

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

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

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

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

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

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

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

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

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

15 “(4) *CERTAIN SITES AND ORGANIZATIONS.—*

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

21 “(B) *SITES AND ORGANIZATIONS.—A site or*
 22 *organization is described in this subparagraph if*
 23 *it is identified in a generic drug submission and*
 24 *is—*

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

3 “(ii) a clinical research organization;

4 “(iii) a contract analytical testing site;

5 or

6 “(iv) a contract repackager site.

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

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

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

18 “(1) GENERIC DRUG BACKLOG FEE.—Failure to
19 pay the fee under subsection (a)(1) shall result in the
20 Secretary placing the person that owns the abbrevi-
21 ated new drug application subject to that fee on a
22 publicly available arrears list, such that no new ab-
23 breviated new drug applications or supplement sub-
24 mitted on or after October 1, 2012, from that person,
25 or any affiliate of that person, will be received within

1 *the meaning of section 505(j)(5)(A) until such out-*
2 *standing fee is paid.*

3 “(2) *DRUG MASTER FILE FEE.*—

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

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

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

1 *master file to pay the drug master file fee as*
 2 *specified in subparagraph (C).*

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

14 *“(ii) If such fee is not paid within 20 cal-*
 15 *endar days of the Secretary providing the notifi-*
 16 *cation, the abbreviated new drug application or*
 17 *supplement to an abbreviated new drug applica-*
 18 *tion shall not be received within the meaning of*
 19 *505(j)(5)(A).*

20 *“(3) ABBREVIATED NEW DRUG APPLICATION FEE*
 21 *AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to*
 22 *pay a fee under subparagraph (A) or (F) of sub-*
 23 *section (a)(3) within 20 calendar days of the applica-*
 24 *ble due date under subparagraph (C) of such sub-*
 25 *section shall result in the abbreviated new drug appli-*

1 *cation or the prior approval supplement to an abbrev-*
 2 *viated new drug application not being received within*
 3 *the meaning of section 505(j)(5)(A) until such out-*
 4 *standing fee is paid.*

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

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

11 *“(i) The Secretary shall place the facil-*
 12 *ity on a publicly available arrears list, such*
 13 *that no new abbreviated new drug applica-*
 14 *tion or supplement submitted on or after*
 15 *October 1, 2012, from the person that is re-*
 16 *sponsible for paying such fee, or any affil-*
 17 *iate of that person, will be received within*
 18 *the meaning of section 505(j)(5)(A).*

19 *“(ii) Any new generic drug submission*
 20 *submitted on or after October 1, 2012, that*
 21 *references such a facility shall not be re-*
 22 *ceived, within the meaning of section*
 23 *505(j)(5)(A) if the outstanding facility fee is*
 24 *not paid within 20 calendar days of the*
 25 *Secretary providing the notification to the*

1 *sponsor of the failure of the owner of the fa-*
2 *cility to pay the facility fee under sub-*
3 *section (a)(4)(C).*

4 *“(iii) All drugs or active pharma-*
5 *ceutical ingredients manufactured in such a*
6 *facility or containing an ingredient manu-*
7 *factured in such a facility shall be deemed*
8 *misbranded under section 502(aa).*

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

14 *“(C) NONRECEIVAL FOR NONPAYMENT.—*

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

1 “(ii) *NONRECEIVAL.*—*If the facility fee*
2 *is not paid within 20 calendar days of the*
3 *Secretary providing the notification under*
4 *clause (i), the abbreviated new drug appli-*
5 *cation or supplement to an abbreviated new*
6 *drug application shall not be received with-*
7 *in the meaning of section 505(j)(5)(A).*

8 “(h) *LIMITATIONS.*—

9 “(1) *IN GENERAL.*—*Fees under subsection (a)*
10 *shall be refunded for a fiscal year beginning after fis-*
11 *cal year 2012, unless appropriations for salaries and*
12 *expenses of the Food and Drug Administration for*
13 *such fiscal year (excluding the amount of fees appro-*
14 *priated for such fiscal year) are equal to or greater*
15 *than the amount of appropriations for the salaries*
16 *and expenses of the Food and Drug Administration*
17 *for fiscal year 2009 (excluding the amount of fees ap-*
18 *propriated for such fiscal year) multiplied by the ad-*
19 *justment factor (as defined in section 744A) applica-*
20 *ble to the fiscal year involved.*

21 “(2) *AUTHORITY.*—*If the Secretary does not as-*
22 *sess fees under subsection (a) during any portion of*
23 *a fiscal year and if at a later date in such fiscal year*
24 *the Secretary may assess such fees, the Secretary may*
25 *assess and collect such fees, without any modification*

1 *in the rate, for Type II active pharmaceutical ingre-*
 2 *dient drug master files, abbreviated new drug appli-*
 3 *cations and prior approval supplements, and generic*
 4 *drug facilities and active pharmaceutical ingredient*
 5 *facilities at any time in such fiscal year notwith-*
 6 *standing the provisions of subsection (a) relating to*
 7 *the date fees are to be paid.*

8 “(i) *CREDITING AND AVAILABILITY OF FEES.*—

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

21 “(2) *COLLECTIONS AND APPROPRIATION ACTS.*—

22 “(A) *IN GENERAL.*—*The fees authorized by*
 23 *this section—*

24 “(i) *subject to subparagraphs (C) and*
 25 *(D), shall be collected and available in each*

1 *fiscal year in an amount not to exceed the*
2 *amount specified in appropriation Acts, or*
3 *otherwise made available for obligation for*
4 *such fiscal year; and*

5 *“(ii) shall be available for a fiscal year*
6 *beginning after fiscal year 2012 to defray*
7 *the costs of human generic drug activities*
8 *(including such costs for an additional*
9 *number of full-time equivalent positions in*
10 *the Department of Health and Human*
11 *Services to be engaged in such activities),*
12 *only if the Secretary allocates for such pur-*
13 *pose an amount for such fiscal year (exclud-*
14 *ing amounts from fees collected under this*
15 *section) no less than \$97,000,000 multiplied*
16 *by the adjustment factor defined in section*
17 *744A(3) applicable to the fiscal year in-*
18 *volved.*

19 *“(B) COMPLIANCE.—The Secretary shall be*
20 *considered to have met the requirements of sub-*
21 *paragraph (A)(ii) in any fiscal year if the costs*
22 *funded by appropriations and allocated for*
23 *human generic activities are not more than 10*
24 *percent below the level specified in such subpara-*
25 *graph.*

1 “(C) *FEE COLLECTION DURING FIRST PRO-*
 2 *GRAM YEAR.*—*Until the date of enactment of an*
 3 *Act making appropriations through September*
 4 *30, 2013 for the salaries and expenses account of*
 5 *the Food and Drug Administration, fees author-*
 6 *ized by this section for fiscal year 2013, may be*
 7 *collected and shall be credited to such account*
 8 *and remain available until expended.*

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

16 “(3) *AUTHORIZATION OF APPROPRIATIONS.*—*For*
 17 *each of the fiscal years 2013 through 2017, there is*
 18 *authorized to be appropriated for fees under this sec-*
 19 *tion an amount equivalent to the total revenue*
 20 *amount determined under subsection (b) for the fiscal*
 21 *year, as adjusted under subsection (c), if applicable,*
 22 *or as otherwise affected under paragraph (2) of this*
 23 *subsection.*

24 “(j) *COLLECTION OF UNPAID FEES.*—*In any case*
 25 *where the Secretary does not receive payment of a fee as-*

1 sessed under subsection (a) within 30 calendar days after
 2 it is due, such fee shall be treated as a claim of the United
 3 States Government subject to subchapter II of chapter 37
 4 of title 31, United States Code.

5 “(k) *CONSTRUCTION.*—This section may not be con-
 6 strued to require that the number of full-time equivalent
 7 positions in the Department of Health and Human Serv-
 8 ices, for officers, employees, and advisory committees not
 9 engaged in human generic drug activities, be reduced to off-
 10 set the number of officers, employees, and advisory commit-
 11 tees so engaged.

12 “(l) *POSITRON EMISSION TOMOGRAPHY DRUGS.*—

13 “(1) *EXEMPTION FROM FEES.*—Submission of an
 14 application for a positron emission tomography drug
 15 or active pharmaceutical ingredient for a positron
 16 emission tomography drug shall not require the pay-
 17 ment of any fee under this section. Facilities that
 18 solely produce positron emission tomography drugs
 19 shall not be required to pay a facility fee as estab-
 20 lished in subsection (a)(4).

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

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

6 “(n) *SUBSTANTIALLY COMPLETE APPLICATIONS.*—An
 7 abbreviated new drug application that is not considered to
 8 be received within the meaning of section 505(j)(5)(A) be-
 9 cause of failure to pay an applicable fee under this provi-
 10 sion within the time period specified in subsection (g) shall
 11 be deemed not to have been ‘substantially complete’ on the
 12 date of its submission within the meaning of section
 13 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug applica-
 14 tion that is not substantially complete on the date of its
 15 submission solely because of failure to pay an applicable
 16 fee under the preceding sentence shall be deemed substan-
 17 tially complete and received within the meaning of section
 18 505(j)(5)(A) as of the date such applicable fee is received.”.

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

20 Part 7 of subchapter C of chapter VII, as added by
 21 section 302 of this Act, is amended by inserting after section
 22 744B the following:

1 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**
2 **MENTS.**

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

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

25 “(c) *PUBLIC AVAILABILITY.*—The Secretary shall make
26 the reports required under subsections (a) and (b) available

1 *to the public on the Internet Web site of the Food and Drug*
 2 *Administration.*

3 “(d) *REAUTHORIZATION.*—

4 “(1) *CONSULTATION.*—*In developing rec-*
 5 *ommendations to present to the Congress with respect*
 6 *to the goals, and plans for meeting the goals, for*
 7 *human generic drug activities for the first 5 fiscal*
 8 *years after fiscal year 2017, and for the reauthoriza-*
 9 *tion of this part for such fiscal years, the Secretary*
 10 *shall consult with—*

11 “(A) *the Committee on Energy and Com-*
 12 *merce of the House of Representatives;*

13 “(B) *the Committee on Health, Education,*
 14 *Labor, and Pensions of the Senate;*

15 “(C) *scientific and academic experts;*

16 “(D) *health care professionals;*

17 “(E) *representatives of patient and con-*
 18 *sumer advocacy groups; and*

19 “(F) *the generic drug industry.*

20 “(2) *PRIOR PUBLIC INPUT.*—*Prior to beginning*
 21 *negotiations with the generic drug industry on the re-*
 22 *authorization of this part, the Secretary shall—*

23 “(A) *publish a notice in the Federal Reg-*
 24 *ister requesting public input on the reauthoriza-*
 25 *tion;*

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

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

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

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

18 “(4) *PUBLIC REVIEW OF RECOMMENDATIONS.*—
19 After negotiations with the generic drug industry, the
20 Secretary shall—

21 “(A) present the recommendations developed
22 under paragraph (1) to the congressional com-
23 mittees specified in such paragraph;

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

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

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

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

10 “(5) TRANSMITTAL OF RECOMMENDATIONS.—Not
11 later than January 15, 2017, the Secretary shall
12 transmit to the Congress the revised recommendations
13 under paragraph (4), a summary of the views and
14 comments received under such paragraph, and any
15 changes made to the recommendations in response to
16 such views and comments.

17 “(6) MINUTES OF NEGOTIATION MEETINGS.—

18 “(A) PUBLIC AVAILABILITY.—Before pre-
19 senting the recommendations developed under
20 paragraphs (1) through (5) to the Congress, the
21 Secretary shall make publicly available, on the
22 Internet Web site of the Food and Drug Admin-
23 istration, minutes of all negotiation meetings
24 conducted under this subsection between the Food

1 *and Drug Administration and the generic drug*
 2 *industry.*

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

9 **SEC. 304. SUNSET DATES.**

10 (a) *AUTHORIZATION.*—*Sections 744A and 744B of the*
 11 *Federal Food, Drug, and Cosmetic Act, as added by section*
 12 *302 of this Act, shall cease to be effective October 1, 2017.*

13 (b) *REPORTING REQUIREMENTS.*—*Section 744C of the*
 14 *Federal Food, Drug, and Cosmetic Act, as added by section*
 15 *303 of this Act, shall cease to be effective January 31, 2018.*

16 **SEC. 305. EFFECTIVE DATE.**

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

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

2 *Section 502 (21 U.S.C. 352) is amended by adding*
 3 *at the end the following:*

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

12 **SEC. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT**
 13 **ACTIVITIES RELATED TO HUMAN GENERIC**
 14 **DRUGS.**

15 *Section 714, as added by section 208 of this Act, is*
 16 *amended—*

17 *(1) by amending subsection (b) to read as fol-*
 18 *lows:*

19 *“(b) ACTIVITIES DESCRIBED.—The activities described*
 20 *in this subsection are—*

21 *“(1) activities under this Act related to the proc-*
 22 *ess for the review of device applications (as defined in*
 23 *section 737(8)); and*

24 *“(2) activities under this Act related to human*
 25 *generic drug activities (as defined in section 744A).”;*
 26 *and*

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

3 “(c) *OBJECTIVES SPECIFIED.—The objectives specified*
 4 *in this subsection are—*

5 “(1) *with respect to the activities under sub-*
 6 *section (b)(1), the goals referred to in section*
 7 *738A(a)(1); and*

8 “(2) *with respect to the activities under sub-*
 9 *section (b)(2), the goals referred to in section*
 10 *744C(a).”.*

11 **SEC. 308. ADDITIONAL REPORTING REQUIREMENTS.**

12 *Subchapter A of chapter VII (21 U.S.C. 371 et seq.),*
 13 *as amended by section 208, is further amended by adding*
 14 *at the end the following:*

15 **“SEC. 715. REPORTING REQUIREMENTS.**

16 “(a) *GENERIC DRUGS.—Beginning with fiscal year*
 17 *2013 and ending after fiscal year 2017, not later than 120*
 18 *days after the end of each fiscal year for which fees are*
 19 *collected under part 7 of subchapter C, the Secretary shall*
 20 *prepare and submit to the Committee on Health, Edu-*
 21 *cation, Labor, and Pensions of the Senate and the Com-*
 22 *mittee on Energy and Commerce of the House of Represent-*
 23 *atives a report concerning, for all applications for approval*
 24 *of a generic drug under section 505(j), amendments to such*

1 applications, and prior approval supplements with respect
2 to such applications filed in the previous fiscal year—

3 “(1) the number of such applications that met
4 the goals identified for purposes of part 7 of sub-
5 chapter C, in the letters from the Secretary of Health
6 and Human Services to the Chairman of the Com-
7 mittee on Health, Education, Labor, and Pensions of
8 the Senate and the Chairman of the Committee on
9 Energy and Commerce of the House of Representa-
10 tives, as set forth in the Congressional Record;

11 “(2) the average total time to decision by the
12 Secretary for applications for approval of a generic
13 drug under section 505(j), amendments to such appli-
14 cations, and prior approval supplements with respect
15 to such applications filed in the previous fiscal year,
16 including the number of calendar days spent during
17 the review by the Food and Drug Administration and
18 the number of calendar days spent by the sponsor re-
19 sponding to a complete response letter;

20 “(3) the total number of applications under sec-
21 tion 505(j), amendments to such applications, and
22 prior approval supplements with respect to such ap-
23 plications that were pending with the Secretary for
24 more than 10 months on the date of enactment of the

1 *Food and Drug Administration Safety and Innova-*
 2 *tion Act; and*

3 “(4) the number of applications described in
 4 paragraph (3) on which the Food and Drug Adminis-
 5 tration took final regulatory action in the previous
 6 fiscal year.”.

7 ***TITLE IV—FEES RELATING TO***
 8 ***BIOSIMILAR BIOLOGICAL***
 9 ***PRODUCTS***

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

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

13 (b) *FINDING.*—The Congress finds that the fees author-
 14 ized by the amendments made in this title will be dedicated
 15 to expediting the process for the review of biosimilar biologi-
 16 cal product applications, including postmarket safety ac-
 17 tivities, as set forth in the goals identified for purposes of
 18 part 8 of subchapter C of chapter VII of the Federal Food,
 19 Drug, and Cosmetic Act, in the letters from the Secretary
 20 of Health and Human Services to the Chairman of the
 21 Committee on Health, Education, Labor, and Pensions of
 22 the Senate and the Chairman of the Committee on Energy
 23 and Commerce of the House of Representatives, as set forth
 24 in the Congressional Record.

1 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
 2 **PRODUCTS.**

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

6 **“PART 8—FEES RELATING TO BIOSIMILAR**
 7 **BIOLOGICAL PRODUCTS**

8 **“SEC. 744G. DEFINITIONS.**

9 *“For purposes of this part:*

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

16 *“(2) The term ‘affiliate’ means a business entity*
 17 *that has a relationship with a second business entity*
 18 *if, directly or indirectly—*

19 *“(A) one business entity controls, or has the*
 20 *power to control, the other business entity; or*

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

23 *“(3) The term ‘biosimilar biological product’*
 24 *means a product for which a biosimilar biological*
 25 *product application has been approved.*

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

5 “(B) *Such term does not include—*

6 “(i) *a supplement to such an application;*

7 “(ii) *an application filed under section*
 8 *351(k) of the Public Health Service Act that cites*
 9 *as the reference product a bovine blood product*
 10 *for topical application licensed before September*
 11 *1, 1992, or a large volume parenteral drug prod-*
 12 *uct approved before such date;*

13 “(iii) *an application filed under section*
 14 *351(k) of the Public Health Service Act with re-*
 15 *spect to—*

16 “(I) *whole blood or a blood component*
 17 *for transfusion;*

18 “(II) *an allergenic extract product;*

19 “(III) *an in vitro diagnostic biological*
 20 *product; or*

21 “(IV) *a biological product for further*
 22 *manufacturing use only; or*

23 “(iv) *an application for licensure under sec-*
 24 *tion 351(k) of the Public Health Service Act that*
 25 *is submitted by a State or Federal Government*

1 *entity for a product that is not distributed com-*
2 *mercially.*

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

9 *“(6) The term ‘biosimilar biological product de-*
10 *velopment program’ means the program under this*
11 *part for expediting the process for the review of sub-*
12 *missions in connection with biosimilar biological*
13 *product development.*

14 *“(7)(A) The term ‘biosimilar biological product*
15 *establishment’ means a foreign or domestic place of*
16 *business—*

17 *“(i) that is at one general physical location*
18 *consisting of one or more buildings, all of which*
19 *are within 5 miles of each other; and*

20 *“(ii) at which one or more biosimilar bio-*
21 *logical products are manufactured in final dos-*
22 *age form.*

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

1 “(8) *The term ‘biosimilar initial advisory meet-*
2 *ing’—*

3 “(A) *means a meeting, if requested, that is*
4 *limited to—*

5 “(i) *a general discussion regarding*
6 *whether licensure under section 351(k) of*
7 *the Public Health Service Act may be fea-*
8 *sible for a particular product; and*

9 “(ii) *if so, general advice on the ex-*
10 *pected content of the development program;*
11 *and*

12 “(B) *does not include any meeting that in-*
13 *volves substantive review of summary data or*
14 *full study reports.*

15 “(9) *The term ‘costs of resources allocated for the*
16 *process for the review of biosimilar biological product*
17 *applications’ means the expenses in connection with*
18 *the process for the review of biosimilar biological*
19 *product applications for—*

20 “(A) *officers and employees of the Food and*
21 *Drug Administration, contractors of the Food*
22 *and Drug Administration, advisory committees,*
23 *and costs related to such officers employees and*
24 *committees and to contracts with such contrac-*
25 *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 equip-
7 ment, and other necessary materials and sup-
8 plies; and

9 “(D) collecting fees under section 744H and
10 accounting for resources allocated for the review
11 of submissions in connection with biosimilar bio-
12 logical product development, biosimilar biologi-
13 cal product applications, and supplements.

14 “(10) The term ‘final dosage form’ means, with
15 respect to a biosimilar biological product, a finished
16 dosage form which is approved for administration to
17 a patient without substantial further manufacturing
18 (such as lyophilized products before reconstitution).

19 “(11) The term ‘financial hold’—

20 “(A) means an order issued by the Sec-
21 retary to prohibit the sponsor of a clinical inves-
22 tigation from continuing the investigation if the
23 Secretary determines that the investigation is in-
24 tended to support a biosimilar biological product
25 application and the sponsor has failed to pay

1 *any fee for the product required under subpara-*
2 *graph (A), (B), or (D) of section 744H(a)(1);*
3 *and*

4 *“(B) does not mean that any of the bases*
5 *for a ‘clinical hold’ under section 505(i)(3) have*
6 *been determined by the Secretary to exist con-*
7 *cerning the investigation.*

8 *“(12) The term ‘person’ includes an affiliate of*
9 *such person.*

10 *“(13) The term ‘process for the review of bio-*
11 *similar biological product applications’ means the fol-*
12 *lowing activities of the Secretary with respect to the*
13 *review of submissions in connection with biosimilar*
14 *biological product development, biosimilar biological*
15 *product applications, and supplements:*

16 *“(A) The activities necessary for the review*
17 *of submissions in connection with biosimilar bio-*
18 *logical product development, biosimilar biologi-*
19 *cal product applications, and supplements.*

20 *“(B) Actions related to submissions in con-*
21 *nection with biosimilar biological product devel-*
22 *opment, the issuance of action letters which ap-*
23 *prove biosimilar biological product applications*
24 *or which set forth in detail the specific defi-*
25 *ciencies in such applications, and where appro-*

1 *priate, the actions necessary to place such appli-*
2 *cations in condition for approval.*

3 *“(C) The inspection of biosimilar biological*
4 *product establishments and other facilities un-*
5 *dertaken as part of the Secretary’s review of*
6 *pending biosimilar biological product applica-*
7 *tions and supplements.*

8 *“(D) Activities necessary for the release of*
9 *lots of biosimilar biological products under sec-*
10 *tion 351(k) of the Public Health Service Act.*

11 *“(E) Monitoring of research conducted in*
12 *connection with the review of biosimilar biologi-*
13 *cal product applications.*

14 *“(F) Postmarket safety activities with re-*
15 *spect to biologics approved under biosimilar bio-*
16 *logical product applications or supplements, in-*
17 *cluding the following activities:*

18 *“(i) Collecting, developing, and review-*
19 *ing safety information on biosimilar bio-*
20 *logical products, including adverse-event re-*
21 *ports.*

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

1 “(iii) *Developing and using improved*
 2 *analytical tools to assess potential safety*
 3 *problems, including access to external data*
 4 *bases.*

5 “(iv) *Implementing and enforcing sec-*
 6 *tion 505(o) (relating to postapproval studies*
 7 *and clinical trials and labeling changes)*
 8 *and section 505(p) (relating to risk evalua-*
 9 *tion and mitigation strategies).*

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

13 “(14) *The term ‘supplement’ means a request to*
 14 *the Secretary to approve a change in a biosimilar bi-*
 15 *ological product application which has been approved,*
 16 *including a supplement requesting that the Secretary*
 17 *determine that the biosimilar biological product meets*
 18 *the standards for interchangeability described in sec-*
 19 *tion 351(k)(4) of the Public Health Service Act.*

20 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
 21 **BIOLOGICAL PRODUCT FEES.**

22 “(a) *TYPES OF FEES.—Beginning in fiscal year 2013,*
 23 *the Secretary shall assess and collect fees in accordance with*
 24 *this section as follows:*

1 “(1) *BIOSIMILAR DEVELOPMENT PROGRAM*
2 *FEES.*—

3 “(A) *INITIAL BIOSIMILAR BIOLOGICAL*
4 *PRODUCT DEVELOPMENT FEE.*—

5 “(i) *IN GENERAL.*—*Each person that*
6 *submits to the Secretary a meeting request*
7 *described under clause (ii) or a clinical pro-*
8 *TOCOL for an investigational new drug pro-*
9 *TOCOL described under clause (iii) shall pay*
10 *for the product named in the meeting re-*
11 *quest or the investigational new drug appli-*
12 *cation the initial biosimilar biological prod-*
13 *uct development fee established under sub-*
14 *section (b)(1)(A).*

15 “(ii) *MEETING REQUEST.*—*The meet-*
16 *ing request described in this clause is a re-*
17 *quest for a biosimilar biological product de-*
18 *velopment meeting for a product.*

19 “(iii) *CLINICAL PROTOCOL FOR IND.*—
20 *A clinical protocol for an investigational*
21 *new drug protocol described in this clause is*
22 *a clinical protocol consistent with the provi-*
23 *sions of section 505(i), including any regu-*
24 *lations promulgated under section 505(i),*
25 *(referred to in this section as ‘investiga-*

1 *tional new drug application’)* describing an
2 *investigation that the Secretary determines*
3 *is intended to support a biosimilar biologi-*
4 *cal product application for a product.*

5 “(iv) *DUE DATE.*—*The initial bio-*
6 *similar biological product development fee*
7 *shall be due by the earlier of the following:*

8 “(I) *Not later than 5 days after*
9 *the Secretary grants a request for a*
10 *biosimilar biological product develop-*
11 *ment meeting.*

12 “(II) *The date of submission of an*
13 *investigational new drug application*
14 *describing an investigation that the*
15 *Secretary determines is intended to*
16 *support a biosimilar biological product*
17 *application.*

18 “(v) *TRANSITION RULE.*—*Each person*
19 *that has submitted an investigational new*
20 *drug application prior to the date of enact-*
21 *ment of the Biosimilars User Fee Act of*
22 *2012 shall pay the initial biosimilar bio-*
23 *logical product development fee by the ear-*
24 *lier of the following:*

1 “(I) Not later than 60 days after
 2 the date of the enactment of the
 3 Biosimilars User Fee Act of 2012, if
 4 the Secretary determines that the in-
 5 vestigational new drug application de-
 6 scribes an investigation that is in-
 7 tended to support a biosimilar biologi-
 8 cal product application.

9 “(II) Not later than 5 days after
 10 the Secretary grants a request for a
 11 biosimilar biological product develop-
 12 ment meeting.

13 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
 14 PRODUCT DEVELOPMENT FEE.—

15 “(i) IN GENERAL.—A person that pays
 16 an initial biosimilar biological product de-
 17 velopment fee for a product shall pay for
 18 such product, beginning in the fiscal year
 19 following the fiscal year in which the initial
 20 biosimilar biological product development
 21 fee was paid, an annual fee established
 22 under subsection (b)(1)(B) for biosimilar bi-
 23 ological product development (referred to in
 24 this section as ‘annual biosimilar biological
 25 product development fee’).

1 “(ii) *DUE DATE.*—*The annual bio-*
 2 *similar biological product development pro-*
 3 *gram fee for each fiscal year will be due on*
 4 *the later of—*

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

7 “(II) *the first business day after*
 8 *the enactment of an appropriations*
 9 *Act providing for the collection and ob-*
 10 *ligation of fees for such year under this*
 11 *section.*

12 “(iii) *EXCEPTION.*—*The annual bio-*
 13 *similar development program fee for each*
 14 *fiscal year will be due on the date specified*
 15 *in clause (ii), unless the person has—*

16 “(I) *submitted a marketing appli-*
 17 *cation for the biological product that*
 18 *was accepted for filing; or*

19 “(II) *discontinued participation*
 20 *in the biosimilar biological product de-*
 21 *velopment program for the product*
 22 *under subparagraph (C).*

23 “(C) *DISCONTINUATION OF FEE OBLIGA-*
 24 *TION.*—*A person may discontinue participation*
 25 *in the biosimilar biological product development*

1 *program for a product effective October 1 of a*
2 *fiscal year by, not later than August 1 of the*
3 *preceding fiscal year—*

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

11 *“(ii) if an investigational new drug*
12 *application concerning the product has been*
13 *submitted, withdrawing the investigational*
14 *new drug application in accordance with*
15 *part 312 of title 21, Code of Federal Regu-*
16 *lations (or any successor regulations).*

17 *“(D) REACTIVATION FEE.—*

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

1 “(I) Not later than 5 days after
 2 the Secretary grants a request for a
 3 biosimilar biological product develop-
 4 ment meeting for the product (after the
 5 date on which such participation was
 6 discontinued).

7 “(II) Upon the date of submission
 8 (after the date on which such partici-
 9 pation was discontinued) of an inves-
 10 tigational new drug application de-
 11 scribing an investigation that the Sec-
 12 retary determines is intended to sup-
 13 port a biosimilar biological product
 14 application for that product.

15 “(ii) APPLICATION OF ANNUAL FEE.—
 16 A person that pays a reactivation fee for a
 17 product shall pay for such product, begin-
 18 ning in the next fiscal year, the annual bio-
 19 similar biological product development fee
 20 under subparagraph (B).

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

23 “(i) NO BIOSIMILAR BIOLOGICAL PROD-
 24 UCT DEVELOPMENT MEETINGS.—If a person
 25 has failed to pay an initial or annual bio-

1 *similar biological product development fee*
 2 *as required under subparagraph (A) or (B),*
 3 *or a reactivation fee as required under sub-*
 4 *paragraph (D), the Secretary shall not pro-*
 5 *vide a biosimilar biological product develop-*
 6 *ment meeting relating to the product for*
 7 *which fees are owed.*

8 “(ii) *NO RECEIPT OF INVESTIGATIONAL*
 9 *NEW DRUG APPLICATIONS.—Except in ex-*
 10 *traordinary circumstances, the Secretary*
 11 *shall not consider an investigational new*
 12 *drug application to have been received*
 13 *under section 505(i)(2) if—*

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

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

24 “(iii) *FINANCIAL HOLD.—Notwith-*
 25 *standing section 505(i)(2), except in ex-*

1 *traordinary circumstances, the Secretary*
2 *shall prohibit the sponsor of a clinical in-*
3 *vestigation from continuing the investiga-*
4 *tion if—*

5 *“(I) the Secretary determines that*
6 *the investigation is intended to support*
7 *a biosimilar biological product appli-*
8 *cation; and*

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

16 *“(iv) NO ACCEPTANCE OF BIOSIMILAR*
17 *BIOLOGICAL PRODUCT APPLICATIONS OR*
18 *SUPPLEMENTS.—If a person has failed to*
19 *pay an initial or annual biosimilar biologi-*
20 *cal product development fee as required*
21 *under subparagraph (A) or (B), or a reac-*
22 *tivation fee as required under subparagraph*
23 *(D), any biosimilar biological product ap-*
24 *plication or supplement submitted by that*
25 *person shall be considered incomplete and*

1 *shall not be accepted for filing by the Sec-*
 2 *retary until all such fees owed by such per-*
 3 *son have been paid.*

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

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

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

20 “(2) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*
 21 *TION AND SUPPLEMENT FEE.—*

22 “(A) *IN GENERAL.—Each person that sub-*
 23 *mits, on or after October 1, 2012, a biosimilar*
 24 *biological product application or a supplement*
 25 *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 a*
5 *biosimilar biological product applica-*
6 *tion for which clinical data (other than*
7 *comparative bioavailability studies)*
8 *with respect to safety or effectiveness*
9 *are required for approval; minus*

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

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

20 “(I) *half of the amount of the fee*
21 *established under subsection (b)(1)(D)*
22 *for a biosimilar biological product ap-*
23 *plication; minus*

24 “(II) *the cumulative amount of*
25 *fees paid, if any, under subparagraphs*

1 (A), (B), and (D) of paragraph (1) for
2 that product.

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

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

23 “(C) PAYMENT DUE DATE.—Any fee re-
24 quired by subparagraph (A) shall be due upon

1 *submission of the application or supplement for*
2 *which such fee applies.*

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

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

22 “(F) *FEEES FOR APPLICATIONS PREVIOUSLY*
23 *REFUSED FOR FILING OR WITHDRAWN BEFORE*
24 *FILING.—A biosimilar biological product appli-*
25 *cation or supplement that was submitted but was*

1 *refused for filing, or was withdrawn before being*
 2 *accepted or refused for filing, shall be subject to*
 3 *the full fee under subparagraph (A) upon being*
 4 *resubmitted or filed over protest, unless the fee is*
 5 *waived under subsection (c).*

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

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

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

1 *similar biological product during such fiscal*
2 *year.*

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

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

7 “(ii) *the first business day after the en-*
8 *actment of an appropriations Act providing*
9 *for the collection and obligation of fees for*
10 *such fiscal year under this section.*

11 “(D) *APPLICATION TO ESTABLISHMENT.*—

12 “(i) *Each biosimilar biological product*
13 *establishment shall be assessed only one fee*
14 *per biosimilar biological product establish-*
15 *ment, notwithstanding the number of bio-*
16 *similar biological products manufactured at*
17 *the establishment, subject to clause (ii).*

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

1 *similar biological product fees under para-*
 2 *graph (4).*

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

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 the*
 18 *biosimilar biological product establishment fee*
 19 *for the fiscal year in which the manufacture of*
 20 *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 biological*
 4 *product fee for a fiscal year shall be due on the*
 5 *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 en-*
 9 *actment of an appropriations Act providing*
 10 *for the collection and obligation of fees for*
 11 *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), the*
 18 *Secretary shall, 60 days before the start of each fiscal*
 19 *year that begins after September 30, 2012, establish,*
 20 *for the next fiscal year, the fees under subsection (a).*
 21 *Except as provided in subsection (c), such fees shall*
 22 *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)(4) for a human drug appli-
 4 cation described in section 736(a)(1)(A)(i) for
 5 that fiscal year.

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

14 “(C) REACTIVATION FEE.—The reactivation
 15 fee under subsection (a)(1)(D) for a fiscal year
 16 shall be equal to 20 percent of the amount of the
 17 fee established under section 736(c)(4) for a
 18 human drug application described in section
 19 736(a)(1)(A)(i) for that fiscal year.

20 “(D) BIOSIMILAR BIOLOGICAL PRODUCT AP-
 21 PPLICATION FEE.—The biosimilar biological prod-
 22 uct application fee under subsection (a)(2) for a
 23 fiscal year shall be equal to the amount estab-
 24 lished under section 736(c)(4) for a human drug

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

3 “(E) *BIOSIMILAR BIOLOGICAL PRODUCT ES-*
 4 *TABLISHMENT FEE.*—*The biosimilar biological*
 5 *product establishment fee under subsection (a)(3)*
 6 *for a fiscal year shall be equal to the amount es-*
 7 *tablished under section 736(c)(4) for a prescrip-*
 8 *tion drug establishment for that fiscal year.*

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

15 “(2) *LIMIT.*—*The total amount of fees charged*
 16 *for a fiscal year under this section may not exceed the*
 17 *total amount for such fiscal year of the costs of re-*
 18 *sources allocated for the process for the review of bio-*
 19 *similar biological product applications.*

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

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

1 *section (a)(2)(A) for the first biosimilar biological*
 2 *product application that a small business or its affil-*
 3 *iate submits to the Secretary for review. After a small*
 4 *business or its affiliate is granted such a waiver, the*
 5 *small business or its affiliate shall pay—*

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

10 *“(B) all supplement fees for all supplements*
 11 *to biosimilar biological product applications sub-*
 12 *mitted to the Secretary for review in the same*
 13 *manner as an entity that is not a small busi-*
 14 *ness.*

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

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

1 *logical product application (as defined in section*
 2 *744G(4)) and introduced or delivered for introduction*
 3 *into interstate commerce.*

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

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

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

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

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

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

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

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

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

12 “(3) *AUTHORIZATION OF APPROPRIATIONS.—For*
 13 *each of fiscal years 2013 through 2017, there is au-*
 14 *thorized to be appropriated for fees under this section*
 15 *an amount equivalent to the total amount of fees as-*
 16 *essed for such fiscal year under this section.*

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

23 “(g) *WRITTEN REQUESTS FOR WAIVERS AND RE-*
 24 *FUNDS.—To qualify for consideration for a waiver under*
 25 *subsection (c), or for a refund of any fee collected in accord-*

1 *ance with subsection (a)(2)(A), a person shall submit to the*
 2 *Secretary a written request for such waiver or refund not*
 3 *later than 180 days after such fee is due.*

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

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

12 *Part 8 of subchapter C of chapter VII, as added by*
 13 *section 402, is further amended by inserting after section*
 14 *744H the following:*

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

17 “(a) *PERFORMANCE REPORT.*—*Beginning with fiscal*
 18 *year 2013, not later than 120 days after the end of each*
 19 *fiscal year for which fees are collected under this part, the*
 20 *Secretary shall prepare and submit to the Committee on*
 21 *Energy and Commerce of the House of Representatives and*
 22 *the Committee on Health, Education, Labor, and Pensions*
 23 *of the Senate a report concerning the progress of the Food*
 24 *and Drug Administration in achieving the goals identified*
 25 *in the letters described in section 401(b) of the Biosimilar*

1 *User Fee Act of 2012 during such fiscal year and the future*
 2 *plans of the Food and Drug Administration for meeting*
 3 *such goals. The report for a fiscal year shall include infor-*
 4 *mation on all previous cohorts for which the Secretary has*
 5 *not given a complete response on all biosimilar biological*
 6 *product applications and supplements in the cohort.*

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

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

21 “(d) *STUDY.*—

22 “(1) *IN GENERAL.*—The Secretary shall contract
 23 *with an independent accounting or consulting firm to*
 24 *study the workload volume and full costs associated*

1 *with the process for the review of biosimilar biological*
 2 *product applications.*

3 “(2) *INTERIM RESULTS.*—*Not later than June 1,*
 4 *2015, the Secretary shall publish, for public comment,*
 5 *interim results of the study described under para-*
 6 *graph (1).*

7 “(3) *FINAL RESULTS.*—*Not later than September*
 8 *30, 2016, the Secretary shall publish, for public com-*
 9 *ment, the final results of the study described under*
 10 *paragraph (1).*

11 “(e) *REAUTHORIZATION.*—

12 “(1) *CONSULTATION.*—*In developing rec-*
 13 *ommendations to present to the Congress with respect*
 14 *to the goals described in subsection (a), and plans for*
 15 *meeting the goals, for the process for the review of bio-*
 16 *similar biological product applications for the first 5*
 17 *fiscal years after fiscal year 2017, and for the reau-*
 18 *thorization of this part for such fiscal years, the Sec-*
 19 *retary shall consult with—*

20 “(A) *the Committee on Energy and Com-*
 21 *merce of the House of Representatives;*

22 “(B) *the Committee on Health, Education,*
 23 *Labor, and Pensions of the Senate;*

24 “(C) *scientific and academic experts;*

25 “(D) *health care professionals;*

1 “(E) representatives of patient and con-
2 sumer advocacy groups; and

3 “(F) the regulated industry.

4 “(2) *PUBLIC REVIEW OF RECOMMENDATIONS.*—
5 *After negotiations with the regulated industry, the*
6 *Secretary shall—*

7 “(A) present the recommendations developed
8 under paragraph (1) to the congressional com-
9 mittees specified in such paragraph;

10 “(B) publish such recommendations in the
11 *Federal Register*;

12 “(C) provide for a period of 30 days for the
13 public to provide written comments on such rec-
14 ommendations;

15 “(D) hold a meeting at which the public
16 may present its views on such recommendations;
17 and

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

21 “(3) *TRANSMITTAL OF RECOMMENDATIONS.*—*Not*
22 *later than January 15, 2017, the Secretary shall*
23 *transmit to the Congress the revised recommendations*
24 *under paragraph (2), a summary of the views and*
25 *comments received under such paragraph, and any*

1 *changes made to the recommendations in response to*
 2 *such views and comments.”.*

3 **SEC. 404. SUNSET DATES.**

4 (a) *AUTHORIZATION.*—Sections 744G and 744H of the
 5 *Federal Food, Drug, and Cosmetic Act, as added by section*
 6 *402 of this Act, shall cease to be effective October 1, 2017.*

7 (b) *REPORTING REQUIREMENTS.*—Section 744I of the
 8 *Federal Food, Drug, and Cosmetic Act, as added by section*
 9 *403 of this Act, shall cease to be effective January 31, 2018.*

10 **SEC. 405. EFFECTIVE DATE.**

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

14 (1) *October 1, 2012; or*

15 (2) *the date of the enactment of this title.*

16 (b) *EXCEPTION.*—Fees under part 8 of subchapter C
 17 *of chapter VII of the Federal Food, Drug, and Cosmetic Act,*
 18 *as added by this title, shall be assessed for all biosimilar*
 19 *biological product applications received on or after October*
 20 *1, 2012, regardless of the date of the enactment of this title.*

21 **SEC. 406. SAVINGS CLAUSE.**

22 *Notwithstanding the amendments made by this title,*
 23 *part 2 of subchapter C of chapter VII of the Federal Food,*
 24 *Drug, and Cosmetic Act, as in effect on the day before the*
 25 *date of the enactment of this title, shall continue to be in*

1 *effect with respect to human drug applications and supple-*
 2 *ments (as defined in such part as of such day) that were*
 3 *accepted by the Food and Drug Administration for filing*
 4 *on or after October 1, 2007, but before October 1, 2012, with*
 5 *respect to assessing and collecting any fee required by such*
 6 *part for a fiscal year prior to fiscal year 2013.*

7 **SEC. 407. CONFORMING AMENDMENT.**

8 *Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amended*
 9 *by striking “or (k)”.*

10 **SEC. 408. ADDITIONAL REPORTING REQUIREMENTS.**

11 *Section 715, as added by section 308 of this Act, is*
 12 *amended by adding at the end the following:*

13 *“(b) BIOSIMILAR BIOLOGICAL PRODUCTS.—*

14 *“(1) IN GENERAL.—Beginning with fiscal year*
 15 *2014, not later than 120 days after the end of each*
 16 *fiscal year for which fees are collected under part 8*
 17 *of subchapter C, the Secretary shall prepare and sub-*
 18 *mit to the Committee on Health, Education, Labor,*
 19 *and Pensions of the Senate and the Committee on*
 20 *Energy and Commerce of the House of Representa-*
 21 *tives a report concerning—*

22 *“(A) the number of applications for ap-*
 23 *proval filed under section 351(k) of the Public*
 24 *Health Service Act; and*

1 “(B) the percentage of applications de-
 2 scribed in subparagraph (A) that were approved
 3 by the Secretary.

4 “(2) *ADDITIONAL INFORMATION*.—As part of the
 5 performance report described in paragraph (1), the
 6 Secretary shall include an explanation of how the
 7 Food and Drug Administration is managing the bio-
 8 logical product review program to ensure that the
 9 user fees collected under part 2 are not used to review
 10 an application under section 351(k) of the Public
 11 Health Service Act.”.

12 ***TITLE V—PEDIATRIC DRUGS*** 13 ***AND DEVICES***

14 ***SEC. 501. PERMANENCE.***

15 (a) *PEDIATRIC STUDIES OF DRUGS*.—Section 505A
 16 (21 U.S.C. 355a) is amended by striking subsection (q) (re-
 17 lating to a sunset).

18 (b) *RESEARCH INTO PEDIATRIC USES FOR DRUGS*
 19 *AND BIOLOGICAL PRODUCTS*.—Section 505B (21 U.S.C.
 20 355c) is amended—

21 (1) by striking subsection (m); and

22 (2) by redesignating subsection (n) as subsection
 23 (m).

24 ***SEC. 502. WRITTEN REQUESTS.***

25 (a) *IN GENERAL*.—

1 (1) *FEDERAL FOOD, DRUG, AND COSMETIC*
 2 *ACT.—Subsection (h) of section 505A (21 U.S.C.*
 3 *355a) is amended to read as follows:*

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

11 (2) *PUBLIC HEALTH SERVICE ACT.—Section*
 12 *351(m)(1) of the Public Health Service Act (42*
 13 *U.S.C. 262(m)(1)) is amended by striking “(f), (i),*
 14 *(j), (k), (l), (p), and (q)” and inserting “(f), (h), (i),*
 15 *(j), (k), (l), (n), and (p)”.*

16 (b) *NEONATES.—Subparagraph (A) of section*
 17 *505A(d)(1) is amended by adding at the end the following:*
 18 *“If a request under this subparagraph does not request stud-*
 19 *ies in neonates, such request shall include a statement de-*
 20 *scribing the rationale for not requesting studies in neo-*
 21 *nates.”.*

22 **SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COM-**
 23 **MITTEE.**

24 *Not later than 1 year after the date of enactment of*
 25 *this Act, the Secretary of Health and Human Services (re-*

1 *ferred to in this title as the “Secretary”) shall issue internal*
 2 *standard operating procedures that provide for the review*
 3 *by the internal review committee established under section*
 4 *505C of the Federal Food, Drug, and Cosmetic Act (21*
 5 *U.S.C. 355d) of any significant modifications to initial pe-*
 6 *diatric study plans, agreed initial pediatric study plans,*
 7 *and written requests under sections 505A and 505B of the*
 8 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a,*
 9 *355c). Such internal standard operating procedures shall*
 10 *be made publicly available on the Internet Web site of the*
 11 *Food and Drug Administration.*

12 **SEC. 504. ACCESS TO DATA.**

13 *Not later than 3 years after the date of enactment of*
 14 *this Act, the Secretary shall make available to the public,*
 15 *including through posting on the Internet Web site of the*
 16 *Food and Drug Administration, the medical, statistical,*
 17 *and clinical pharmacology reviews of, and corresponding*
 18 *written requests issued to an applicant, sponsor, or holder*
 19 *for, pediatric studies submitted between January 4, 2002,*
 20 *and September 27, 2007, under subsection (b) or (c) of sec-*
 21 *tion 505A of the Federal Food, Drug, and Cosmetic Act (21*
 22 *U.S.C. 355a) for which 6 months of market exclusivity was*
 23 *granted and that resulted in a labeling change. The Sec-*
 24 *retary shall make public the information described in the*
 25 *preceding sentence in a manner consistent with how the*

1 *Secretary releases information under section 505A(k) of the*
 2 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(k)).*

3 **SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC**
 4 **STUDIES.**

5 *(a) EXTENSION OF DEADLINE FOR DEFERRED STUD-*
 6 *IES.—Section 505B (21 U.S.C. 355c) is amended—*

7 *(1) in subsection (a)(3)—*

8 *(A) by redesignating subparagraph (B) as*
 9 *subparagraph (C);*

10 *(B) by inserting after subparagraph (A) the*
 11 *following:*

12 *“(B) DEFERRAL EXTENSION.—*

13 *“(i) IN GENERAL.—On the initiative of*
 14 *the Secretary or at the request of the appli-*
 15 *cant, the Secretary may grant an extension*
 16 *of a deferral approved under subparagraph*
 17 *(A) for submission of some or all assess-*
 18 *ments required under paragraph (1) if—*

19 *“(I) the Secretary determines that*
 20 *the conditions described in subclause*
 21 *(II) or (III) of subparagraph (A)(i)*
 22 *continue to be met; and*

23 *“(II) the applicant submits a new*
 24 *timeline under subparagraph*
 25 *(A)(ii)(IV) and any significant up-*

1 *dates to the information required*
2 *under subparagraph (A)(ii).*

3 “(ii) *TIMING AND INFORMATION.—If*
4 *the deferral extension under this subpara-*
5 *graph is requested by the applicant, the ap-*
6 *plicant shall submit the deferral extension*
7 *request containing the information de-*
8 *scribed in this subparagraph not less than*
9 *90 days prior to the date that the deferral*
10 *would expire. The Secretary shall respond*
11 *to such request not later than 45 days after*
12 *the receipt of such letter. If the Secretary*
13 *grants such an extension, the specified date*
14 *shall be the extended date. The sponsor of*
15 *the required assessment under paragraph*
16 *(1) shall not be issued a letter described in*
17 *subsection (d) unless the specified or ex-*
18 *tended date of submission for such required*
19 *studies has passed or if the request for an*
20 *extension is pending. For a deferral that*
21 *has expired prior to the date of enactment*
22 *of the Food and Drug Administration Safe-*
23 *ty and Innovation Act or that will expire*
24 *prior to 270 days after the date of enact-*
25 *ment of such Act, a deferral extension shall*

1 *be requested by an applicant not later than*
 2 *180 days after the date of enactment of such*
 3 *Act. The Secretary shall respond to any*
 4 *such request as soon as practicable, but not*
 5 *later than 1 year after the date of enact-*
 6 *ment of such Act. Nothing in this clause*
 7 *shall prevent the Secretary from updating*
 8 *the status of a study or studies publicly if*
 9 *components of such study or studies are late*
 10 *or delayed.”; and*

11 *(C) in subparagraph (C), as so redesign-*
 12 *ated—*

13 *(i) in clause (i), by adding at the end*
 14 *the following:*

15 *“(III) Projected completion date*
 16 *for pediatric studies.*

17 *“(IV) The reason or reasons why*
 18 *a deferral or deferral extension con-*
 19 *tinues to be necessary.”; and*

20 *(ii) by amending clause (ii) to read as*
 21 *follows:*

22 *“(ii) PUBLIC AVAILABILITY.—Not later*
 23 *than 90 days after the submission to the*
 24 *Secretary of the information submitted*
 25 *through the annual review under clause (i),*

1 *the Secretary shall make available to the*
 2 *public in an easily accessible manner, in-*
 3 *cluding through the Internet Web site of the*
 4 *Food and Drug Administration—*

5 *“(I) such information;*

6 *“(II) the name of the applicant*
 7 *for the product subject to the assess-*
 8 *ment;*

9 *“(III) the date on which the prod-*
 10 *uct was approved; and*

11 *“(IV) the date of each deferral or*
 12 *deferral extension under this para-*
 13 *graph for the product.”; and*

14 *(2) in subsection (f)—*

15 *(A) in the subsection heading, by inserting*
 16 *“DEFERRAL EXTENSIONS,” after “DEFERRALS,”;*

17 *(B) in paragraph (1), by inserting “, defer-*
 18 *ral extension,” after “deferral”; and*

19 *(C) in paragraph (4)—*

20 *(i) in the paragraph heading, by in-*
 21 *serting “DEFERRAL EXTENSIONS,” after*
 22 *“DEFERRALS,”; and*

23 *(ii) by inserting “, deferral exten-*
 24 *sions,” after “deferrals”.*

1 (b) *TRACKING OF EXTENSIONS; ANNUAL INFORMA-*
 2 *TION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D)) is*
 3 *amended to read as follows:*

4 “(D) aggregated on an annual basis—

5 “(i) the total number of deferrals and
 6 deferral extensions requested and granted
 7 under this section and, if granted, the rea-
 8 sons for each such deferral or deferral exten-
 9 sion;

10 “(ii) the timeline for completion of the
 11 assessments; and

12 “(iii) the number of assessments com-
 13 pleted and pending;”.

14 (c) *ACTION ON FAILURE TO COMPLETE STUDIES.—*

15 (1) *ISSUANCE OF LETTER.—Subsection (d) of*
 16 *section 505B (21 U.S.C. 355c) is amended to read as*
 17 *follows:*

18 “(d) *SUBMISSION OF ASSESSMENTS.—If a person fails*
 19 *to submit a required assessment described in subsection*
 20 *(a)(2), fails to meet the applicable requirements in sub-*
 21 *section (a)(3), or fails to submit a request for approval of*
 22 *a pediatric formulation described in subsection (a) or (b),*
 23 *in accordance with applicable provisions of subsections (a)*
 24 *and (b), the following shall apply:*

1 “(1) Beginning 270 days after the date of enact-
2 ment of the Food and Drug Administration Safety
3 and Innovation Act, the Secretary shall issue a non-
4 compliance letter to such person informing them of
5 such failure to submit or meet the requirements of the
6 applicable subsection. Such letter shall require the
7 person to respond in writing within 45 calendar days
8 of issuance of such letter. Such response may include
9 the person’s request for a deferral extension if appli-
10 cable. Such letter and the person’s written response to
11 such letter shall be made publicly available on the
12 Internet Web site of the Food and Drug Administra-
13 tion 60 calendar days after issuance, with redactions
14 for any trade secrets and confidential commercial in-
15 formation. If the Secretary determines that the letter
16 was issued in error, the requirements of this para-
17 graph shall not apply.

18 “(2) The drug or biological product that is the
19 subject of an assessment described in subsection
20 (a)(2), applicable requirements in subsection (a)(3),
21 or request for approval of a pediatric formulation,
22 may be considered misbranded solely because of that
23 failure and subject to relevant enforcement action (ex-
24 cept that the drug or biological product shall not be

1 *subject to action under section 303), but such failure*
 2 *shall not be the basis for a proceeding—*

3 “(A) to withdraw approval for a drug
 4 under section 505(e); or

5 “(B) to revoke the license for a biological
 6 product under section 351 of the Public Health
 7 Service Act.”.

8 (2) *TRACKING OF LETTERS ISSUED.*—Subpara-
 9 *graph (D) of section 505B(f)(6) (21 U.S.C.*
 10 *355c(f)(6)), as amended by subsection (b), is further*
 11 *amended—*

12 (A) in clause (ii), by striking “; and” and
 13 inserting a semicolon;

14 (B) in clause (iii), by adding “and” at the
 15 end; and

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

17 “(iv) the number of postmarket non-
 18 compliance letters issued pursuant to sub-
 19 section (d), and the recipients of such let-
 20 ters;”.

21 **SEC. 506. PEDIATRIC STUDY PLANS.**

22 (a) *IN GENERAL.*—Subsection (e) of section 505B (21
 23 *U.S.C. 355c) is amended to read as follows:*

24 “(e) *PEDIATRIC STUDY PLANS.*—

1 “(1) *IN GENERAL.*—An applicant subject to sub-
 2 section (a) shall submit to the Secretary an initial
 3 pediatric study plan prior to the submission of the
 4 assessments described under subsection (a)(2).

5 “(2) *TIMING; CONTENT; MEETING.*—

6 “(A) *TIMING.*—An applicant shall submit
 7 the initial pediatric plan under paragraph (1)—

8 “(i) before the date on which the appli-
 9 cant submits the assessments under sub-
 10 section (a)(2); and

11 “(ii) not later than—

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

17 “(II) such other time as may be
 18 agreed upon between the Secretary and
 19 the applicant.

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

24 “(B) *CONTENT OF INITIAL PLAN.*—The ini-
 25 tial pediatric study plan shall include—

1 “(i) *an outline of the pediatric study*
2 *or studies that the applicant plans to con-*
3 *duct (including, to the extent practicable*
4 *study objectives and design, age groups, rel-*
5 *evant endpoints, and statistical approach);*

6 “(ii) *any request for a deferral, partial*
7 *waiver, or waiver under this section, if ap-*
8 *plicable, along with any supporting infor-*
9 *mation; and*

10 “(iii) *other information specified in*
11 *the regulations promulgated under para-*
12 *graph (7).*

13 “(C) *MEETING.—The Secretary—*

14 “(i) *shall meet with the applicant to*
15 *discuss the initial pediatric study plan as*
16 *soon as practicable, but not later than 90*
17 *calendar days after the receipt of such plan*
18 *under subparagraph (A);*

19 “(ii) *may determine that a written re-*
20 *sponse to the initial pediatric study plan is*
21 *sufficient to communicate comments on the*
22 *initial pediatric study plan, and that no*
23 *meeting is necessary; and*

24 “(iii) *if the Secretary determines that*
25 *no meeting is necessary, shall so notify the*

1 *applicant and provide written comments of*
 2 *the Secretary as soon as practicable, but not*
 3 *later than 90 calendar days after the receipt*
 4 *of the initial pediatric study plan.*

5 “(3) *AGREED INITIAL PEDIATRIC STUDY PLAN.*—
 6 *Not later than 90 calendar days following the meeting*
 7 *under paragraph (2)(C)(i) or the receipt of a written*
 8 *response from the Secretary under paragraph*
 9 *(2)(C)(iii), the applicant shall document agreement*
 10 *on the initial pediatric study plan in a submission*
 11 *to the Secretary marked ‘Agreed Initial Pediatric*
 12 *Study Plan’, and the Secretary shall confirm such*
 13 *agreement to the applicant in writing not later than*
 14 *30 calendar days of receipt of such agreed initial pe-*
 15 *diatric study plan.*

16 “(4) *DEFERRAL AND WAIVER.*—*If the agreed ini-*
 17 *tial pediatric study plan contains a request from the*
 18 *applicant for a deferral, partial waiver, or waiver*
 19 *under this section, the written confirmation under*
 20 *paragraph (3) shall include a recommendation from*
 21 *the Secretary as to whether such request meets the*
 22 *standards under paragraphs (3) or (4) of subsection*
 23 *(a).*

24 “(5) *AMENDMENTS TO THE PLAN.*—*At the initia-*
 25 *tive of the Secretary or the applicant, the agreed ini-*

1 *tial pediatric study plan may be amended at any*
 2 *time. The requirements of paragraph (2)(C) shall*
 3 *apply to any such proposed amendment in the same*
 4 *manner and to the same extent as such requirements*
 5 *apply to an initial pediatric study plan under para-*
 6 *graph (1). The requirements of paragraphs (3) and*
 7 *(4) shall apply to any agreement resulting from such*
 8 *proposed amendment in the same manner and to the*
 9 *same extent as such requirements apply to an agreed*
 10 *initial pediatric study plan.*

11 “(6) *INTERNAL COMMITTEE.*—*The Secretary*
 12 *shall consult the internal committee under section*
 13 *505C on the review of the initial pediatric study*
 14 *plan, agreed initial pediatric plan, and any signifi-*
 15 *cant amendments to such plans.*

16 “(7) *REQUIRED RULEMAKING.*—*Not later than 1*
 17 *year after the date of enactment of the Food and Drug*
 18 *Administration Safety and Innovation Act, the Sec-*
 19 *retary shall promulgate proposed regulations and*
 20 *issue guidance to implement the provisions of this*
 21 *subsection.”.*

22 (b) *CONFORMING AMENDMENTS.*—*Section 505B (21*
 23 *U.S.C. 355c) is amended—*

24 (1) *by amending subclause (II) of subsection*
 25 (a)(3)(A)(ii) *to read as follows:*

1 “(II) a pediatric study plan as
2 described in subsection (e);” and

3 (2) in subsection (f)—

4 (A) in the subsection heading, by striking
5 “PEDIATRIC PLANS,” and inserting “PEDIATRIC
6 STUDY PLANS,”;

7 (B) in paragraph (1), by striking “all pedi-
8 atric plans” and inserting “initial pediatric
9 study plans, agreed initial pediatric study
10 plans,”; and

11 (C) in paragraph (4)—

12 (i) in the paragraph heading, by strik-
13 ing “PEDIATRIC PLANS,” and inserting
14 “PEDIATRIC STUDY PLANS,”; and

15 (ii) by striking “pediatric plans” and
16 inserting “initial pediatric study plans,
17 agreed initial pediatric study plans,”.

18 (c) *EFFECTIVE DATE.*—

19 (1) *IN GENERAL.*—Subject to paragraph (2), the
20 amendments made by this section shall take effect 180
21 calendar days after the date of enactment of this Act,
22 irrespective of whether the Secretary has promulgated
23 final regulations to carry out such amendments.

24 (2) *RULE OF CONSTRUCTION.*—Paragraph (1)
25 shall not be construed to affect the deadline for pro-

1 mulgation of proposed regulations under section
 2 505B(e)(7) of the Federal Food, Drug, and Cosmetic
 3 Act, as added by subsection (a) of this section.

4 **SEC. 507. REAUTHORIZATIONS.**

5 (a) *PEDIATRIC ADVISORY COMMITTEE*.—Section 14(d)
 6 of the *Best Pharmaceuticals for Children Act* (42 U.S.C.
 7 284m note) is amended by striking “during the five-year
 8 period beginning on the date of the enactment of the *Best*
 9 *Pharmaceuticals for Children Act of 2007*” and inserting
 10 “to carry out the advisory committee’s responsibilities
 11 under sections 505A, 505B, and 520(m) of the *Federal*
 12 *Food, Drug, and Cosmetic Act* (21 U.S.C. 355a, 355c, and
 13 360j(m))”.

14 (b) *PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC*
 15 *DRUGS ADVISORY COMMITTEE*.—Section 15(a)(3) of the
 16 *Best Pharmaceuticals for Children Act* (Public Law 107–
 17 109), as amended by section 502(e) of the *Food and Drug*
 18 *Administration Amendments Act of 2007* (Public Law 110–
 19 85), is amended by striking “during the five-year period
 20 beginning on the date of the enactment of the *Best Pharma-*
 21 *ceuticals for Children Act of 2007*” and inserting “for the
 22 duration of the operation of the *Oncologic Drugs Advisory*
 23 *Committee*”.

24 (c) *HUMANITARIAN DEVICE EXEMPTION EXTEN-*
 25 *SION*.—Section 520(m)(6)(A)(iv) of the *Federal Food, Drug,*

1 *and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended*
 2 *by striking “2012” and inserting “2017”.*

3 *(d) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN*
 4 *PHSA.—Section 409I(e)(1) of the Public Health Service*
 5 *Act (42 U.S.C. 284m(e)(1)) is amended by striking “to*
 6 *carry out this section” and all that follows through the end*
 7 *of paragraph (1) and inserting “to carry out this section,*
 8 *\$25,000,000 for each of fiscal years 2013 through 2017.”.*

9 **SEC. 508. REPORT.**

10 *(a) IN GENERAL.—Not later than four years after the*
 11 *date of enactment of this Act and every five years thereafter,*
 12 *the Secretary shall prepare and submit to the Committee*
 13 *on Health, Education, Labor, and Pensions of the Senate*
 14 *and the Committee on Energy and Commerce of the House*
 15 *of Representatives, and make publicly available, including*
 16 *through posting on the Internet Web site of the Food and*
 17 *Drug Administration, a report on the implementation of*
 18 *sections 505A and 505B of the Federal Food, Drug, and*
 19 *Cosmetic Act (21 U.S.C. 355a, 355c).*

20 *(b) CONTENTS.—Each report under subsection (a)*
 21 *shall include—*

22 *(1) an assessment of the effectiveness of sections*
 23 *505A and 505B of the Federal Food, Drug, and Cos-*
 24 *metic Act in improving information about pediatric*
 25 *uses for approved drugs and biological products, in-*

cluding the number and type of labeling changes made since the date of enactment of this Act and the importance of such uses in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section 505B, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted;

(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under subsection (d) of such section 505B;

(3) an assessment of the timeliness and effectiveness of pediatric study planning since the date of enactment of this Act, including the number of initial pediatric study plans not submitted in accordance with the requirements of subsection (e) of such section 505B and any resulting rulemaking;

(4) the number of written requests issued, accepted, and declined under such section 505A since the date of enactment of this Act, and a listing of any important gaps in pediatric information as a result of such declined requests;

1 (5) *a description and current status of referrals*
2 *made under subsection (n) of such section 505A;*

3 (6) *an assessment of the effectiveness of studying*
4 *biological products in pediatric populations under*
5 *such sections 505A and 505B and section 409I of the*
6 *Public Health Service Act (42 U.S.C. 284m);*

7 (7)(A) *the efforts made by the Secretary to in-*
8 *crease the number of studies conducted in the neo-*
9 *natal population (including efforts made to encourage*
10 *the conduct of appropriate studies in neonates by*
11 *companies with products that have sufficient safety*
12 *and other information to make the conduct of the*
13 *studies ethical and safe); and*

14 (B) *the results of such efforts;*

15 (8)(A) *the number and importance of drugs and*
16 *biological products for children with cancer that are*
17 *being tested as a result of the programs under such*
18 *sections 505A and 505B and under section 409I of the*
19 *Public Health Service Act; and*

20 (B) *any recommendations for modifications to*
21 *such programs that would lead to new and better*
22 *therapies for children with cancer, including a de-*
23 *tailed rationale for each recommendation;*

24 (9) *any recommendations for modification to*
25 *such programs that would improve pediatric drug re-*

1 *search and increase pediatric labeling of drugs and*
2 *biological products;*

3 *(10) an assessment of the successes of and limita-*
4 *tions to studying drugs for rare diseases under such*
5 *sections 505A and 505B; and*

6 *(11) an assessment of the Secretary's efforts to*
7 *address the suggestions and options described in any*
8 *prior report issued by the Comptroller General, Insti-*
9 *tute of Medicine, or the Secretary, and any subse-*
10 *quent reports, including recommendations therein, re-*
11 *garding the topics addressed in the reports under this*
12 *section, including with respect to—*

13 *(A) improving public access to information*
14 *from pediatric studies conducted under such sec-*
15 *tions 505A and 505B; and*

16 *(B) improving the timeliness of pediatric*
17 *studies and pediatric study planning under such*
18 *sections 505A and 505B.*

19 *(c) STAKEHOLDER COMMENT.—At least 180 days*
20 *prior to the submission of each report under subsection (a),*
21 *the Secretary shall consult with representatives of patient*
22 *groups (including pediatric patient groups), consumer*
23 *groups, regulated industry, academia, and other interested*
24 *parties to obtain any recommendations or information rel-*
25 *evant to the report including suggestions for modifications*

1 *that would improve pediatric drug research and pediatric*
 2 *labeling of drugs and biological products.*

3 **SEC. 509. TECHNICAL AMENDMENTS.**

4 *(a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Sec-*
 5 *tion 505A (21 U.S.C. 355a) is amended—*

6 *(1) in subsection (k)(2), by striking “subsection*
 7 *(f)(3)(F)” and inserting “subsection (f)(6)(F)”;*

8 *(2) in subsection (l)—*

9 *(A) in paragraph (1)—*

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

13 *(ii) by striking “one-year” and insert-*
 14 *ing “18-month”;*

15 *(B) in paragraph (2)—*

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

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

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

22 *(D) by inserting after paragraph (2) the fol-*
 23 *lowing:*

24 *“(3) PRESERVATION OF AUTHORITY.—Nothing in*
 25 *this subsection shall prohibit the Office of Pediatric*

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

6 *(3) in subsection (n)—*

7 *(A) in the subsection heading, by striking*
 8 *“COMPLETED” and inserting “SUBMITTED”; and*

9 *(B) in paragraph (1)—*

10 *(i) in the matter preceding subpara-*
 11 *graph (A), by striking “have not been com-*
 12 *pleted” and inserting “have not been sub-*
 13 *mitted by the date specified in the written*
 14 *request issued or if the applicant or holder*
 15 *does not agree to the request”;*

16 *(ii) in subparagraph (A)—*

17 *(I) in the first sentence, by insert-*
 18 *ing “, or for which a period of exclu-*
 19 *sivity eligible for extension under sub-*
 20 *section (b)(1) or (c)(1) of this section*
 21 *or under subsection (m)(2) or (m)(3) of*
 22 *section 351 of the Public Health Serv-*
 23 *ice Act has not ended” after “expired”;*
 24 *and*

1 (II) by striking “Prior to” and all
 2 that follows through the period at the
 3 end; and

4 (iii) in subparagraph (B), by striking
 5 “no listed patents or has 1 or more listed
 6 patents that have expired,” and inserting
 7 “no unexpired listed patents and for which
 8 no unexpired periods of exclusivity eligible
 9 for extension under subsection (b)(1) or
 10 (c)(1) of this section or under subsection
 11 (m)(2) or (m)(3) of section 351 of the Pub-
 12 lic Health Service Act apply,”; and

13 (4) in subsection (o)(2), by amending subpara-
 14 graph (B) to read as follows:

15 “(B) a statement of any appropriate pedi-
 16 atric contraindications, warnings, precautions,
 17 or other information that the Secretary considers
 18 necessary to assure safe use.”.

19 (b) *RESEARCH INTO PEDIATRIC USES FOR DRUGS*
 20 *AND BIOLOGICAL PROJECTS IN FFDCA.*—Section 505B (21
 21 U.S.C. 355c) is amended—

22 (1) in subsection (a)—

23 (A) in paragraph (1), in the matter before
 24 subparagraph (A), by inserting “for a drug”
 25 after “(or supplement to an application)”; and

1 (B) in paragraph (4)(C)—

2 (i) in the first sentence, by inserting

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

4 (ii) in the second sentence, by striking

5 “either a full or” and inserting “such a”;

6 (2) in subsection (b)(1), in the matter preceding

7 subparagraph (A), by striking “After providing no-

8 tice” and all that follows through “studies), the” and

9 inserting “The”;

10 (3) in subsection (g)—

11 (A) in paragraph (1)(A), by inserting “that

12 receives a priority review or 330 days after the

13 date of the submission of an application or sup-

14 plement that receives a standard review” after

15 “after the date of the submission of the applica-

16 tion or supplement”; and

17 (B) in paragraph (2), by striking “the label

18 of such product” and inserting “the labeling of

19 such product”;

20 (4) in subsection (h)(1)—

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

22 plement to an application) that contains” after

23 “date of submission of”; and

24 (B) by inserting “if the application (or sup-

25 plement) receives a priority review, or not later

1 *than 330 days after the date of submission of an*
 2 *application (or supplement to an application)*
 3 *that contains a pediatric assessment under this*
 4 *section, if the application (or supplement) re-*
 5 *ceives a standard review,” after “under this sec-*
 6 *tion,”; and*

7 *(5) in subsection (i)—*

8 *(A) in paragraph (1)—*

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

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

14 *(B) in paragraph (2)—*

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

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

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

21 *(D) by inserting after paragraph (2) the fol-*
 22 *lowing:*

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

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

5 *(c) INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC*
 6 *PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTEN-*
 7 *SIONS, AND WAIVERS.—Section 505C (21 U.S.C. 355d) is*
 8 *amended—*

9 *(1) in the section heading, by inserting “**DEFER-***
 10 ***RAL EXTENSIONS,**” after “**DEFERRALS,**”; and*

11 *(2) by inserting “neonatology,” after “pediatric*
 12 *ethics,”.*

13 *(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—*
 14 *Section 409I(c) of the Public Health Service Act (42 U.S.C.*
 15 *284m(c)) is amended—*

16 *(1) in paragraph (1)—*

17 *(A) in the matter preceding subparagraph*
 18 *(A), by inserting “or section 351(m) of this Act,”*
 19 *after “Cosmetic Act,”;*

20 *(B) in subparagraph (A)(i), by inserting*
 21 *“or section 351(k) of this Act” after “Cosmetic*
 22 *Act”; and*

23 *(C) by amending subparagraph (B) to read*
 24 *as follows:*

1 “(B) there remains no patent listed pursu-
 2 ant to section 505(b)(1) of the Federal Food,
 3 Drug, and Cosmetic Act, and every three-year
 4 and five-year period referred to in subsection
 5 (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv),
 6 (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of sec-
 7 tion 505 of the Federal Food, Drug, and Cos-
 8 metic Act, or applicable twelve-year period re-
 9 ferred to in section 351(k)(7) of this Act, and
 10 any seven-year period referred to in section 527
 11 of the Federal Food, Drug, and Cosmetic Act has
 12 ended for at least one form of the drug; and”;
 13 and
 14 (2) in paragraph (2)—

15 (A) in the paragraph heading, by striking
 16 “FOR DRUGS LACKING EXCLUSIVITY”;

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

19 (C) by striking “505A of such Act” and in-
 20 serting “505A of the Federal Food, Drug, and
 21 Cosmetic Act or section 351(m) of this Act”.

22 (e) *PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC*
 23 *ADVISORY COMMITTEE.*—Section 15(a) of the *Best Pharma-*
 24 *ceuticals for Children Act* (Public Law 107–109), as
 25 amended by section 502(e) of the *Food and Drug Adminis-*

1 *tration Amendments Act of 2007 (Public Law 110–85), is*
 2 *amended in paragraph (1)(D), by striking “section*
 3 *505B(f)” and inserting “section 505C”.*

4 (f) *FOUNDATION OF NATIONAL INSTITUTES OF*
 5 *HEALTH.—Section 499(c)(1)(C) of the Public Health Serv-*
 6 *ice Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking*
 7 *“for which the Secretary issues a certification in the affirm-*
 8 *ative under section 505A(n)(1)(A) of the Federal Food,*
 9 *Drug, and Cosmetic Act”.*

10 (g) *APPLICATION; TRANSITION RULE.—*

11 (1) *APPLICATION.—Notwithstanding any provi-*
 12 *sion of section 505A and 505B of the Federal Food,*
 13 *Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) stat-*
 14 *ing that a provision applies beginning on the date of*
 15 *the enactment of the Best Pharmaceuticals for Chil-*
 16 *dren Act of 2007 or the date of the enactment of the*
 17 *Pediatric Research Equity Act of 2007, any amend-*
 18 *ment made by this Act to such a provision applies be-*
 19 *ginning on the date of the enactment of this Act.*

20 (2) *TRANSITIONAL RULE FOR ADVERSE EVENT*
 21 *REPORTING.—With respect to a drug for which a la-*
 22 *beling change described under section 505A(l)(1) or*
 23 *505B(i)(1) of the Federal Food, Drug, and Cosmetic*
 24 *Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved or*
 25 *made, respectively, during the one-year period that*

1 ends on the day before the date of enactment of this
 2 Act, the Secretary shall apply section 505A(l) and
 3 section 505B(i), as applicable, to such drug, as such
 4 sections were in effect on such day.

5 **SEC. 510. PEDIATRIC RARE DISEASES.**

6 (a) *PUBLIC MEETING*.—Not later than 18 months after
 7 the date of enactment of this Act, the Secretary shall hold
 8 at least one public meeting to discuss ways to encourage
 9 and accelerate the development of new therapies for pedi-
 10 atric rare diseases.

11 (b) *REPORT*.—Not later than 180 days after the date
 12 of the public meeting under subsection (a), the Secretary
 13 shall issue a report that includes a strategic plan for en-
 14 couraging and accelerating the development of new thera-
 15 pies for treating pediatric rare diseases.

16 **SEC. 511. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.**

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

19 (1) in subsection (c)—

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

22 (B) by redesignating paragraph (2) as
 23 paragraph (4); and

24 (C) by inserting after paragraph (1) the fol-
 25 lowing:

1 “(2) *subject to subsection (d), one or more addi-*
 2 *tional individuals with necessary expertise in a pedi-*
 3 *atric subpopulation that is, as determined through*
 4 *consideration of the reports and recommendations*
 5 *issued by the Institute of Medicine and the Comp-*
 6 *troller General of the United States, less likely to be*
 7 *studied as a part of a written request issued under*
 8 *section 505A of the Federal Food, Drug, and Cosmetic*
 9 *Act or an assessment under section 505B of such Act;*

10 “(3) *one or more additional individuals with ex-*
 11 *pertise in pediatric epidemiology; and*”;
 12 *and*

12 (2) *by adding at the end the following:*

13 “(d) *NEONATOLOGY EXPERTISE.—For the 5-year pe-*
 14 *riod beginning on the date of enactment of this subsection,*
 15 *at least one of the individuals described in subsection (c)(2)*
 16 *shall have expertise in neonatology.*”.

17 ***TITLE VI—MEDICAL DEVICE***
 18 ***REGULATORY IMPROVEMENTS***

19 ***SEC. 601. INVESTIGATIONAL DEVICE EXEMPTIONS.***

20 *Section 520(g) (21 U.S.C. 360j(g)) is amended—*

21 (1) *in paragraph (2)(B)(ii), by inserting “safety*
 22 *or effectiveness” before “data obtained”; and*

23 (2) *in paragraph (4), by adding at the end the*
 24 *following:*

1 “(C) Consistent with paragraph (1), the Secretary
2 shall not disapprove an application under this subsection
3 because the Secretary determines that—

4 “(i) the investigation may not support a sub-
5 stantial equivalence or de novo classification deter-
6 mination or approval of the device;

7 “(ii) the investigation may not meet a require-
8 ment, including a data requirement, relating to the
9 approval or clearance of a device; or

10 “(iii) an additional or different investigation
11 may be necessary to support clearance or approval of
12 the device.”.

13 **SEC. 602. CLARIFICATION OF LEAST BURDENSOME STAND-**
14 **ARD.**

15 (a) *PREMARKET APPROVAL*.—Section 513(a)(3)(D)
16 (21 U.S.C. 360c(a)(3)(D)) is amended—

17 (1) by redesignating clause (iii) as clause (v);
18 and

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

20 “(iii) For purposes of clause (ii), the term ‘necessary’
21 means the minimum required information that would sup-
22 port a determination by the Secretary that an application
23 provides reasonable assurance of the effectiveness of the de-
24 vice.

1 “(iv) *Nothing in this subparagraph shall alter the cri-*
 2 *teria for evaluating an application for premarket approval*
 3 *of a device.*”.

4 (b) *PREMARKET NOTIFICATION UNDER SECTION*
 5 *510(k).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is*
 6 *amended—*

7 (1) *by striking “(D) Whenever” and inserting*
 8 *“(D)(i) Whenever”; and*

9 (2) *by adding at the end the following:*

10 “(ii) *For purposes of clause (i), the term ‘necessary’*
 11 *means the minimum required information that would sup-*
 12 *port a determination of substantial equivalence between a*
 13 *new device and a predicate device.*

14 “(iii) *Nothing in this subparagraph shall alter the*
 15 *standard for determining substantial equivalence between*
 16 *a new device and a predicate device.*”.

17 **SEC. 603. AGENCY DOCUMENTATION AND REVIEW OF SIG-**
 18 **NIFICANT DECISIONS.**

19 *Chapter V is amended by inserting after section 517*
 20 *(21 U.S.C. 360g) the following:*

21 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIG-**
 22 **NIFICANT DECISIONS REGARDING DEVICES.**

23 “(a) *DOCUMENTATION OF RATIONALE FOR SIGNIFI-*
 24 *CANT DECISIONS.—*

1 “(1) *IN GENERAL.*—*The Secretary shall provide*
2 *a substantive summary of the scientific and regu-*
3 *latory rationale for any significant decision of the*
4 *Center for Devices and Radiological Health regarding*
5 *submission or review of a report under section 510(k),*
6 *an application under section 515, or an application*
7 *for an exemption under section 520(g), including docu-*
8 *mentation of significant controversies or differences*
9 *of opinion and the resolution of such controversies or*
10 *differences of opinion.*

11 “(2) *PROVISION OF DOCUMENTATION.*—*Upon re-*
12 *quest, the Secretary shall furnish such substantive*
13 *summary to the person who is seeking to submit, or*
14 *who has submitted, such report or application.*

15 “(b) *REVIEW OF SIGNIFICANT DECISIONS.*—

16 “(1) *REQUEST FOR SUPERVISORY REVIEW OF*
17 *SIGNIFICANT DECISION.*—*Any person may request a*
18 *supervisory review of the significant decision de-*
19 *scribed in subsection (a)(1). Such review may be con-*
20 *ducted at the next supervisory level or higher above*
21 *the individual who made the significant decision.*

22 “(2) *SUBMISSION OF REQUEST.*—*A person re-*
23 *questing a supervisory review under paragraph (1)*
24 *shall submit such request to the Secretary not later*
25 *than 30 days after such decision and shall indicate*

1 *in the request whether such person seeks an in-person*
 2 *meeting or a teleconference review.*

3 “(3) *TIMEFRAME.*—

4 “(A) *IN GENERAL.*—*Except as provided in*
 5 *subparagraph (B), the Secretary shall schedule*
 6 *an in-person or teleconference review, if so re-*
 7 *quested, not later than 30 days after such request*
 8 *is made. The Secretary shall issue a decision to*
 9 *the person requesting a review under this sub-*
 10 *section not later than 45 days after the request*
 11 *is made under paragraph (1), or, in the case of*
 12 *a person who requests an in-person meeting or*
 13 *teleconference, 30 days after such meeting or tele-*
 14 *conference.*

15 “(B) *EXCEPTION.*—*Subparagraph (A) shall*
 16 *not apply in cases that are referred to experts*
 17 *outside of the Food and Drug Administration.”.*

18 **SEC. 604. DEVICE MODIFICATIONS REQUIRING PREMARKET**

19 **NOTIFICATION PRIOR TO MARKETING.**

20 *Section 510(n) (21 U.S.C. 360(n)) is amended by—*

21 *(1) striking “(n) The Secretary” and inserting*

22 *“(n)(1) The Secretary”; and*

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

24 *“(2)(A) Not later than 18 months after the date*
 25 *of enactment of this paragraph, the Secretary shall*

1 submit to the Committee on Energy and Commerce of
2 the House of Representatives and the Committee on
3 Health, Education, Labor, and Pensions of the Senate
4 a report regarding when a premarket notification
5 under subsection (k) should be submitted for a modi-
6 fication or change to a legally marketed device. The
7 report shall include the Secretary's interpretation of
8 the following terms: 'could significantly affect the
9 safety or effectiveness of the device', 'a significant
10 change or modification in design, material, chemical
11 composition, energy source, or manufacturing proc-
12 ess', and 'major change or modification in the in-
13 tended use of the device'. The report also shall discuss
14 possible processes for industry to use to determine
15 whether a new submission under subsection (k) is re-
16 quired and shall analyze how to leverage existing
17 quality system requirements to reduce premarket bur-
18 den, facilitate continual device improvement, and
19 provide reasonable assurance of safety and effective-
20 ness of modified devices. In developing such report,
21 the Secretary shall consider the input of interested
22 stakeholders.

23 “(B) The Secretary shall withdraw the Food and
24 Drug Administration draft guidance entitled ‘Guid-
25 ance for Industry and FDA Staff—510(k) Device

1 *Modifications: Deciding When to Submit a 510(k) for*
2 *a Change to an Existing Device’, dated July 27,*
3 *2011, and shall not use this draft guidance as part*
4 *of, or for the basis of, any premarket review or any*
5 *compliance or enforcement decisions or actions. The*
6 *Secretary shall not issue—*

7 “(i) any draft guidance or proposed regula-
8 tion that addresses when to submit a premarket
9 notification submission for changes and modi-
10 fications made to a manufacturer’s previously
11 cleared device before the receipt by the Committee
12 on Energy and Commerce of the House of Rep-
13 resentatives and the Committee on Health, Edu-
14 cation, Labor, and Pensions of the Senate of the
15 report required in subparagraph (A); and

16 “(ii) any final guidance or regulation on
17 that topic for one year after date of receipt of
18 such report by the Committee on Energy and
19 Commerce of the House of Representatives and
20 the Committee on Health, Education, Labor, and
21 Pensions of the Senate.

22 “(C) The Food and Drug Administration guid-
23 ance entitled ‘Deciding When to Submit a 510(k) for
24 a Change to an Existing Device’, dated January 10,
25 1997, shall be in effect until the subsequent issuance

1 of guidance or promulgation, if appropriate, of a reg-
 2 ulation described in subparagraph (B), and the Sec-
 3 retary shall interpret such guidance in a manner that
 4 is consistent with the manner in which the Secretary
 5 has interpreted such guidance since 1997.”.

6 **SEC. 605. PROGRAM TO IMPROVE THE DEVICE RECALL SYS-**
 7 **TEM.**

8 Chapter V is amended by inserting after section 518
 9 (21 U.S.C. 360h) the following:

10 **“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**
 11 **SYSTEM.**

12 “(a) *IN GENERAL.*—The Secretary shall—

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

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

21 “(3) develop detailed criteria for assessing wheth-
 22 er a person performing a device recall has performed
 23 an effective correction or action plan for the recall;
 24 and

1 “(4) document the basis for each termination by
2 the Food and Drug Administration of a device recall.

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

6 “(1) trends in the number and types of device re-
7 calls;

8 “(2) devices that are most frequently the subject
9 of a recall; and

10 “(3) underlying causes of device recalls.

11 “(c) *TERMINATION OF RECALLS.*—The Secretary shall
12 document the basis for the termination by the Food and
13 Drug Administration of a device recall.

14 “(d) *DEFINITION.*—In this section, the term ‘recall’
15 means—

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

19 “(2) the correction or removal from the market
20 of a device at the initiative of the manufacturer or
21 importer of the device that is required to be reported
22 to the Secretary under section 519(g).”.

1 **SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE**

2 **EXEMPTIONS.**

3 *Section 520(g) (21 U.S.C. 360j(g)) is amended by add-*
4 *ing at the end the following:*

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

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

16 *“(i) the device involved represents an unreason-*
17 *able risk to the safety of the persons who are the sub-*
18 *jects of the clinical investigation, taking into account*
19 *the qualifications of the clinical investigators, infor-*
20 *mation about the device, the design of the clinical in-*
21 *vestigation, the condition for which the device is to be*
22 *investigated, and the health status of the subjects in-*
23 *volved; or*

24 *“(ii) the clinical hold should be issued for such*
25 *other reasons as the Secretary may by regulation es-*
26 *tablish.*

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

7 **SEC. 607. MODIFICATION OF DE NOVO APPLICATION PROC-**
 8 **ESS.**

9 (a) *IN GENERAL.*—Section 513(f)(2) (21 U.S.C.
 10 360c(f)(2)) is amended—

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

12 (2) in subparagraph (A)(i), as so designated by
 13 paragraph (1), by striking “under the criteria set
 14 forth” and all that follows through the end of sub-
 15 paragraph (A) and inserting a period;

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

18 “(ii) In lieu of submitting a report under section
 19 510(k) and submitting a request for classification under
 20 clause (i) for a device, if a person determines there is no
 21 legally marketed device upon which to base a determination
 22 of substantial equivalence (as defined in subsection (i)), a
 23 person may submit a request under this clause for the Sec-
 24 retary to classify the device.

1 “(iii) Upon receipt of a request under clause (i) or
2 (ii), the Secretary shall classify the device subject to the re-
3 quest under the criteria set forth in subparagraphs (A)
4 through (C) of subsection (a)(1) within 120 days.

5 “(iv) Notwithstanding clause (iii), the Secretary may
6 decline to undertake a classification request submitted
7 under clause (ii) if the Secretary identifies a legally mar-
8 keted device that could provide a reasonable basis for review
9 of substantial equivalence under paragraph (1), or when the
10 Secretary determines that the device submitted is not of low-
11 moderate risk or that general controls would be inadequate
12 to control the risks and special controls to mitigate the risks
13 cannot be developed.

14 “(v) The person submitting the request for classifica-
15 tion under this subparagraph may recommend to the Sec-
16 retary a classification for the device and shall, if recom-
17 mending classification in class II, include in the request
18 an initial draft proposal for applicable special controls, as
19 described in subsection (a)(1)(B), that are necessary, in
20 conjunction with general controls, to provide reasonable as-
21 surance of safety and effectiveness and a description of how
22 the special controls provide such assurance. Any such re-
23 quest shall describe the device and provide detailed informa-
24 tion and reasons for the recommended classification.”; and

1 (4) in subparagraph (B), by striking “Not later
2 than 60 days after the date of the submission of the
3 request under subparagraph (A), the Secretary” and
4 inserting “The Secretary”.

5 (b) *CONFORMING AMENDMENTS.*—Section 513(f) (21
6 U.S.C. 360c(f)) is amended in paragraph (1)—

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

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

11 (3) by inserting after subparagraph (B) the fol-
12 lowing:

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

15 **SEC. 608. RECLASSIFICATION PROCEDURES.**

16 (a) *CLASSIFICATION CHANGES.*—

17 (1) *IN GENERAL.*—Section 513(e)(1) (21 U.S.C.
18 360c(e)(1)) is amended to read as follows:

19 “(e)(1)(A)(i) Based on new information respecting a
20 device, the Secretary may, upon the initiative of the Sec-
21 retary or upon petition of an interested person, change the
22 classification of such device, and revoke, on account of the
23 change in classification, any regulation or requirement in
24 effect under section 514 or 515 with respect to such device,
25 by administrative order published in the Federal Register

1 *following publication of a proposed reclassification order in*
2 *the Federal Register, a meeting of a device classification*
3 *panel described in subsection (b), and consideration of com-*
4 *ments to a public docket, notwithstanding subchapter II of*
5 *chapter 5 of title 5, United States Code. The proposed re-*
6 *classification order published in the Federal Register shall*
7 *set forth the proposed reclassification, and a substantive*
8 *summary of the valid scientific evidence concerning the pro-*
9 *posed reclassification, including—*

10 “(I) *the public health benefit of the use of the de-*
11 *vice, and the nature and, if known, incidence of the*
12 *risk of the device;*

13 “(II) *in the case of a reclassification from class*
14 *II to class III, why general controls pursuant to sub-*
15 *section (a)(1)(A) and special controls pursuant to*
16 *subsection (a)(1)(B) together are not sufficient to pro-*
17 *vide a reasonable assurance of safety and effectiveness*
18 *for such device; and*

19 “(III) *in the case of reclassification from class*
20 *III to class II, why general controls pursuant to sub-*
21 *section (a)(1)(A) and special controls pursuant to*
22 *subsection (a)(1)(B) together are sufficient to provide*
23 *a reasonable assurance of safety and effectiveness for*
24 *such device.*

1 “(ii) *An order under this subsection changing the clas-*
 2 *sification of a device from class III to class II may provide*
 3 *that such classification shall not take effect until the effec-*
 4 *tive date of a performance standard established under sec-*
 5 *tion 514 for such device.*

6 “(B) *Authority to issue such administrative order shall*
 7 *not be delegated below the Director of the Center for Devices*
 8 *and Radiological Health, acting in consultation with the*
 9 *Commissioner.*”.

10 (2) *TECHNICAL AND CONFORMING AMEND-*
 11 *MENTS.—*

12 (A) *Section 513(e)(2) (21 U.S.C. 360c(e)(2))*
 13 *is amended by striking “regulation promul-*
 14 *gated” and inserting “an order issued”.*

15 (B) *Section 514(a)(1) (21 U.S.C.*
 16 *360d(a)(1)) is amended by striking “under a*
 17 *regulation under section 513(e) but such regula-*
 18 *tion” and inserting “under an administrative*
 19 *order under section 513(e) (or a regulation pro-*
 20 *mulgated under such section prior to the date of*
 21 *enactment of the Food and Drug Administration*
 22 *Safety and Innovation Act) but such order (or*
 23 *regulation)”.*

24 (C) *Section 517(a)(1) (21 U.S.C.*
 25 *360g(a)(1)) is amended by striking “or changing*

1 *the classification of a device to class I” and in-*
2 *serting “, an administrative order changing the*
3 *classification of a device to class I,”.*

4 *(3) DEVICES RECLASSIFIED PRIOR TO THE DATE*
5 *OF ENACTMENT OF THIS ACT.—*

6 *(A) IN GENERAL.—The amendments made*
7 *by this subsection shall have no effect on a regu-*
8 *lation promulgated with respect to the classifica-*
9 *tion of a device under section 513(e) of the Fed-*
10 *eral Food, Drug, and Cosmetic Act prior to the*
11 *date of enactment of this Act.*

12 *(B) APPLICABILITY OF OTHER PROVI-*
13 *SIONS.—In the case of a device reclassified under*
14 *section 513(e) of the Federal Food, Drug, and*
15 *Cosmetic Act by regulation prior to the date of*
16 *enactment of this Act, section 517(a)(1) of the*
17 *Federal Food, Drug, and Cosmetic Act (21*
18 *U.S.C. 360g(a)(1)) shall apply to such regulation*
19 *promulgated under section 513(e) of such Act*
20 *with respect to such device in the same manner*
21 *such section 517(a)(1) applies to an administra-*
22 *tive order issued with respect to a device reclassi-*
23 *fied after the date of enactment of this Act.*

24 *(b) DEVICES MARKETING BEFORE MAY 28, 1976.—*

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

3 (A) in subsection (a), by striking “regula-
4 tion promulgated under subsection (b)” and in-
5 serting “an order issued under subsection (b) (or
6 a regulation promulgated under such subsection
7 prior to the date of enactment of the Food and
8 Drug Administration Safety and Innovation
9 Act)”;

10 (B) in subsection (b)—

11 (i) in paragraph (1)—

12 (I) in the heading, by striking
13 “Regulation” and inserting “Order”;
14 and

15 (II) in the matter following sub-
16 paragraph (B)—

17 (aa) by striking “by regula-
18 tion, promulgated in accordance
19 with this subsection” and insert-
20 ing “by administrative order fol-
21 lowing publication of a proposed
22 order in the Federal Register, a
23 meeting of a device classification
24 panel described in section 513(b),
25 and consideration of comments

1 *from all affected stakeholders, in-*
 2 *cluding patients, payors, and pro-*
 3 *viders, notwithstanding sub-*
 4 *chapter II of chapter 5 of title 5,*
 5 *United States Code”; and*

6 *(bb) by adding at the end the*
 7 *following: “Authority to issue such*
 8 *administrative order shall not be*
 9 *delegated below the Director of the*
 10 *Center for Devices and Radio-*
 11 *logical Health, acting in consulta-*
 12 *tion with the Commissioner.”;*

13 *(ii) in paragraph (2)—*

14 *(I) by striking subparagraph (B);*

15 *and*

16 *(II) in subparagraph (A)—*

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

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

3 (bb) by redesignating clauses
4 (i) through (iv) as subparagraphs
5 (A) through (D), respectively;

6 (cc) in subparagraph (A), as
7 so redesignated, by striking “regu-
8 lation” and inserting “order”;
9 and

10 (dd) in subparagraph (C), as
11 so redesignated, by striking “regu-
12 lation” and inserting “order”;

13 (iii) in paragraph (3)—

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

17 (II) by striking “paragraph (2)
18 and after” and inserting “paragraph
19 (2),”;

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

24 (IV) by striking “(A) promulgate
25 such regulation” and inserting “(A)

1 *issue an administrative order under*
2 *paragraph (1)”;*

3 (V) *by striking “paragraph*
4 *(2)(A)(ii)” and inserting “paragraph*
5 *(2)(B)”; and*

6 (VI) *by striking “promulgation of*
7 *the regulation” and inserting*
8 *“issuance of the administrative order”;*
9 *and*

10 *(iv) by striking paragraph (4); and*
11 *(C) in subsection (i)—*

12 *(i) in paragraph (2)—*

13 *(I) in the matter preceding sub-*
14 *paragraph (A)—*

15 *(aa) by striking “December*
16 *1, 1995” and inserting “the date*
17 *that is 2 years after the date of*
18 *enactment of the Food and Drug*
19 *Administration Safety and Inno-*
20 *vation Act”; and*

21 *(bb) by striking “publish a*
22 *regulation in the Federal Reg-*
23 *ister” and inserting “issue an ad-*
24 *ministrative order following pub-*
25 *lication of a proposed order in the*

1 *Federal Register, a meeting of a*
2 *device classification panel de-*
3 *scribed in section 513(b), and con-*
4 *sideration of comments from all*
5 *affected stakeholders, including*
6 *patients, payors, and providers,*
7 *notwithstanding subchapter II of*
8 *chapter 5 of title 5, United States*
9 *Code,”;*

10 *(II) in subparagraph (B), by*
11 *striking “final regulation has been pro-*
12 *mulgated under section 515(b)” and*
13 *inserting “administrative order has*
14 *been issued under subsection (b) (or no*
15 *regulation has been promulgated under*
16 *such subsection prior to the date of en-*
17 *actment of the Food and Drug Admin-*
18 *istration Safety and Innovation Act)”;*

19 *(III) in the matter following sub-*
20 *paragraph (B), by striking “regulation*
21 *requires” and inserting “administra-*
22 *tive order issued under this paragraph*
23 *requires”;* and

24 *(IV) by striking the third and*
25 *fourth sentences; and*

1 (ii) in paragraph (3)—

2 (I) by striking “regulation requir-
3 ing” each place such term appears and
4 inserting “order requiring”; and

5 (II) by striking “promulgation of
6 a section 515(b) regulation” and in-
7 serting “issuance of an administrative
8 order under subsection (b)”.

9 (2) *TECHNICAL AND CONFORMING AMEND-*
10 *MENTS.*—Section 501(f) (21 U.S.C. 351(f)) is amend-
11 ed—

12 (A) in subparagraph (1)(A)—

13 (i) in subclause (i), by striking “a reg-
14 ulation promulgated” and inserting “an
15 order issued”; and

16 (ii) in subclause (ii), by striking “pro-
17 mulgation of such regulation” and inserting
18 “issuance of such order”;

19 (B) in subparagraph (2)(B)—

20 (i) by striking “a regulation promul-
21 gated” and inserting “an order issued”; and

22 (ii) by striking “promulgation of such
23 regulation” and inserting “issuance of such
24 order”; and

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

1 “(3) *In the case of a device with respect to which a*
 2 *regulation was promulgated under section 515(b) prior to*
 3 *the date of enactment of the Food and Drug Administration*
 4 *Safety and Innovation Act, a reference in this subsection*
 5 *to an order issued under section 515(b) shall be deemed to*
 6 *include such regulation.*”.

7 (3) *APPROVAL BY REGULATION PRIOR TO THE*
 8 *DATE OF ENACTMENT OF THIS ACT.—The amend-*
 9 *ments made by this subsection shall have no effect on*
 10 *a regulation that was promulgated prior to the date*
 11 *of enactment of this Act requiring that a device have*
 12 *an approval under section 515 of the Federal Food,*
 13 *Drug, and Cosmetic Act (21 U.S.C. 360e) of an appli-*
 14 *cation for premarket approval.*

15 (c) *REPORTING.—The Secretary of Health and*
 16 *Human Services shall annually post on the Internet Web*
 17 *site of the Food and Drug Administration—*

18 (1) *the number and type of class I and class II*
 19 *devices reclassified as class II or class III in the pre-*
 20 *vious calendar year under section 513(e)(1) of the*
 21 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 22 *360c(e)(1));*

23 (2) *the number and type of class II and class III*
 24 *devices reclassified as class I or class II in the pre-*
 25 *vious calendar year under such section 513(e)(1); and*

1 (3) the number and type of devices reclassified in
 2 the previous calendar year under section 515 of the
 3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 4 360e).

5 **SEC. 609. HARMONIZATION OF DEVICE PREMARKET RE-**
 6 **VIEW, INSPECTION, AND LABELING SYMBOLS.**

7 Paragraph (4) of section 803(c) (21 U.S.C. 383(c)) is
 8 amended to read as follows:

9 “(4) With respect to devices, the Secretary may, when
 10 appropriate, enter into arrangements with nations regard-
 11 ing methods and approaches to harmonizing regulatory re-
 12 quirements for activities, including inspections and com-
 13 mon international labeling symbols.”.

14 **SEC. 610. PARTICIPATION IN INTERNATIONAL FORA.**

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

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

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

20 “(B) In carrying out subparagraph (A), the Secretary
 21 may participate in appropriate fora, including the Inter-
 22 national Medical Device Regulators Forum, and may—

23 “(i) provide guidance to such fora on strategies,
 24 policies, directions, membership, and other activities
 25 of a forum as appropriate;

1 “(ii) to the extent appropriate, solicit, review,
2 and consider comments from industry, academia,
3 health care professionals, and patient groups regard-
4 ing the activities of such fora; and

5 “(iii) to the extent appropriate, inform the pub-
6 lic of the Secretary’s activities within such fora, and
7 share with the public any documentation relating to
8 a forum’s strategies, policies, and other activities of
9 such fora.”.

10 **SEC. 611. REAUTHORIZATION OF THIRD-PARTY REVIEW.**

11 (a) *PERIODIC REACCREDITATION*.—Section 523(b)(2)
12 (21 U.S.C. 360m(b)(2)) is amended by adding at the end
13 of the following:

14 “(E) *PERIODIC REACCREDITATION*.—

15 “(i) *PERIOD*.—Subject to suspension or
16 withdrawal under subparagraph (B), any
17 accreditation under this section shall be
18 valid for a period of 3 years after its
19 issuance.

20 “(ii) *RESPONSE TO REACCREDITATION*
21 *REQUEST*.—Upon the submission of a re-
22 quest by an accredited person for reaccredi-
23 tation under this section, the Secretary shall
24 approve or deny such request not later than
25 60 days after receipt of the request.

1 “(iii) *CRITERIA.*—Not later than 120
 2 days after the date of the enactment of this
 3 subparagraph, the Secretary shall establish
 4 and publish in the *Federal Register* criteria
 5 to reaccredit or deny reaccreditation to per-
 6 sons under this section. The reaccreditation
 7 of persons under this section shall specify
 8 the particular activities under subsection
 9 (a), and the devices, for which such persons
 10 are reaccredited.”.

11 (b) *DURATION OF AUTHORITY.*—Section 523(c) (21
 12 U.S.C. 360m(c)) is amended by striking “October 1, 2012”
 13 and inserting “October 1, 2017”.

14 **SEC. 612. REAUTHORIZATION OF THIRD-PARTY INSPEC-**
 15 **TION.**

16 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amended
 17 by striking “October 1, 2012” and inserting “October 1,
 18 2017”.

19 **SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.**

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

22 (1) in paragraph (6)—

23 (A) in subparagraph (A)—

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

1 “(i) *The device with respect to which the exemp-*
2 *tion is granted—*

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

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

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

17 “(ii) *During any calendar year, the number of*
18 *such devices distributed during that year under each*
19 *exemption granted under this subsection does not ex-*
20 *ceed the annual distribution number for such device.*
21 *In this paragraph, the term ‘annual distribution*
22 *number’ means the number of such devices reasonably*
23 *needed to treat, diagnose, or cure a population of*
24 *4,000 individuals in the United States. The Secretary*

1 *shall determine the annual distribution number when*
 2 *the Secretary grants such exemption.”; and*

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

5 “(C) *A person may petition the Secretary to modify*
 6 *the annual distribution number determined by the Sec-*
 7 *retary under subparagraph (A)(ii) with respect to a device*
 8 *if additional information arises, and the Secretary may*
 9 *modify such annual distribution number.”;*

10 *(2) in paragraph (7), by striking “regarding a*
 11 *device” and inserting “regarding a device described*
 12 *in paragraph (6)(A)(i)(I)”;* and

13 *(3) in paragraph (8), by striking “of all devices*
 14 *described in paragraph (6)” and inserting “of all de-*
 15 *vices described in paragraph (6)(A)(i)(I)”.*

16 *(b) APPLICABILITY TO EXISTING DEVICES.—A sponsor*
 17 *of a device for which an exemption was approved under*
 18 *paragraph (2) of section 520(m) of the Federal Food, Drug,*
 19 *and Cosmetic Act (21 U.S.C. 360j(m)) before the date of*
 20 *enactment of this Act may seek a determination under sub-*
 21 *clause (I) or (II) of section 520(m)(6)(A)(i) (as amended*
 22 *by subsection (a)). If the Secretary of Health and Human*
 23 *Services determines that such subclause (I) or (II) applies*
 24 *with respect to a device, clauses (ii), (iii), and (iv) of sub-*
 25 *paragraph (A) and subparagraphs (B), (C), (D), and (E)*

1 of paragraph (6) of such section 520(m) shall apply to such
 2 device, and the Secretary shall determine the annual dis-
 3 tribution number for purposes of clause (ii) of such sub-
 4 paragraph (A) when making the determination under this
 5 subsection.

6 **SEC. 614. UNIQUE DEVICE IDENTIFIER.**

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

8 (1) by striking “The Secretary shall promulgate”
 9 and inserting “Not later than December 31, 2012, the
 10 Secretary shall issue proposed”; and

11 (2) by adding at the end the following: “The Sec-
 12 retary shall finalize the proposed regulations not later
 13 than 6 months after the close of the comment period
 14 and shall implement the final regulations with respect
 15 to devices that are implantable, life-saving, and life
 16 sustaining not later than 2 years after the regulations
 17 are finalized, taking into account patient access to
 18 medical devices and therapies.”.

19 **SEC. 615. SENTINEL.**

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

22 “(h) *INCLUSION OF DEVICES IN THE POSTMARKET*
 23 *RISK IDENTIFICATION AND ANALYSIS SYSTEM.*—

24 “(1) *IN GENERAL.*—

1 “(A) *APPLICATION TO DEVICES.*—The Sec-
2 retary shall amend the procedures established
3 and maintained under clauses (i), (ii), (iii), and
4 (v) of section 505(k)(3)(C) in order to expand the
5 postmarket risk identification and analysis sys-
6 tem established under such section to include and
7 apply to devices.

8 “(B) *EXCEPTION.*—Subclause (II) of clause
9 (i) of section 505(k)(3)(C) shall not apply to de-
10 vices.

11 “(C) *CLARIFICATION.*—With respect to de-
12 vices, the private sector health-related electronic
13 data provided under section
14 505(k)(3)(C)(i)(III)(bb) may include medical de-
15 vice utilization data, health insurance claims
16 data, and procedure and device registries.

17 “(2) *DATA.*—In expanding the system as de-
18 scribed in paragraph (1)(A), the Secretary shall use
19 relevant data with respect to devices cleared under
20 section 510(k) or approved under section 515, includ-
21 ing claims data, patient survey data, and any other
22 data deemed appropriate by the Secretary.

23 “(3) *STAKEHOLDER INPUT.*—To help ensure ef-
24 fective implementation of the system as described in
25 paragraph (1) with respect to devices, the Secretary

1 *shall engage outside stakeholders in development of*
 2 *the system, and gather information from outside*
 3 *stakeholders regarding the content of an effective sen-*
 4 *tinel program, through a public hearing, advisory*
 5 *committee meeting, maintenance of a public docket, or*
 6 *other similar public measures.*

7 “(4) *VOLUNTARY SURVEYS.*—Chapter 35 of title
 8 44, United States Code, shall not apply to the collec-
 9 tion of voluntary information from health care pro-
 10 viders, such as voluntary surveys or questionnaires,
 11 initiated by the Secretary for purposes of postmarket
 12 risk identification, mitigation, and analysis for de-
 13 vices.”.

14 **SEC. 616. POSTMARKET SURVEILLANCE.**

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

16 *(1) in subsection (a)(1)(A), in the matter pre-*
 17 *ceding clause (i), by inserting “, at the time of ap-*
 18 *proval or clearance of a device or at any time there-*
 19 *after,” after “by order”; and*

20 *(2) in subsection (b)(1), by inserting “The man-*
 21 *ufacturer shall commence surveillance under this sec-*
 22 *tion not later than 15 months after the day on which*
 23 *the Secretary issues an order under this section.”*
 24 *after the second sentence.*

1 **SEC. 617. CUSTOM DEVICES.**

2 *Section 520(b) (21 U.S.C. 360j(b)) is amended to read*
 3 *as follows:*

4 “(b) *CUSTOM DEVICES.*—

5 “(1) *IN GENERAL.*—*The requirements of sections*
 6 *514 and 515 shall not apply to a device that—*

7 “(A) *is created or modified in order to com-*
 8 *ply with the order of an individual physician or*
 9 *dentist (or any other specially qualified person*
 10 *designated under regulations promulgated by the*
 11 *Secretary after an opportunity for an oral hear-*
 12 *ing);*

13 “(B) *in order to comply with an order de-*
 14 *scribed in subparagraph (A), necessarily deviates*
 15 *from an otherwise applicable performance stand-*
 16 *ard under section 514 or requirement under sec-*
 17 *tion 515;*

18 “(C) *is not generally available in the*
 19 *United States in finished form through labeling*
 20 *or advertising by the manufacturer, importer, or*
 21 *distributor for commercial distribution;*

22 “(D) *is designed to treat a unique pathology*
 23 *or physiological condition that no other device is*
 24 *domestically available to treat;*

25 “(E)(i) *is intended to meet the special needs*
 26 *of such physician or dentist (or other specially*

1 *qualified person so designated) in the course of*
 2 *the professional practice of such physician or*
 3 *dentist (or other specially qualified person so*
 4 *designated); or*

5 *“(ii) is intended for use by an individual*
 6 *patient named in such order of such physician*
 7 *or dentist (or other specially qualified person so*
 8 *designated);*

9 *“(F) is assembled from components or man-*
 10 *ufactured and finished on a case-by-case basis to*
 11 *accommodate the unique needs of individuals de-*
 12 *scribed in clause (i) or (ii) of subparagraph (E);*
 13 *and*

14 *“(G) may have common, standardized de-*
 15 *sign characteristics, chemical and material com-*
 16 *positions, and manufacturing processes as com-*
 17 *mercially distributed devices.*

18 *“(2) LIMITATIONS.—Paragraph (1) shall apply*
 19 *to a device only if—*

20 *“(A) such device is for the purpose of treat-*
 21 *ing a sufficiently rare condition, such that con-*
 22 *ducting clinical investigations on such device*
 23 *would be impractical;*

24 *“(B) production of such device under para-*
 25 *graph (1) is limited to no more than 5 units per*

1 year of a particular device type, provided that
 2 such replication otherwise complies with this sec-
 3 tion; and

4 “(C) the manufacturer of such device noti-
 5 fies the Secretary on an annual basis, in a man-
 6 ner prescribed by the Secretary, of the manufac-
 7 ture of such device.

8 “(3) *GUIDANCE.*—Not later than 2 years after
 9 the date of enactment of this section, the Secretary
 10 shall issue final guidance on replication of multiple
 11 devices described in paragraph (2)(B).”.

12 **SEC. 618. HEALTH INFORMATION TECHNOLOGY.**

13 (a) *REPORT.*—Not later than 18 months after the date
 14 of enactment of this Act, the Secretary of Health and
 15 Human Services (referred to in this section as the “Sec-
 16 retary”), acting through the Commissioner of Food and
 17 Drugs, and in consultation with the National Coordinator
 18 for Health Information Technology and the Chairman of
 19 the Federal Communications Commission, shall post on the
 20 Internet Web sites of the Food and Drug Administration,
 21 the Federal Communications Commission, and the Office
 22 of the National Coordinator for Health Information Tech-
 23 nology, a report that contains a proposed strategy and rec-
 24 ommendations on an appropriate, risk-based regulatory
 25 framework pertaining to health information technology, in-

1 *cluding mobile medical applications, that promotes innova-*
 2 *tion, protects patient safety, and avoids regulatory duplica-*
 3 *tion.*

4 *(b) WORKING GROUP.—*

5 *(1) IN GENERAL.—In carrying out subsection*
 6 *(a), the Secretary may convene a working group of*
 7 *external stakeholders and experts to provide appro-*
 8 *priate input on the strategy and recommendations re-*
 9 *quired for the report under subsection (a).*

10 *(2) REPRESENTATIVES.—If the Secretary con-*
 11 *venes the working group under paragraph (1), the*
 12 *Secretary, in consultation with the Commissioner of*
 13 *Food and Drugs, the National Coordinator for Health*
 14 *Information Technology, and the Chairman of the*
 15 *Federal Communications Commission, shall deter-*
 16 *mine the number of representatives participating in*
 17 *the working group, and shall, to the extent prac-*
 18 *ticable, ensure that the working group is geographi-*
 19 *cally diverse and includes representatives of patients,*
 20 *consumers, health care providers, startup companies,*
 21 *health plans or other third-party payers, venture cap-*
 22 *ital investors, information technology vendors, health*
 23 *information technology vendors, small businesses, pur-*
 24 *chasers, employers, and other stakeholders with rel-*
 25 *evant expertise, as determined by the Secretary.*

1 **SEC. 619. GOOD GUIDANCE PRACTICES RELATING TO DE-**
 2 **VICES.**

3 *Subparagraph (C) of section 701(h)(1) (21 U.S.C.*
 4 *371(h)(1)) is amended—*

5 *(1) by striking “(C) For guidance documents”*
 6 *and inserting “(C)(i) For guidance documents”; and*

7 *(2) by adding at the end the following:*

8 *“(ii) With respect to devices, if a notice to indus-*
 9 *try guidance letter, a notice to industry advisory let-*
 10 *ter, or any similar notice sets forth initial interpreta-*
 11 *tions of a regulation or policy or sets forth changes*
 12 *in interpretation or policy, such notice shall be treat-*
 13 *ed as a guidance document for purposes of this sub-*
 14 *paragraph.”.*

15 **SEC. 620. PEDIATRIC DEVICE CONSORTIA.**

16 *(a) IN GENERAL.—Section 305(e) of Pediatric Medical*
 17 *Device Safety and Improvement Act (Public Law 110–85;*
 18 *42 U.S.C. 282 note)) is amended by striking “\$6,000,000*
 19 *for each of fiscal years 2008 through 2012” and inserting*
 20 *“\$5,250,000 for each of fiscal years 2013 through 2017”.*

21 *(b) FINAL RULE RELATING TO TRACKING OF PEDI-*
 22 *ATRIC USES OF DEVICES.—The Secretary of Health and*
 23 *Human Services shall issue—*

24 *(1) a proposed rule implementing section*
 25 *515A(a)(2) of the Federal Food, Drug, and Cosmetic*

1 *Act (21 U.S.C. 360e–1(a)(2)) not later than December*
 2 *31, 2012; and*

3 *(2) a final rule implementing such section not*
 4 *later than December 31, 2013.*

5 ***TITLE VII—DRUG SUPPLY CHAIN***

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

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

9 *(1) in subsection (b)—*

10 *(A) in paragraph (1), by striking “On or*
 11 *before” and all that follows through the period at*
 12 *the end and inserting the following: “During the*
 13 *period beginning on October 1 and ending on*
 14 *December 31 of each year, every person who*
 15 *owns or operates any establishment in any State*
 16 *engaged in the manufacture, preparation, propa-*
 17 *gation, compounding, or processing of a drug or*
 18 *drugs shall register with the Secretary the name*
 19 *of such person, places of business of such person,*
 20 *all such establishments, the unique facility iden-*
 21 *tifier of each such establishment, and a point of*
 22 *contact e-mail address.; and*

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

24 *“(3) The Secretary shall specify the unique facility*
 25 *identifier system that shall be used by registrants under*

1 paragraph (1). The requirement to include a unique facility
 2 identifier in a registration under paragraph (1) shall not
 3 apply until the date that the identifier system is specified
 4 by the Secretary under the preceding sentence.”; and

5 (2) in subsection (c), by striking “with the Sec-
 6 retary his name, place of business, and such establish-
 7 ment” and inserting “with the Secretary—

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

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

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

13 (a) **ENFORCEMENT OF REGISTRATION OF FOREIGN**
 14 **ESTABLISHMENTS.**—Section 502(o) (21 U.S.C. 352(o)) is
 15 amended by striking “in any State”.

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

18 (1) in paragraph (1)—

19 (A) by amending the matter preceding sub-
 20 paragraph (A) to read as follows: “Every person
 21 who owns or operates any establishment within
 22 any foreign country engaged in the manufacture,
 23 preparation, propagation, compounding, or proc-
 24 essing of a drug or device that is imported or of-
 25 fered for import into the United States shall,

1 *through electronic means in accordance with the*
2 *criteria of the Secretary—”;*

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

5 *“(A) upon first engaging in any such activity,*
6 *immediately submit a registration to the Secretary*
7 *that includes—*

8 *“(i) with respect to drugs, the name and*
9 *place of business of such person, all such estab-*
10 *lishments, the unique facility identifier of each*
11 *such establishment, a point of contact e-mail ad-*
12 *dress, the name of the United States agent of*
13 *each such establishment, the name of each im-*
14 *porter of such drug in the United States that is*
15 *known to the establishment, and the name of*
16 *each person who imports or offers for import*
17 *such drug to the United States for purposes of*
18 *importation; and*

19 *“(ii) with respect to devices, the name and*
20 *place of business of the establishment, the name*
21 *of the United States agent for the establishment,*
22 *the name of each importer of such device in the*
23 *United States that is known to the establishment,*
24 *and the name of each person who imports or of-*

1 *fers for import such device to the United States*
 2 *for purposes of importation; and”; and*

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

5 *“(B) each establishment subject to the require-*
 6 *ments of subparagraph (A) shall thereafter register*
 7 *with the Secretary during the period beginning on*
 8 *October 1 and ending on December 31 of each year.”;*
 9 *and*

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

11 *“(4) The Secretary shall specify the unique facility*
 12 *identifier system that shall be used by registrants under*
 13 *paragraph (1) with respect to drugs. The requirement to*
 14 *include a unique facility identifier in a registration under*
 15 *paragraph (1) with respect to drugs shall not apply until*
 16 *the date that the identifier system is specified by the Sec-*
 17 *retary under the preceding sentence.”.*

18 **SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMA-**
 19 **TION WITH PRODUCT LISTING.**

20 *Section 510(j) (21 U.S.C. 360(j)) is amended—*

21 *(1) in paragraph (1)—*

22 *(A) in subparagraph (C), by striking “;*
 23 *and” and inserting a semicolon;*

24 *(B) in subparagraph (D), by striking the*
 25 *period at the end and inserting “; and”; and*

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

2 “(E) in the case of a drug contained in the ap-
 3 plicable list, the name and place of business of each
 4 manufacturer of an excipient of the listed drug with
 5 which the person listing the drug conducts business,
 6 including all establishments used in the production of
 7 such excipient, the unique facility identifier of each
 8 such establishment, and a point of contact e-mail ad-
 9 dress for each such excipient manufacturer.”; and

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

11 “(4) The Secretary shall require persons subject to this
 12 subsection to use, for purposes of this subsection, the unique
 13 facility identifier systems specified under subsections (b)(3)
 14 and (i)(4) with respect to drugs. Such requirement shall
 15 not apply until the date that the identifier system under
 16 subsection (b)(3) or (i)(4), as applicable, is specified by the
 17 Secretary.”.

18 **SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND**

19 **LISTING.**

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

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

23 “(p) **ELECTRONIC REGISTRATION AND LISTING.**—

24 “(1) **IN GENERAL.**—Registrations and listings”;

25 and

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

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

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

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

19 “(3) *RISK-BASED INFORMATION AND COORDINA-*
20 *TION.*—*The Secretary shall ensure the accuracy and*
21 *coordination of relevant Food and Drug Administra-*
22 *tion databases in order to identify and inform risk-*
23 *based inspections under section 510(h).’’.*

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

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

4 “(h) *INSPECTIONS.*—

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

9 “(2) *BIENNIAL INSPECTIONS FOR DEVICES.*—
 10 *Every establishment described in paragraph (1), in*
 11 *any State, that is engaged in the manufacture, propa-*
 12 *gation, compounding, or processing of a device or de-*
 13 *vices classified in class II or III shall be so inspected*
 14 *by one or more officers or employees duly designated*
 15 *by the Secretary, or by persons accredited to conduct*
 16 *inspections under section 704(g), at least once in the*
 17 *2-year period beginning with the date of registration*
 18 *of such establishment pursuant to this section and at*
 19 *least once in every successive 2-year period thereafter.*

20 “(3) *RISK-BASED SCHEDULE FOR DRUGS.*—*The*
 21 *Secretary, acting through one or more officers or em-*
 22 *ployees duly designated by the Secretary, shall inspect*
 23 *establishments described in paragraph (1) that are*
 24 *engaged in the manufacture, preparation, propaga-*
 25 *tion, compounding, or processing of a drug or drugs*
 26 *(referred to in this subsection as ‘drug establish-*

ments') in accordance with a risk-based schedule established by the Secretary.

“(4) *RISK FACTORS.*—In establishing the risk-based schedule under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

“(A) *The compliance history of the establishment.*

“(B) *The record, history, and nature of recalls linked to the establishment.*

“(C) *The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.*

“(D) *The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.*

“(E) *Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.*

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

1 “(5) *EFFECT OF STATUS.*—In determining the
2 *risk associated with an establishment for purposes of*
3 *establishing a risk-based schedule under paragraph*
4 *(3), the Secretary shall not consider whether the drugs*
5 *manufactured, prepared, propagated, compounded, or*
6 *processed by such establishment are drugs described in*
7 *section 503(b).*

8 “(6) *ANNUAL REPORT ON INSPECTIONS OF ES-*
9 *TABLISHMENTS.*—Beginning in 2014, not later than
10 *February 1 of each year, the Secretary shall make*
11 *available on the Internet Web site of the Food and*
12 *Drug Administration a report regarding—*

13 “(A)(i) *the number of domestic and foreign*
14 *establishments registered pursuant to this section*
15 *in the previous fiscal year; and*

16 “(ii) *the number of such domestic establish-*
17 *ments and the number of such foreign establish-*
18 *ments that the Secretary inspected in the pre-*
19 *vious fiscal year;*

20 “(B) *with respect to establishments that*
21 *manufacture, prepare, propagate, compound, or*
22 *process an active ingredient of a drug, a finished*
23 *drug product, or an excipient of a drug, the*
24 *number of each such type of establishment; and*

1 “(C) the percentage of the budget of the
2 Food and Drug Administration used to fund the
3 inspections described under subparagraph (A).”.

4 **SEC. 706. RECORDS FOR INSPECTION.**

5 Section 704(a) (21 U.S.C. 374(a)) is amended by add-
6 ing at the end the following:

7 “(4)(A) Any records or other information that the Sec-
8 retary may inspect under this section from a person that
9 owns or operates an establishment that is engaged in the
10 manufacture, preparation, propagation, compounding, or
11 processing of a drug shall, upon the request of the Secretary,
12 be provided to the Secretary by such person, in advance
13 of or in lieu of an inspection, within a reasonable time-
14 frame, within reasonable limits, and in a reasonable man-
15 ner, and in either electronic or physical form, at the expense
16 of such person. The Secretary’s request shall include a suffi-
17 cient description of the records requested.

18 “(B) Upon receipt of the records requested under sub-
19 paragraph (A), the Secretary shall provide to the person
20 confirmation of receipt.

21 “(C) Nothing in this paragraph supplants the author-
22 ity of the Secretary to conduct inspections otherwise per-
23 mitted under this Act in order to ensure compliance with
24 this Act.”.

1 **SEC. 707. PROHIBITION AGAINST DELAYING, DENYING, LIM-**
 2 **ITING, OR REFUSING INSPECTION.**

3 (a) *IN GENERAL.*—Section 501 (21 U.S.C. 351) is
 4 amended by adding at the end the following:

5 “(j) *If it is a drug and it has been manufactured, proc-*
 6 *essed, packed, or held in any factory, warehouse, or estab-*
 7 *lishment and the owner, operator, or agent of such factory,*
 8 *warehouse, or establishment delays, denies, or limits an in-*
 9 *spection, or refuses to permit entry or inspection.”.*

10 (b) *GUIDANCE.*—Not later than 1 year after the date
 11 of enactment of this section, the Secretary of Health and
 12 Human Services shall issue guidance that defines the cir-
 13 cumstances that would constitute delaying, denying, or lim-
 14 iting inspection, or refusing to permit entry or inspection,
 15 for purposes of section 501(j) of the Federal Food, Drug,
 16 and Cosmetic Act (as added by subsection (a)).

17 **SEC. 708. DESTRUCTION OF ADULTERATED, MISBRANDED,**
 18 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
 19 **PORT.**

20 (a) *IN GENERAL.*—The sixth sentence of section 801(a)
 21 (21 U.S.C. 381(a)) is amended by inserting before the pe-
 22 riod at the end the following: “, except that the Secretary
 23 of Health and Human Services may destroy, without the
 24 opportunity for export, any drug refused admission under
 25 this section, if such drug is valued at an amount that is
 26 \$2,500 or less (or such higher amount as the Secretary of

1 *the Treasury may set by regulation pursuant to section*
 2 *498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))*
 3 *and was not brought into compliance as described under*
 4 *subsection (b).”.*

5 (b) NOTICE.—Subsection (a) of section 801 (21 U.S.C.
 6 381), as amended by subsection (a), is further amended by
 7 inserting after the sixth sentence the following: “The Sec-
 8 retary of Health and Human Services shall issue regula-
 9 tions providing for notice and an opportunity to appear
 10 before the Secretary of Health and Human Services and
 11 introduce testimony, as described in the first sentence of this
 12 subsection, on destruction of a drug under the sixth sentence
 13 of this subsection. The regulations shall provide that prior
 14 to destruction, appropriate due process is available to the
 15 owner or consignee seeking to challenge the decision to de-
 16 stroy the drug. Where the Secretary of Health and Human
 17 Services provides notice and an opportunity to appear and
 18 introduce testimony on the destruction of a drug, the Sec-
 19 retary of Health and Human Services shall store and, as
 20 applicable, dispose of the drug after the issuance of the no-
 21 tice, except that the owner and consignee shall remain liable
 22 for costs pursuant to subsection (c). Such process may be
 23 combined with the notice and opportunity to appear before
 24 the Secretary and introduce testimony, as described in the

1 *first sentence of this subsection, as long as appropriate no-*
 2 *tice is provided to the owner or consignee.”.*

3 (c) *APPLICABILITY.—The amendment made by sub-*
 4 *section (a) shall apply beginning on the effective date of*
 5 *the regulations promulgated pursuant to the amendment*
 6 *made by subsection (b).*

7 (d) *REGULATIONS.—*

8 (1) *IN GENERAL.—Not later than 2 years after*
 9 *the date of enactment of this Act, the Secretary of*
 10 *Health and Human Services shall adopt final regula-*
 11 *tions implementing the amendments made this sec-*
 12 *tion.*

13 (2) *PROCEDURE.—In promulgating a regulation*
 14 *implementing the amendments made by this section,*
 15 *the Secretary of Health and Human Services shall—*

16 (A) *issue a notice of proposed rulemaking*
 17 *that includes a copy of the proposed regulation;*

18 (B) *provide a period of not less than 60*
 19 *days for comments on the proposed regulation;*
 20 *and*

21 (C) *publish the final regulation not less*
 22 *than 30 days before the effective date of the regu-*
 23 *lation.*

24 (3) *RESTRICTIONS.—Notwithstanding any other*
 25 *provision of law, the Secretary of Health and Human*

1 *Services shall promulgate regulations implementing*
 2 *the amendments made by this section only as de-*
 3 *scribed in paragraph (2).*

4 **SEC. 709. ADMINISTRATIVE DETENTION.**

5 *(a) IN GENERAL.—Section 304(g) (21 U.S.C. 335a(g))*
 6 *is amended—*

7 *(1) in paragraph (1), by inserting “, drug,”*
 8 *after “device”, each place it appears;*

9 *(2) in paragraph (2)(A), by inserting “, drug,”*
 10 *after “(B), a device”; and*

11 *(3) in paragraph (2)(B), by inserting “or drug”*
 12 *after “device” each place it appears.*

13 *(b) REGULATIONS.—*

14 *(1) IN GENERAL.—Not later than 2 years after*
 15 *the date of the enactment of this Act, the Secretary of*
 16 *Health and Human Services shall promulgate regula-*
 17 *tions in accordance with section 304(i) of the Federal*
 18 *Food, Drug, and Cosmetic Act, as added by para-*
 19 *graph (2) of this subsection, to implement adminis-*
 20 *trative detention authority with respect to drugs, as*
 21 *authorized by the amendments made by subsection*
 22 *(a). Before promulgating such regulations, the Sec-*
 23 *retary shall consult with stakeholders, including man-*
 24 *ufacturers of drugs.*

1 (2) *IN GENERAL.*—Section 304 (21 U.S.C. 334)
 2 is amended by adding at the end the following:

3 “(i) *PROCEDURES FOR PROMULGATING REGULA-*
 4 *TIONS.*—

5 “(1) *IN GENERAL.*—In promulgating a regula-
 6 tion implementing this section, the Secretary shall—

7 “(A) issue a notice of proposed rulemaking
 8 that includes the proposed regulation;

9 “(B) provide a period of not less than 60
 10 days for comments on the proposed regulation;
 11 and

12 “(C) publish the final regulation not less
 13 than 30 days before the regulation’s effective
 14 date.

15 “(2) *RESTRICTIONS.*—Notwithstanding any other
 16 provision of Federal law, in implementing this sec-
 17 tion, the Secretary shall only promulgate regulations
 18 as described in paragraph (1).”.

19 “(c) *EFFECTIVE DATE.*—The amendments made by sub-
 20 section (a) shall not take effect until the Secretary has
 21 issued a final regulation under subsection (b).

22 **SEC. 710. EXCHANGE OF INFORMATION.**

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

1 (1) *by striking “CONFIDENTIAL INFORMATION”*
 2 *and all that follows through “The Secretary may pro-*
 3 *vide” and inserting the following:*

4 **“SEC. 708. CONFIDENTIAL INFORMATION.**

5 “(a) *CONTRACTORS.—The Secretary may provide*”;
 6 *and*

7 (2) *by adding at the end the following:*

8 “(b) *ABILITY TO RECEIVE AND PROTECT CONFIDEN-*
 9 *TIAL INFORMATION OBTAINED FROM FOREIGN GOVERN-*
 10 *MENTS.—*

11 “(1) *IN GENERAL.—The Secretary shall not be*
 12 *required to disclose under section 552 of title 5,*
 13 *United States Code (commonly referred to as the*
 14 *‘Freedom of Information Act’), or any other provision*
 15 *of law, any information relating to drugs obtained*
 16 *from a foreign government agency, if—*

17 “(A) *the information concerns the inspec-*
 18 *tion of a facility, is part of an investigation,*
 19 *alerts the United States to the potential need for*
 20 *an investigation, or concerns a drug that has a*
 21 *reasonable probability of causing serious adverse*
 22 *health consequences or death to humans or ani-*
 23 *mals;*

24 “(B) *the information is provided or made*
 25 *available to the United States Government vol-*

1 *untarily on the condition that it not be released*
2 *to the public; and*

3 “(C) *the information is covered by, and sub-*
4 *ject to, a written agreement between the Sec-*
5 *retary and the foreign government.*

6 “(2) *TIME LIMITATIONS.—The written agreement*
7 *described in paragraph (1)(C) shall specify the time*
8 *period for which paragraph (1) shall apply to the vol-*
9 *untarily disclosed information. Paragraph (1) shall*
10 *not apply with respect to such information after the*
11 *date specified in such agreement, but all other appli-*
12 *cable legal protections, including the provisions of sec-*
13 *tion 552 of title 5, United States Code, and section*
14 *319L(e)(1) of the Public Health Service Act, as appli-*
15 *cable, shall continue to apply to such information. If*
16 *no date is specified in the written agreement, para-*
17 *graph (1) shall not apply with respect to such infor-*
18 *mation for a period of more than 36 months.*

19 “(3) *DISCLOSURES NOT AFFECTED.—Nothing in*
20 *this section authorizes any official to withhold, or to*
21 *authorize the withholding of, information from Con-*
22 *gress or information required to be disclosed pursuant*
23 *to an order of a court of the United States.*

24 “(4) *RELATION TO OTHER LAW.—For purposes*
25 *of section 552 of title 5, United States Code, this sub-*

1 *section shall be considered a statute described in sub-*
 2 *section (b)(3)(B) of such section 552.*

3 *“(c) AUTHORITY TO ENTER INTO MEMORANDA OF UN-*
 4 *DERSTANDING FOR PURPOSES OF INFORMATION EX-*
 5 *CHANGE.—The Secretary may enter into written agree-*
 6 *ments to provide information referenced in section 301(j)*
 7 *to foreign governments subject to the following criteria:*

8 *“(1) CERTIFICATION.—The Secretary may enter*
 9 *into a written agreement to provide information*
 10 *under this subsection to a foreign government only if*
 11 *the Secretary has certified such government as having*
 12 *the authority and demonstrated ability to protect*
 13 *trade secret information from disclosure. Responsi-*
 14 *bility for this certification shall not be delegated to*
 15 *any officer or employee other than the Commissioner*
 16 *of Food and Drugs.*

17 *“(2) WRITTEN AGREEMENT.—The written agree-*
 18 *ment to provide information to the foreign govern-*
 19 *ment under this subsection shall include a commit-*
 20 *ment by the foreign government to protect informa-*
 21 *tion exchanged under this subsection from disclosure*
 22 *unless and until the sponsor gives written permission*
 23 *for disclosure or the Secretary makes a declaration of*
 24 *a public health emergency pursuant to section 319 of*

1 *the Public Health Service Act that is relevant to the*
2 *information.*

3 “(3) *INFORMATION EXCHANGE.*—*The Secretary*
4 *may provide to a foreign government that has been*
5 *certified under paragraph (1) and that has executed*
6 *a written agreement under paragraph (2) informa-*
7 *tion referenced in section 301(j) in only the following*
8 *circumstances:*

9 “(A) *Information concerning the inspection*
10 *of a facility may be provided to a foreign gov-*
11 *ernment if—*

12 “(i) *the Secretary reasonably believes,*
13 *or the written agreement described in para-*
14 *graph (2) establishes, that the government*
15 *has authority to otherwise obtain such in-*
16 *formation; and*

17 “(ii) *the written agreement executed*
18 *under paragraph (2) limits the recipient’s*
19 *use of the information to the recipient’s*
20 *civil regulatory purposes.*

21 “(B) *Information not described in subpara-*
22 *graph (A) may be provided as part of an inves-*
23 *tigation, or to alert the foreign government to the*
24 *potential need for an investigation, if the Sec-*
25 *retary has reasonable grounds to believe that a*

1 *drug has a reasonable probability of causing se-*
 2 *rious adverse health consequences or death to hu-*
 3 *mans or animals.*

4 “(4) *EFFECT OF SUBSECTION.*—*Nothing in this*
 5 *subsection affects the ability of the Secretary to enter*
 6 *into any written agreement authorized by other provi-*
 7 *sions of law to share confidential information.”.*

8 **SEC. 711. ENHANCING THE SAFETY AND QUALITY OF THE**
 9 **DRUG SUPPLY.**

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

12 *“For purposes of paragraph (a)(2)(B), the term ‘current*
 13 *good manufacturing practice’ includes the implementation*
 14 *of oversight and controls over the manufacture of drugs to*
 15 *ensure quality, including managing the risk of and estab-*
 16 *lishing the safety of raw materials, materials used in the*
 17 *manufacturing of drugs, and finished drug products.”.*

18 **SEC. 712. RECOGNITION OF FOREIGN GOVERNMENT IN-**
 19 **SPECTIONS.**

20 *Chapter VIII (21 U.S.C. 381 et seq.) is amended by*
 21 *adding at the end the following:*

22 **“SEC. 809. RECOGNITION OF FOREIGN GOVERNMENT IN-**
 23 **SPECTIONS.**

24 “(a) *INSPECTION.*—*The Secretary—*

1 “(1) may enter into arrangements and agree-
2 ments with a foreign government or an agency of a
3 foreign government to recognize the inspection of for-
4 eign establishments registered under section 510(i) in
5 order to facilitate risk-based inspections in accord-
6 ance with the schedule established in section
7 510(h)(3);

8 “(2) may enter into arrangements and agree-
9 ments with a foreign government or an agency of a
10 foreign government under this section only with a for-
11 eign government or an agency of a foreign govern-
12 ment that the Secretary has determined as having the
13 capability of conducting inspections that meet the ap-
14 plicable requirements of this Act; and

15 “(3) shall perform such reviews and audits of
16 drug safety programs, systems, and standards of a
17 foreign government or agency for the foreign govern-
18 ment as the Secretary deems necessary to determine
19 that the foreign government or agency of the foreign
20 government is capable of conducting inspections that
21 meet the applicable requirements of this Act.

22 “(b) RESULTS OF INSPECTION.—The results of inspec-
23 tions performed by a foreign government or an agency of
24 a foreign government under this section may be used as—

1 “(1) evidence of compliance with section
2 501(a)(2)(B) or section 801(r); and

3 “(2) for any other purposes as determined ap-
4 propriate by the Secretary.”.

5 **SEC. 713. STANDARDS FOR ADMISSION OF IMPORTED**
6 **DRUGS.**

7 Section 801 (21 U.S.C. 381) is amended—

8 (1) in subsection (o), by striking “drug or”; and

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

10 “(r)(1) The Secretary may require, pursuant to the
11 regulations promulgated under paragraph (4)(A), as a con-
12 dition of granting admission to a drug imported or offered
13 for import into the United States, that the importer elec-
14 tronically submit information demonstrating that the drug
15 complies with applicable requirements of this Act.

16 “(2) The information described under paragraph (1)
17 may include—

18 “(A) information demonstrating the regulatory
19 status of the drug, such as the new drug application,
20 abbreviated new drug application, or investigational
21 new drug or drug master file number;

22 “(B) facility information, such as proof of reg-
23 istration and the unique facility identifier;

24 “(C) indication of compliance with current good
25 manufacturing practice, testing results, certifications

1 *relating to satisfactory inspections, and compliance*
2 *with the country of export regulations; and*

3 “(D) *any other information deemed necessary*
4 *and appropriate by the Secretary to assess compli-*
5 *ance of the article being offered for import.*

6 “(3) *Information requirements referred to in para-*
7 *graph (2)(C) may, at the discretion of the Secretary, be sat-*
8 *isfied—*

9 “(A) *through representation by a foreign govern-*
10 *ment, if an inspection is conducted by a foreign gov-*
11 *ernment using standards and practices as determined*
12 *appropriate by the Secretary;*

13 “(B) *through representation by a foreign govern-*
14 *ment or an agency of a foreign government recognized*
15 *under section 809; or*

16 “(C) *other appropriate documentation or evi-*
17 *dence as described by the Secretary.*

18 “(4)(A) *Not later than 18 months after the date of en-*
19 *actment of the Food and Drug Administration Safety and*
20 *Innovation Act, the Secretary shall adopt final regulations*
21 *implementing this subsection. Such requirements shall be*
22 *appropriate for the type of import, such as whether the drug*
23 *is for import into the United States for use in preclinical*
24 *research or in a clinical investigation under an investiga-*
25 *tional new drug exemption under 505(i).*

1 “(B) In promulgating the regulations under subpara-
2 graph (A), the Secretary—

3 “(i) may, as appropriate, take into account dif-
4 ferences among importers and types of imports, and,
5 based on the level of risk posed by the imported drug,
6 provide for expedited clearance for those importers
7 that volunteer to participate in partnership programs
8 for highly compliant companies and pass a review of
9 internal controls, including sourcing of foreign manu-
10 facturing inputs, and plant inspections; and

11 “(ii) shall—

12 “(I) issue a notice of proposed rulemaking
13 that includes the proposed regulation;

14 “(II) provide a period of not less than 60
15 days for comments on the proposed regulation;
16 and

17 “(III) publish the final regulation not less
18 than 30 days before the effective date of the regu-
19 lation.

20 “(C) Notwithstanding any other provision of law, the
21 Secretary shall promulgate regulations implementing this
22 subsection only as described in subparagraph (B).”.

23 **SEC. 714. REGISTRATION OF COMMERCIAL IMPORTERS.**

24 (a) *PROHIBITIONS.*—Section 301 (21 U.S.C. 331) is
25 amended by adding at the end the following:

1 “(aaa) *The failure to register in accordance with sec-*
2 *tion 801(s).*”.

3 (b) *REGISTRATION.—Section 801 (21 U.S.C. 381), as*
4 *amended by section 713 of this Act, is further amended by*
5 *adding at the end the following:*

6 “(s) *REGISTRATION OF COMMERCIAL IMPORTERS.—*

7 “(1) *REGISTRATION.—The Secretary shall re-*
8 *quire a commercial importer of drugs—*

9 “(A) *to be registered with the Secretary in*
10 *a form and manner specified by the Secretary;*
11 *and*

12 “(B) *subject to paragraph (4), to submit, at*
13 *the time of registration, a unique identifier for*
14 *the principal place of business for which the im-*
15 *porter is required to register under this sub-*
16 *section.*

17 “(2) *REGULATIONS.—*

18 “(A) *IN GENERAL.—The Secretary, in con-*
19 *sultation with the Secretary of Homeland Secu-*
20 *rity acting through U.S. Customs and Border*
21 *Protection, shall promulgate regulations to estab-*
22 *lish good importer practices that specify the*
23 *measures an importer shall take to ensure im-*
24 *ported drugs are in compliance with the require-*

1 *ments of this Act and the Public Health Service*
2 *Act.*

3 “(B) *PROCEDURE.*—*In promulgating a reg-*
4 *ulation under subparagraph (A), the Secretary*
5 *shall—*

6 “(i) *issue a notice of proposed rule-*
7 *making that includes the proposed regula-*
8 *tion;*

9 “(ii) *provide a period of not less than*
10 *60 days for comments on the proposed regu-*
11 *lation; and*

12 “(iii) *publish the final regulation not*
13 *less than 30 days before the regulation’s ef-*
14 *fective date.*

15 “(C) *RESTRICTIONS.*—*Notwithstanding any*
16 *other provision of Federal law, in implementing*
17 *this subsection, the Secretary shall only promul-*
18 *gate regulations as described in subparagraph*
19 *(B).*

20 “(3) *DISCONTINUANCE OF REGISTRATION.*—*The*
21 *Secretary shall discontinue the registration of any*
22 *commercial importer of drugs that fails to comply*
23 *with the regulations promulgated under this sub-*
24 *section.*

1 “(4) *UNIQUE FACILITY IDENTIFIER.*—*The Sec-*
2 *retary shall specify the unique facility identifier sys-*
3 *tem that shall be used by registrants under paragraph*
4 *(1). The requirement to include a unique facility*
5 *identifier in a registration under paragraph (1) shall*
6 *not apply until the date that the identifier system is*
7 *specified by the Secretary under the preceding sen-*
8 *tence.*

9 “(5) *EXEMPTIONS.*—*The Secretary, by notice in*
10 *the Federal Register, may establish exemptions from*
11 *the requirements of this subsection.”.*

12 *(c) MISBRANDING.*—*Section 502(o) (21 U.S.C. 352) is*
13 *amended by inserting “if it is a drug and was imported*
14 *or offered for import by a commercial importer of drugs*
15 *not duly registered under section 801(s),” after “not duly*
16 *registered under section 510,”.*

17 *(d) REGULATIONS.*—

18 *(1) IN GENERAL.*—*Not later than 36 months*
19 *after the date of the enactment of this Act, the Sec-*
20 *retary of Health and Human Services, in consulta-*
21 *tion with the Secretary of Homeland Security acting*
22 *through U.S. Customs and Border Protection, shall*
23 *promulgate the regulations required to carry out sec-*
24 *tion 801(s) of the Federal Food, Drug, and Cosmetic*
25 *Act, as added by subsection (b).*

1 (2) *PROCEDURES FOR PROMULGATING REGULA-*
2 *TIONS.—*

3 (A) *IN GENERAL.—In promulgating a regu-*
4 *lation under paragraph (1), the Secretary*
5 *shall—*

6 (i) *issue a notice of proposed rule-*
7 *making that includes the proposed regula-*
8 *tion;*

9 (ii) *provide a period of not less than*
10 *60 days for comments on the proposed regu-*
11 *lation; and*

12 (iii) *publish the final regulation not*
13 *less than 30 days before the regulation’s ef-*
14 *fective date.*

15 (B) *RESTRICTIONS.—Notwithstanding any*
16 *other provision of Federal law, in implementing*
17 *section 801(s) of the Federal Food, Drug, and*
18 *Cosmetic Act, as added by subsection (b), the*
19 *Secretary shall promulgate regulations only as*
20 *described in subparagraph (A).*

21 (3) *EFFECTIVE DATE.—In establishing the effec-*
22 *tive date of the regulations under paragraph (1), the*
23 *Secretary of Health and Human Services shall, in*
24 *consultation with the Secretary of Homeland Security*
25 *acting through U.S. Customs and Border Protection,*

1 *as determined appropriate by the Secretary of Health*
 2 *and Human Services, provide a reasonable period of*
 3 *time for an importer of a drug to comply with good*
 4 *importer practices, taking into account differences*
 5 *among importers and types of imports, including*
 6 *based on the level of risk posed by the imported prod-*
 7 *uct.*

8 **SEC. 715. NOTIFICATION.**

9 *(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331),*
 10 *as amended by section 714 of this Act, is further amended*
 11 *by adding at the end the following:*

12 *“(bbb) The failure to notify the Secretary in violation*
 13 *of section 568.”.*

14 *(b) NOTIFICATION.—Subchapter E of chapter V (21*
 15 *U.S.C. 360bbb et seq.) is amended by adding at the end*
 16 *the following:*

17 **“SEC. 568. NOTIFICATION.**

18 *“(a) NOTIFICATION TO SECRETARY.—With respect to*
 19 *a drug, the Secretary may require notification to the Sec-*
 20 *retary by a regulated person if the regulated person*
 21 *knows—*

22 *“(1) that the use of such drug in the United*
 23 *States may result in serious injury or death;*

24 *“(2) of a significant loss or known theft of such*
 25 *drug intended for use in the United States; or*

1 “(3) *that—*

2 “(A) *such drug has been or is being counter-*
3 *feited; and*

4 “(B)(i) *the counterfeit product is in com-*
5 *merce in the United States or could be reason-*
6 *ably expected to be introduced into commerce in*
7 *the United States; or*

8 “(ii) *such drug has been or is being im-*
9 *ported into the United States or may reasonably*
10 *be expected to be offered for import into the*
11 *United States.*

12 “(b) *MANNER OF NOTIFICATION.—Notification under*
13 *this section shall be made in such manner and by such*
14 *means as the Secretary may specify by regulation or guid-*
15 *ance.*

16 “(c) *SAVINGS CLAUSE.—Nothing in this section shall*
17 *be construed as limiting any other authority of the Sec-*
18 *retary to require notifications related to a drug under any*
19 *other provision of this Act or the Public Health Service Act.*

20 “(d) *DEFINITION.—In this section, the term ‘regulated*
21 *person’ means—*

22 “(1) *a person who is required to register under*
23 *section 510 or 801(s);*

24 “(2) *a wholesale distributor of a drug product; or*

1 “(3) any other person that distributes drugs ex-
 2 cept a person that distributes drugs exclusively for re-
 3 tail sale.”.

4 **SEC. 716. PROTECTION AGAINST INTENTIONAL ADULTERA-**
 5 **TION.**

6 Section 303(b) (21 U.S.C. 333(b)) is amended by add-
 7 ing at the end the following:

8 “(7) Notwithstanding subsection (a)(2), any person
 9 that knowingly and intentionally adulterates a drug such
 10 that the drug is adulterated under subsection (a)(1), (b),
 11 (c), or (d) of section 501 and has a reasonable probability
 12 of causing serious adverse health consequences or death to
 13 humans or animals shall be imprisoned for not more than
 14 20 years or fined not more than \$1,000,000, or both.”.

15 **SEC. 717. PENALTIES FOR COUNTERFEITING DRUGS.**

16 (a) COUNTERFEIT DRUG PENALTY ENHANCEMENT.—

17 (1) OFFENSE.—Section 2320(a) of title 18,
 18 United States Code, is amended—

19 (A) by striking “or” at the end of para-
 20 graph (2);

21 (B) by inserting “or” at the end of para-
 22 graph (3);

23 (C) by inserting after paragraph (3) the fol-
 24 lowing:

25 “(4) traffics in a counterfeit drug,”; and

1 (D) by striking “through (3)” and inserting
2 “through (4)”.

3 (2) *PENALTIES*.—Section 2320(b)(3) of title 18,
4 *United States Code*, is amended—

5 (A) in the heading, by inserting “AND
6 COUNTERFEIT DRUGS” after “SERVICES”; and

7 (B) by inserting “or counterfeit drug” after
8 “service”.

9 (3) *DEFINITION*.—Section 2320(f) of title 18,
10 *United States Code*, is amended—

11 (A) by striking “and” at the end of para-
12 graph (4);

13 (B) by striking the period at the end of
14 paragraph (5) and inserting “; and”; and

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

16 “(6) the term ‘counterfeit drug’ means a drug, as
17 defined by section 201 of the Federal Food, Drug, and
18 Cosmetic Act, that uses a counterfeit mark on or in
19 connection with the drug.”.

20 (4) *PRIORITY GIVEN TO CERTAIN INVESTIGA-*
21 *TIONS AND PROSECUTIONS*.—The Attorney General
22 shall give increased priority to efforts to investigate
23 and prosecute offenses under section 2320 of title 18,
24 *United States Code*, that involve counterfeit drugs.

25 (b) *SENTENCING COMMISSION DIRECTIVE*.—

1 (1) *DIRECTIVE TO SENTENCING COMMISSION.*—
2 *Pursuant to its authority under section 994(p) of title*
3 *28, United States Code, and in accordance with this*
4 *subsection, the United States Sentencing Commission*
5 *shall review and amend, if appropriate, its guidelines*
6 *and its policy statements applicable to persons con-*
7 *victed of an offense described in section 2320(a)(4) of*
8 *title 18, United States Code, as amended by sub-*
9 *section (a), in order to reflect the intent of Congress*
10 *that such penalties be increased in comparison to*
11 *those currently provided by the guidelines and policy*
12 *statements.*

13 (2) *REQUIREMENTS.*—*In carrying out this sub-*
14 *section, the Commission shall—*

15 (A) *ensure that the sentencing guidelines*
16 *and policy statements reflect the intent of Con-*
17 *gress that the guidelines and policy statements*
18 *reflect the serious nature of the offenses described*
19 *in paragraph (1) and the need for an effective*
20 *deterrent and appropriate punishment to prevent*
21 *such offenses;*

22 (B) *consider the extent to which the guide-*
23 *lines may or may not appropriately account for*
24 *the potential and actual harm to the public re-*
25 *sulting from the offense;*

1 (C) assure reasonable consistency with other
2 relevant directives and with other sentencing
3 guidelines;

4 (D) account for any additional aggravating
5 or mitigating circumstances that might justify
6 exceptions to the generally applicable sentencing
7 ranges;

8 (E) make any necessary conforming changes
9 to the sentencing guidelines; and

10 (F) assure that the guidelines adequately
11 meet the purposes of sentencing as set forth in
12 section 3553(a)(2) of title 18, United States
13 Code.

14 **SEC. 718. EXTRATERRITORIAL JURISDICTION.**

15 Chapter III (21 U.S.C. 331 et seq.) is amended by add-
16 ing at the end the following:

17 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

18 “There is extraterritorial jurisdiction over any viola-
19 tion of this Act relating to any article regulated under this
20 Act if such article was intended for import into the United
21 States or if any act in furtherance of the violation was com-
22 mitted in the United States.”.

1 **TITLE VIII—GENERATING**
 2 **ANTIBIOTIC INCENTIVES NOW**

3 **SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

4 (a) *IN GENERAL.*—Chapter V (21 U.S.C. 351 et seq.)
 5 is amended by inserting after section 505D the following:

6 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**
 7 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

8 “(a) *EXTENSION.*—If the Secretary approves an appli-
 9 cation pursuant to section 505 for a drug that has been
 10 designated as a qualified infectious disease product under
 11 subsection (d), the 4- and 5-year periods described in sub-
 12 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the
 13 3-year periods described in clauses (iii) and (iv) of sub-
 14 section (c)(3)(E) and clauses (iii) and (iv) of subsection
 15 (j)(5)(F) of section 505, or the 7-year period described in
 16 section 527, as applicable, shall be extended by 5 years.

17 “(b) *RELATION TO PEDIATRIC EXCLUSIVITY.*—Any ex-
 18 tension under subsection (a) of a period shall be in addition
 19 to any extension of the period under section 505A with re-
 20 spect to the drug.

21 “(c) *LIMITATIONS.*—Subsection (a) does not apply to
 22 the approval of—

23 “(1) a supplement to an application under sec-
 24 tion 505(b) for any qualified infectious disease prod-

1 *uct for which an extension described in subsection (a)*
2 *is in effect or has expired;*

3 *“(2) a subsequent application filed with respect*
4 *to a product approved under section 505 for a change*
5 *that results in a new indication, route of administra-*
6 *tion, dosing schedule, dosage form, delivery system,*
7 *delivery device, or strength; or*

8 *“(3) a product that does not meet the definition*
9 *of a qualified infectious disease product under sub-*
10 *section (g) based upon its approved uses.*

11 *“(d) DESIGNATION.—*

12 *“(1) IN GENERAL.—The manufacturer or sponsor*
13 *of a drug may request the Secretary to designate a*
14 *drug as a qualified infectious disease product at any*
15 *time before the submission of an application under*
16 *section 505(b) for such drug. The Secretary shall, not*
17 *later than 60 days after the submission of such a re-*
18 *quest, determine whether the drug is a qualified infec-*
19 *tious disease product.*

20 *“(2) LIMITATION.—Except as provided in para-*
21 *graph (3), a designation under this subsection shall*
22 *not be withdrawn for any reason, including modifica-*
23 *tions to the list of qualifying pathogens under sub-*
24 *section (f)(2)(C).*

1 “(3) *REVOCATION OF DESIGNATION.*—*The Sec-*
 2 *retary may revoke a designation of a drug as a quali-*
 3 *fied infectious disease product if the Secretary finds*
 4 *that the request for such designation contained an un-*
 5 *true statement of material fact.*

6 “(e) *REGULATIONS.*—

7 “(1) *IN GENERAL.*—*Not later than 2 years after*
 8 *the date of enactment of the Food and Drug Adminis-*
 9 *tration Safety and Innovation Act, the Secretary*
 10 *shall adopt final regulations implementing this sec-*
 11 *tion, including developing the list of qualifying*
 12 *pathogens described in subsection (f).*

13 “(2) *PROCEDURE.*—*In promulgating a regula-*
 14 *tion implementing this section, the Secretary shall—*

15 “(A) *issue a notice of proposed rulemaking*
 16 *that includes the proposed regulation;*

17 “(B) *provide a period of not less than 60*
 18 *days for comments on the proposed regulation;*
 19 *and*

20 “(C) *publish the final regulation not less*
 21 *than 30 days before the effective date of the regu-*
 22 *lation.*

23 “(3) *RESTRICTIONS.*—*Notwithstanding any other*
 24 *provision of law, the Secretary shall promulgate regu-*
 25 *lations implementing this section only as described in*

1 paragraph (2), except that the Secretary may issue
 2 interim guidance for sponsors seeking designation
 3 under subsection (d) prior to the promulgation of
 4 such regulations.

5 “(4) DESIGNATION PRIOR TO REGULATIONS.—
 6 The Secretary shall designate drugs as qualified infec-
 7 tious disease products under subsection (d) prior to
 8 the promulgation of regulations under this subsection,
 9 if such drugs meet the definition of a qualified infec-
 10 tious disease product described in subsection (g).

11 “(f) QUALIFYING PATHOGEN.—

12 “(1) DEFINITION.—In this section, the term
 13 ‘qualifying pathogen’ means a pathogen identified
 14 and listed by the Secretary under paragraph (2) that
 15 has the potential to pose a serious threat to public
 16 health, such as—

17 “(A) resistant gram positive pathogens, in-
 18 cluding methicillin-resistant *Staphylococcus*
 19 *aureus*, vancomycin-resistant *Staphylococcus*
 20 *aureus*, and vancomycin-resistant enterococcus;

21 “(B) multi-drug resistant gram negative
 22 bacteria, including *Acinetobacter*, *Klebsiella*,
 23 *Pseudomonas*, and *E. coli* species;

24 “(C) multi-drug resistant tuberculosis; and

25 “(D) *Clostridium difficile*.

1 “(2) *LIST OF QUALIFYING PATHOGENS.*—

2 “(A) *IN GENERAL.*—*The Secretary shall es-*
 3 *tablish and maintain a list of qualifying patho-*
 4 *gens, and shall make public the methodology for*
 5 *developing such list.*

6 “(B) *CONSIDERATIONS.*—*In establishing*
 7 *and maintaining the list of pathogens described*
 8 *under this section, the Secretary shall—*

9 “(i) *consider—*

10 “(I) *the impact on the public*
 11 *health due to drug-resistant organisms*
 12 *in humans;*

13 “(II) *the rate of growth of drug-*
 14 *resistant organisms in humans;*

15 “(III) *the increase in resistance*
 16 *rates in humans; and*

17 “(IV) *the morbidity and mortality*
 18 *in humans; and*

19 “(ii) *consult with experts in infectious*
 20 *diseases and antibiotic resistance, including*
 21 *the Centers for Disease Control and Preven-*
 22 *tion, the Food and Drug Administration,*
 23 *medical professionals, and the clinical re-*
 24 *search community.*

1 “(C) *REVIEW.*—Every 5 years, or more
 2 often as needed, the Secretary shall review, pro-
 3 vide modifications to, and publish the list of
 4 qualifying pathogens under subparagraph (A)
 5 and shall by regulation revise the list as nec-
 6 essary, in accordance with subsection (e).

7 “(g) *QUALIFIED INFECTIOUS DISEASE PRODUCT.*—
 8 The term ‘qualified infectious disease product’ means an
 9 antibacterial or antifungal drug for human use intended
 10 to treat serious or life-threatening infections, including
 11 those caused by—

12 “(1) an antibacterial or antifungal resistant
 13 pathogen, including novel or emerging infectious
 14 pathogens; or

15 “(2) qualifying pathogens listed by the Secretary
 16 under subsection (f).”.

17 (b) *APPLICATION.*—Section 505E of the Federal Food,
 18 Drug, and Cosmetic Act, as added by subsection (a), applies
 19 only with respect to a drug that is first approved under
 20 section 505(c) of such Act (21 U.S.C. 355(c)) on or after
 21 the date of the enactment of this Act.

22 **SEC. 802. PRIORITY REVIEW.**

23 (a) *AMENDMENT.*—Chapter V (21 U.S.C. 351 et seq.)
 24 is amended by inserting after section 524 the following:

1 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**
 2 **DISEASE PRODUCTS.**

3 *“If the Secretary designates a drug under section*
 4 *505E(d) as a qualified infectious disease product, then the*
 5 *Secretary shall give priority review to any application sub-*
 6 *mitted for approval for such drug under section 505(b).”.*

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

12 **SEC. 803. FAST TRACK PRODUCT.**

13 *Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended*
 14 *by section 901(b) of this Act, is amended by inserting “,*
 15 *or if the Secretary designates the drug as a qualified infec-*
 16 *tious disease product under section 505E(d)” before the pe-*
 17 *riod at the end of the first sentence.*

18 **SEC. 804. CLINICAL TRIALS.**

19 *(a) REVIEW AND REVISION OF GUIDANCE DOCU-*
 20 *MENTS.—*

21 *(1) IN GENERAL.—The Secretary of Health and*
 22 *Human Services (referred to in this section as the*
 23 *“Secretary”) shall review and, as appropriate, revise*
 24 *not fewer than 3 guidance documents per year, which*
 25 *shall include—*

1 (A) reviewing the guidance documents of the
2 Food and Drug Administration for the conduct
3 of clinical trials with respect to antibacterial
4 and antifungal drugs; and

5 (B) as appropriate, revising such guidance
6 documents to reflect developments in scientific
7 and medical information and technology and to
8 ensure clarity regarding the procedures and re-
9 quirements for approval of antibacterial and
10 antifungal drugs under chapter V of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et
12 seq.).

13 (2) *ISSUES FOR REVIEW.*—At a minimum, the
14 review under paragraph (1) shall address the appro-
15 priate animal models of infection, in vitro techniques,
16 valid microbiological surrogate markers, the use of
17 noninferiority versus superiority trials, trial enroll-
18 ment, data requirements, and appropriate delta val-
19 ues for noninferiority trials.

20 (3) *RULE OF CONSTRUCTION.*—Except to the ex-
21 tent to which the Secretary makes revisions under
22 paragraph (1)(B), nothing in this section shall be
23 construed to repeal or otherwise effect the guidance
24 documents of the Food and Drug Administration.

25 (b) *RECOMMENDATIONS FOR INVESTIGATIONS.*—

1 (1) *REQUEST.*—*The sponsor of a drug intended*
2 *to be designated as a qualified infectious disease prod-*
3 *uct may request that the Secretary provide written*
4 *recommendations for nonclinical and clinical inves-*
5 *tigations which the Secretary believes may be nec-*
6 *essary to be conducted with the drug before such drug*
7 *may be approved under section 505 of the Federal*
8 *Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use*
9 *in treating, detecting, preventing, or identifying a*
10 *qualifying pathogen, as defined in section 505E of*
11 *such Act.*

12 (2) *RECOMMENDATIONS.*—*If the Secretary has*
13 *reason to believe that a drug for which a request is*
14 *made under this subsection is a qualified infectious*
15 *disease product, the Secretary shall provide the person*
16 *making the request written recommendations for the*
17 *nonclinical and clinical investigations which the Sec-*
18 *retary believes, on the basis of information available*
19 *to the Secretary at the time of the request, would be*
20 *necessary for approval under section 505 of the Fed-*
21 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)*
22 *of such drug for the use described in paragraph (1).*

23 (c) *QUALIFIED INFECTIOUS DISEASE PRODUCT.*—*For*
24 *purposes of this section, the term “qualified infectious dis-*
25 *ease product” has the meaning given such term in section*

1 505E(g) of the Federal Food, Drug, and Cosmetic Act, as
2 added by section 801 of this Act.

3 **SEC. 805. REASSESSMENT OF QUALIFIED INFECTIOUS DIS-**
4 **EASE PRODUCT INCENTIVES IN 5 YEARS.**

5 (a) *IN GENERAL.*—Not later than 5 years after the
6 date of enactment of this Act, the Secretary of Health and
7 Human Services shall, in consultation with the Food and
8 Drug Administration, the Centers for Disease Control and
9 Prevention, and other appropriate agencies, submit to the
10 Committee on Energy and Commerce of the House of Rep-
11 resentatives and the Committee on Health, Education,
12 Labor, and Pensions of the Senate a report that contains
13 the following:

14 (1)(A) *The number of initial designations of*
15 *drugs as qualified infectious disease products under*
16 *section 505E of the Federal Food, Drug, and Cosmetic*
17 *Act.*

18 (B) *The number of qualified infectious disease*
19 *products approved under such section 505E.*

20 (C) *Whether such products address the need for*
21 *antibacterial and antifungal drugs to treat serious*
22 *and life-threatening infections.*

23 (D) *A list of qualified infectious disease products*
24 *with information on the types of exclusivity granted*
25 *for each product, consistent with the information pub-*

lished under section 505(j)(7)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)(iii)).

(E) The progress made regarding the review and revision of the clinical trial guidance documents required under section 804 and the impact such review and revision has had on the review and approval of qualified infectious disease products.

(F) The Federal contribution, if any, to funding of the clinical trials for each qualified infectious disease product for each phase.

(2) Recommendations—

(A) based on the information under paragraph (1) and any other relevant data, on any changes that should be made to the list of pathogens that are defined as qualifying pathogens under section 505E(f)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 801 of this Act; and

(B) on whether any additional program (such as the development of public-private collaborations to advance antibacterial drug innovation) or changes to the incentives under this subtitle may be needed to promote the development of antibacterial drugs.

1 (3) *An examination of—*

2 (A) *the adoption of programs to measure*
3 *the use of antibacterial drugs in health care set-*
4 *tings; and*

5 (B) *the implementation and effectiveness of*
6 *antimicrobial stewardship protocols across all*
7 *health care settings.*

8 (4) *Any recommendations for ways to encourage*
9 *further development and establishment of stewardship*
10 *programs.*

11 (5) *A description of the regulatory challenges*
12 *and impediments to clinical development, approval,*
13 *and licensure of qualified infectious disease products,*
14 *and the steps the Secretary has taken and will take*
15 *to address such challenges and ensure regulatory cer-*
16 *tainty and predictability with respect to qualified in-*
17 *fectious disease products.*

18 (b) *DEFINITION.—For purposes of this section, the*
19 *term “qualified infectious disease product” has the meaning*
20 *given such term in section 505E(g) of the Federal Food,*
21 *Drug, and Cosmetic Act, as added by section 801 of this*
22 *Act.*

1 **SEC. 806. GUIDANCE ON PATHOGEN-FOCUSED ANTI-**
 2 **BACTERIAL DRUG DEVELOPMENT.**

3 (a) *DRAFT GUIDANCE.*—Not later than June 30, 2013,
 4 in order to facilitate the development of antibacterial drugs
 5 for serious or life-threatening bacterial infections, particu-
 6 larly in areas of unmet need, the Secretary of Health and
 7 Human Services shall publish draft guidance that—

8 (1) specifies how preclinical and clinical data
 9 can be utilized to inform an efficient and streamlined
 10 pathogen-focused antibacterial drug development pro-
 11 gram that meets the approval standards of the Food
 12 and Drug Administration; and

13 (2) provides advice on approaches for the devel-
 14 opment of antibacterial drugs that target a more lim-
 15 ited spectrum of pathogens.

16 (b) *FINAL GUIDANCE.*—Not later than December 31,
 17 2014, after notice and opportunity for public comment on
 18 the draft guidance under subsection (a), the Secretary of
 19 Health and Human Services shall publish final guidance
 20 consistent with this section.

21 **TITLE IX—DRUG APPROVAL AND**
 22 **PATIENT ACCESS**

23 **SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT AC-**
 24 **CESS TO NEW MEDICAL TREATMENTS.**

25 (a) *FINDINGS; SENSE OF CONGRESS.*—

26 (1) *FINDINGS.*—Congress finds as follows:

1 (A) *The Food and Drug Administration (re-*
2 *ferred to in this section as the “FDA”)* serves a
3 *critical role in helping to assure that new medi-*
4 *cines are safe and effective. Regulatory innova-*
5 *tion is 1 element of the Nation’s strategy to ad-*
6 *dress serious and life-threatening diseases or con-*
7 *ditions by promoting investment in and develop-*
8 *ment of innovative treatments for unmet medical*
9 *needs.*

10 (B) *During the 2 decades following the es-*
11 *tablishment of the accelerated approval mecha-*
12 *nism, advances in medical sciences, including*
13 *genomics, molecular biology, and bioinformatics,*
14 *have provided an unprecedented understanding*
15 *of the underlying biological mechanism and*
16 *pathogenesis of disease. A new generation of*
17 *modern, targeted medicines is under development*
18 *to treat serious and life-threatening diseases,*
19 *some applying drug development strategies based*
20 *on biomarkers or pharmacogenomics, predictive*
21 *toxicology, clinical trial enrichment techniques,*
22 *and novel clinical trial designs, such as adaptive*
23 *clinical trials.*

24 (C) *As a result of these remarkable scientific*
25 *and medical advances, the FDA should be en-*

1 *couraged to implement more broadly effective*
2 *processes for the expedited development and re-*
3 *view of innovative new medicines intended to*
4 *address unmet medical needs for serious or life-*
5 *threatening diseases or conditions, including*
6 *those for rare diseases or conditions, using a*
7 *broad range of surrogate or clinical endpoints*
8 *and modern scientific tools earlier in the drug*
9 *development cycle when appropriate. This may*
10 *result in fewer, smaller, or shorter clinical trials*
11 *for the intended patient population or targeted*
12 *subpopulation without compromising or altering*
13 *the high standards of the FDA for the approval*
14 *of drugs.*

15 *(D) Patients benefit from expedited access to*
16 *safe and effective innovative therapies to treat*
17 *unmet medical needs for serious or life-threat-*
18 *ening diseases or conditions.*

19 *(E) For these reasons, the statutory author-*
20 *ity in effect on the day before the date of enact-*
21 *ment of this Act governing expedited approval of*
22 *drugs for serious or life-threatening diseases or*
23 *conditions should be amended in order to en-*
24 *hance the authority of the FDA to consider ap-*
25 *propriate scientific data, methods, and tools, and*

1 to expedite development and access to novel
 2 treatments for patients with a broad range of se-
 3 rious or life-threatening diseases or conditions.

4 (2) *SENSE OF CONGRESS.*—*It is the sense of*
 5 *Congress that the Food and Drug Administration*
 6 *should apply the accelerated approval and fast track*
 7 *provisions set forth in section 506 of the Federal*
 8 *Food, Drug, and Cosmetic Act (21 U.S.C. 356), as*
 9 *amended by this section, to help expedite the develop-*
 10 *ment and availability to patients of treatments for se-*
 11 *rious or life-threatening diseases or conditions while*
 12 *maintaining safety and effectiveness standards for*
 13 *such treatments.*

14 (b) *EXPEDITED APPROVAL OF DRUGS FOR SERIOUS*
 15 *OR LIFE-THREATENING DISEASES OR CONDITIONS.*—*Sec-*
 16 *tion 506 (21 U.S.C. 356) is amended to read as follows:*

17 **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**
 18 **OR LIFE-THREATENING DISEASES OR CONDI-**
 19 **TIONS.**

20 “(a) *DESIGNATION OF DRUG AS FAST TRACK PROD-*
 21 *UCT.*—

22 “(1) *IN GENERAL.*—*The Secretary shall, at the*
 23 *request of the sponsor of a new drug, facilitate the de-*
 24 *velopment and expedite the review of such drug if it*
 25 *is intended, whether alone or in combination with one*

1 or more other drugs, for the treatment of a serious or
 2 life-threatening disease or condition, and it dem-
 3 onstrates the potential to address unmet medical
 4 needs for such a disease or condition. (In this section,
 5 such a drug is referred to as a ‘fast track product’.)

6 “(2) *REQUEST FOR DESIGNATION.*—The sponsor
 7 of a new drug may request the Secretary to designate
 8 the drug as a fast track product. A request for the des-
 9 ignation may be made concurrently with, or at any
 10 time after, submission of an application for the inves-
 11 tigation of the drug under section 505(i) or section
 12 351(a)(3) of the Public Health Service Act.

13 “(3) *DESIGNATION.*—Within 60 calendar days
 14 after the receipt of a request under paragraph (2), the
 15 Secretary shall determine whether the drug that is the
 16 subject of the request meets the criteria described in
 17 paragraph (1). If the Secretary finds that the drug
 18 meets the criteria, the Secretary shall designate the
 19 drug as a fast track product and shall take such ac-
 20 tions as are appropriate to expedite the development
 21 and review of the application for approval of such
 22 product.

23 “(b) *ACCELERATED APPROVAL OF A DRUG FOR A SE-*
 24 *RIOUS OR LIFE-THREATENING DISEASE OR CONDITION, IN-*
 25 *CLUDING A FAST TRACK PRODUCT.*—

1 “(1) *IN GENERAL.*—

2 “(A) *ACCELERATED APPROVAL.*—*The Sec-*
 3 *retary may approve an application for approval*
 4 *of a product for a serious or life-threatening dis-*
 5 *ease or condition, including a fast track product,*
 6 *under section 505(c) or section 351(a) of the*
 7 *Public Health Service Act upon a determination*
 8 *that the product has an effect on a surrogate*
 9 *endpoint that is reasonably likely to predict clin-*
 10 *ical benefit, or on a clinical endpoint that can*
 11 *be measured earlier than irreversible morbidity*
 12 *or mortality, that is reasonably likely to predict*
 13 *an effect on irreversible morbidity or mortality*
 14 *or other clinical benefit, taking into account the*
 15 *severity, rarity, or prevalence of the condition*
 16 *and the availability or lack of alternative treat-*
 17 *ments. The approval described in the preceding*
 18 *sentence is referred to in this section as ‘acceler-*
 19 *ated approval’.*

20 “(B) *EVIDENCE.*—*The evidence to support*
 21 *that an endpoint is reasonably likely to predict*
 22 *clinical benefit under subparagraph (A) may in-*
 23 *clude epidemiological, pathophysiological, thera-*
 24 *peutic, pharmacologic, or other evidence devel-*

1 *oped using biomarkers, for example, or other sci-*
2 *entific methods or tools.*

3 “(2) *LIMITATION.—Approval of a product under*
4 *this subsection may be subject to 1 or both of the fol-*
5 *lowing requirements:*

6 “(A) *That the sponsor conduct appropriate*
7 *postapproval studies to verify and describe the*
8 *predicted effect on irreversible morbidity or mor-*
9 *tality or other clinical benefit.*

10 “(B) *That the sponsor submit copies of all*
11 *promotional materials related to the product*
12 *during the preapproval review period and, fol-*
13 *lowing approval and for such period thereafter*
14 *as the Secretary determines to be appropriate, at*
15 *least 30 days prior to dissemination of the mate-*
16 *rials.*

17 “(3) *EXPEDITED WITHDRAWAL OF APPROVAL.—*
18 *The Secretary may withdraw approval of a product*
19 *approved under accelerated approval using expedited*
20 *procedures (as prescribed by the Secretary in regula-*
21 *tions which shall include an opportunity for an infor-*
22 *mal hearing) if—*

23 “(A) *the sponsor fails to conduct any re-*
24 *quired postapproval study of the drug with due*
25 *diligence;*

1 “(B) a study required to verify and describe
2 the predicted effect on irreversible morbidity or
3 mortality or other clinical benefit of the product
4 fails to verify and describe such effect or benefit;

5 “(C) other evidence demonstrates that the
6 product is not safe or effective under the condi-
7 tions of use; or

8 “(D) the sponsor disseminates false or mis-
9 leading promotional materials with respect to
10 the product.

11 “(c) *REVIEW OF INCOMPLETE APPLICATIONS FOR AP-*
12 *PROVAL OF A FAST TRACK PRODUCT.—*

13 “(1) *IN GENERAL.—If the Secretary determines,*
14 *after preliminary evaluation of clinical data sub-*
15 *mitted by the sponsor, that a fast track product may*
16 *be effective, the Secretary shall evaluate for filing, and*
17 *may commence review of portions of, an application*
18 *for the approval of the product before the sponsor sub-*
19 *mits a complete application. The Secretary shall com-*
20 *mence such review only if the applicant—*

21 “(A) provides a schedule for submission of
22 information necessary to make the application
23 complete; and

24 “(B) pays any fee that may be required
25 under section 736.

1 “(2) *EXCEPTION.*—*Any time period for review of*
2 *human drug applications that has been agreed to by*
3 *the Secretary and that has been set forth in goals*
4 *identified in letters of the Secretary (relating to the*
5 *use of fees collected under section 736 to expedite the*
6 *drug development process and the review of human*
7 *drug applications) shall not apply to an application*
8 *submitted under paragraph (1) until the date on*
9 *which the application is complete.*

10 “(d) *AWARENESS EFFORTS.*—*The Secretary shall—*

11 “(1) *develop and disseminate to physicians, pa-*
12 *tient organizations, pharmaceutical and biotechnology*
13 *companies, and other appropriate persons a descrip-*
14 *tion of the provisions of this section applicable to ac-*
15 *celerated approval and fast track products; and*

16 “(2) *establish a program to encourage the devel-*
17 *opment of surrogate and clinical endpoints, including*
18 *biomarkers, and other scientific methods and tools*
19 *that can assist the Secretary in determining whether*
20 *the evidence submitted in an application is reason-*
21 *ably likely to predict clinical benefit for serious or*
22 *life-threatening conditions for which significant*
23 *unmet medical needs exist.*

24 “(e) *CONSTRUCTION.*—

1 “(1) *PURPOSE.*—*The amendments made by the*
2 *Food and Drug Administration Safety and Innova-*
3 *tion Act to this section are intended to encourage the*
4 *Secretary to utilize innovative and flexible approaches*
5 *to the assessment of products under accelerated ap-*
6 *proval for treatments for patients with serious or life-*
7 *threatening diseases or conditions and unmet medical*
8 *needs.*

9 “(2) *CONSTRUCTION.*—*Nothing in this section*
10 *shall be construed to alter the standards of evidence*
11 *under subsection (c) or (d) of section 505 (including*
12 *the substantial evidence standard in section 505(d))*
13 *of this Act or under section 351(a) of the Public*
14 *Health Service Act. Such sections and standards of*
15 *evidence apply to the review and approval of products*
16 *under this section, including whether a product is*
17 *safe and effective. Nothing in this section alters the*
18 *ability of the Secretary to rely on evidence that does*
19 *not come from adequate and well-controlled investiga-*
20 *tions for the purpose of determining whether an end-*
21 *point is reasonably likely to predict clinical benefit as*
22 *described in subsection (b)(1)(B).”.*

23 *(c) GUIDANCE; AMENDED REGULATIONS.*—

24 *(1) DRAFT GUIDANCE.*—*Not later than 1 year*
25 *after the date of enactment of this Act, the Secretary*

1 of Health and Human Services (referred to in this
2 section as the “Secretary”) shall issue draft guidance
3 to implement the amendments made by this section.
4 In developing such guidance, the Secretary shall spe-
5 cifically consider issues arising under the accelerated
6 approval and fast track processes under section 506
7 of the Federal Food, Drug, and Cosmetic Act, as
8 amended by subsection (b), for drugs designated for a
9 rare disease or condition under section 526 of such
10 Act (21 U.S.C. 360bb) and shall also consider any
11 unique issues associated with very rare diseases.

12 (2) *FINAL GUIDANCE*.—Not later than 1 year
13 after the issuance of draft guidance under paragraph
14 (1), and after an opportunity for public comment, the
15 Secretary shall—

16 (A) issue final guidance; and

17 (B) amend the regulations governing accel-
18 erated approval in parts 314 and 601 of title 21,
19 Code of Federal Regulations, as necessary to con-
20 form such regulations with the amendment made
21 by subsection (b).

22 (3) *CONSIDERATION*.—In developing the guid-
23 ance under paragraphs (1) and (2)(A) and the
24 amendments under paragraph (2)(B), the Secretary
25 shall consider how to incorporate novel approaches to

1 *the review of surrogate endpoints based on patho-*
2 *physiologic and pharmacologic evidence in such guid-*
3 *ance, especially in instances where the low prevalence*
4 *of a disease renders the existence or collection of other*
5 *types of data unlikely or impractical.*

6 (4) *CONFORMING CHANGES.—The Secretary shall*
7 *issue, as necessary, conforming amendments to the*
8 *applicable regulations under title 21, Code of Federal*
9 *Regulations, governing accelerated approval.*

10 (5) *NO EFFECT OF INACTION ON REQUESTS.—*
11 *The issuance (or nonissuance) of guidance or con-*
12 *forming regulations implementing the amendment*
13 *made by subsection (b) shall not preclude the review*
14 *of, or action on, a request for designation or an ap-*
15 *plication for approval submitted pursuant to section*
16 *506 of the Federal Food, Drug, and Cosmetic Act, as*
17 *amended by subsection (b).*

18 (d) *INDEPENDENT REVIEW.—The Secretary may, in*
19 *conjunction with other planned reviews, contract with an*
20 *independent entity with expertise in assessing the quality*
21 *and efficiency of biopharmaceutical development and regu-*
22 *latory review programs to evaluate the Food and Drug Ad-*
23 *ministration's application of the processes described in sec-*
24 *tion 506 of the Federal Food, Drug, and Cosmetic Act, as*
25 *amended by subsection (b), and the impact of such processes*

1 *on the development and timely availability of innovative*
2 *treatments for patients suffering from serious or life-threat-*
3 *ening conditions. Any such evaluation shall include con-*
4 *sultation with regulated industries, patient advocacy and*
5 *disease research foundations, and relevant academic med-*
6 *ical centers.*

7 **SEC. 902. BREAKTHROUGH THERAPIES.**

8 *(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as*
9 *amended by section 901 of this Act, is further amended—*

10 *(1) by redesignating subsections (a) through (c)*
11 *as subsections (b) through (d), respectively;*

12 *(2) by redesignating subsection (d) as subsection*
13 *(f);*

14 *(3) by inserting before subsection (b), as so redes-*
15 *ignated, the following:*

16 *“(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH*
17 *THERAPY.—*

18 *“(1) IN GENERAL.—The Secretary shall, at the*
19 *request of the sponsor of a drug, expedite the develop-*
20 *ment and review of such drug if the drug is intended,*
21 *alone or in combination with 1 or more other drugs,*
22 *to treat a serious or life-threatening disease or condi-*
23 *tion and preliminary clinical evidence indicates that*
24 *the drug may demonstrate substantial improvement*
25 *over existing therapies on 1 or more clinically signifi-*

1 *cant endpoints, such as substantial treatment effects*
2 *observed early in clinical development. (In this sec-*
3 *tion, such a drug is referred to as a 'breakthrough*
4 *therapy'.)*

5 *“(2) REQUEST FOR DESIGNATION.—The sponsor*
6 *of a drug may request the Secretary to designate the*
7 *drug as a breakthrough therapy. A request for the des-*
8 *ignation may be made concurrently with, or at any*
9 *time after, the submission of an application for the*
10 *investigation of the drug under section 505(i) or sec-*
11 *tion 351(a)(3) of the Public Health Service Act.*

12 *“(3) DESIGNATION.—*

13 *“(A) IN GENERAL.—Not later than 60 cal-*
14 *endar days after the receipt of a request under*
15 *paragraph (2), the Secretary shall determine*
16 *whether the drug that is the subject of the request*
17 *meets the criteria described in paragraph (1). If*
18 *the Secretary finds that the drug meets the cri-*
19 *teria, the Secretary shall designate the drug as*
20 *a breakthrough therapy and shall take such ac-*
21 *tions as are appropriate to expedite the develop-*
22 *ment and review of the application for approval*
23 *of such drug.*

24 *“(B) ACTIONS.—The actions to expedite the*
25 *development and review of an application under*

1 subparagraph (A) may include, as appro-
2 priate—

3 “(i) holding meetings with the sponsor
4 and the review team throughout the develop-
5 ment of the drug;

6 “(ii) providing timely advice to, and
7 interactive communication with, the spon-
8 sor regarding the development of the drug to
9 ensure that the development program to
10 gather the nonclinical and clinical data
11 necessary for approval is as efficient as
12 practicable;

13 “(iii) involving senior managers and
14 experienced review staff, as appropriate, in
15 a collaborative, cross-disciplinary review;

16 “(iv) assigning a cross-disciplinary
17 project lead for the Food and Drug Admin-
18 istration review team to facilitate an effi-
19 cient review of the development program
20 and to serve as a scientific liaison between
21 the review team and the sponsor; and

22 “(v) taking steps to ensure that the de-
23 sign of the clinical trials is as efficient as
24 practicable, when scientifically appropriate,
25 such as by minimizing the number of pa-

1 *tients exposed to a potentially less effica-*
 2 *cious treatment.”; and*

3 *(4) in subsection (f)(1), as so redesignated, by*
 4 *striking “applicable to accelerated approval” and in-*
 5 *serting “applicable to breakthrough therapies, acceler-*
 6 *ated approval, and”.*

7 *(b) GUIDANCE; AMENDED REGULATIONS.—*

8 *(1) IN GENERAL.—*

9 *(A) GUIDANCE.—Not later than 18 months*
 10 *after the date of enactment of this Act, the Sec-*
 11 *retary of Health and Human Services (referred*
 12 *to in this section as the “Secretary”) shall issue*
 13 *draft guidance on implementing the require-*
 14 *ments with respect to breakthrough therapies, as*
 15 *set forth in section 506(a) of the Federal Food,*
 16 *Drug, and Cosmetic Act (21 U.S.C. 356(a)), as*
 17 *amended by this section. The Secretary shall*
 18 *issue final guidance not later than 1 year after*
 19 *the close of the comment period for the draft*
 20 *guidance.*

21 *(B) AMENDED REGULATIONS.—*

22 *(i) IN GENERAL.—If the Secretary de-*
 23 *termines that it is necessary to amend the*
 24 *regulations under title 21, Code of Federal*
 25 *Regulations in order to implement the*

1 *amendments made by this section to section*
2 *506(a) of the Federal Food, Drug, and Cos-*
3 *metic Act, the Secretary shall amend such*
4 *regulations not later than 2 years after the*
5 *date of enactment of this Act.*

6 (ii) *PROCEDURE.—In amending regu-*
7 *lations under clause (i), the Secretary*
8 *shall—*

9 *(I) issue a notice of proposed rule-*
10 *making that includes the proposed reg-*
11 *ulation;*

12 *(II) provide a period of not less*
13 *than 60 days for comments on the pro-*
14 *posed regulation; and*

15 *(III) publish the final regulation*
16 *not less than 30 days before the effec-*
17 *tive date of the regulation.*

18 (iii) *RESTRICTIONS.—Notwithstanding*
19 *any other provision of law, the Secretary*
20 *shall promulgate regulations implementing*
21 *the amendments made by this section only*
22 *as described in clause (ii).*

23 (2) *REQUIREMENTS.—Guidance issued under*
24 *this section shall—*

1 (A) specify the process and criteria by
 2 which the Secretary makes a designation under
 3 section 506(a)(3) of the Federal Food, Drug, and
 4 Cosmetic Act; and

5 (B) specify the actions the Secretary shall
 6 take to expedite the development and review of a
 7 breakthrough therapy pursuant to such designa-
 8 tion under such section 506(a)(3), including up-
 9 dating good review management practices to re-
 10 flect breakthrough therapies.

11 (c) *CONFORMING AMENDMENTS.*—Section 506B(e) (21
 12 U.S.C. 356b) is amended by striking “section 506(b)(2)(A)”
 13 each place such term appears and inserting “section
 14 506(c)(2)(A)”.

15 **SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON**
 16 **RARE DISEASES, TARGETED THERAPIES, AND**
 17 **GENETIC TARGETING OF TREATMENTS.**

18 Subchapter E of chapter V (21 U.S.C. 360bbb et seq.),
 19 as amended by section 715 of this Act, is further amended
 20 by adding at the end the following:

21 **“SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON**
 22 **RARE DISEASES, TARGETED THERAPIES, AND**
 23 **GENETIC TARGETING OF TREATMENTS.**

24 “(a) *IN GENERAL.*—For the purpose of promoting the
 25 efficiency of and informing the review by the Food and

1 *Drug Administration of new drugs and biological products*
2 *for rare diseases and drugs and biological products that are*
3 *genetically targeted, the following shall apply:*

4 “(1) *CONSULTATION WITH STAKEHOLDERS.—*
5 *Consistent with sections X.C and IX.E.4 of the*
6 *PDUFA Reauthorization Performance Goals and Pro-*
7 *cedures Fiscal Years 2013 through 2017, as referenced*
8 *in the letters described in section 101(b) of the Pre-*
9 *scription Drug User Fee Amendments of 2012, the*
10 *Secretary shall ensure that opportunities exist, at a*
11 *time the Secretary determines appropriate, for con-*
12 *sultations with stakeholders on the topics described in*
13 *subsection (b).*

14 “(2) *CONSULTATION WITH EXTERNAL EX-*
15 *PERTS.—*

16 “(A) *IN GENERAL.—The Secretary shall de-*
17 *velop and maintain a list of external experts*
18 *who, because of their special expertise, are quali-*
19 *fied to provide advice on rare disease issues, in-*
20 *cluding topics described in subsection (c). The*
21 *Secretary may, when appropriate to address a*
22 *specific regulatory question, consult such exter-*
23 *nal experts on issues related to the review of new*
24 *drugs and biological products for rare diseases*
25 *and drugs and biological products that are ge-*

netically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.

“(B) *EXTERNAL EXPERTS.*—For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

“(b) *TOPICS FOR CONSULTATION.*—Topics for consultation pursuant to this section may include—

“(1) rare diseases;

“(2) the severity of rare diseases;

“(3) the unmet medical need associated with rare diseases;

“(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

“(5) an assessment of the benefits and risks of therapies to treat rare diseases;

“(6) the general design of clinical trials for rare disease populations and subpopulations; and

1 “(7) *the demographics and the clinical descrip-*
2 *tion of patient populations.*

3 “(c) *CLASSIFICATION AS SPECIAL GOVERNMENT EM-*
4 *PLOYEES.—The external experts who are consulted under*
5 *this section may be considered special government employ-*
6 *ees, as defined under section 202 of title 18, United States*
7 *Code.*

8 “(d) *PROTECTION OF CONFIDENTIAL INFORMATION*
9 *AND TRADE SECRETS.—*

10 “(1) *RULE OF CONSTRUCTION.—Nothing in this*
11 *section shall be construed to alter the protections of-*
12 *fered by laws, regulations, and policies governing dis-*
13 *closure of confidential commercial or trade secret in-*
14 *formation, and any other information exempt from*
15 *disclosure pursuant to section 552(b) of title 5,*
16 *United States Code, as such provisions would be ap-*
17 *plied to consultation with individuals and organiza-*
18 *tions prior to the date of enactment of this section.*

19 “(2) *CONSENT REQUIRED FOR DISCLOSURE.—*
20 *The Secretary shall not disclose confidential commer-*
21 *cial or trade secret information to an expert consulted*
22 *under this section without the written consent of the*
23 *sponsor unless the expert is a special government em-*
24 *ployee (as defined under section 202 of title 18,*

1 *United States Code*) or the disclosure is otherwise au-
 2 thorized by law.

3 “(e) *OTHER CONSULTATION*.—Nothing in this section
 4 shall be construed to limit the ability of the Secretary to
 5 consult with individuals and organizations as authorized
 6 prior to the date of enactment of this section.

7 “(f) *NO RIGHT OR OBLIGATION*.—

8 “(1) *NO RIGHT TO CONSULTATION*.—Nothing in
 9 this section shall be construed to create a legal right
 10 for a consultation on any matter or require the Sec-
 11 retary to meet with any particular expert or stake-
 12 holder.

13 “(2) *NO ALTERING OF GOALS*.—Nothing in this
 14 section shall be construed to alter agreed upon goals
 15 and procedures identified in the letters described in
 16 section 101(b) of the Prescription Drug User Fee
 17 Amendments of 2012.

18 “(3) *NO CHANGE TO NUMBER OF REVIEW CY-*
 19 *CLES*.—Nothing in this section is intended to increase
 20 the number of review cycles as in effect before the date
 21 of enactment of this section.

22 “(g) *NO DELAY IN PRODUCT REVIEW*.—

23 “(1) *IN GENERAL*.—Prior to a consultation with
 24 an external expert, as described in this section, relat-
 25 ing to an investigational new drug application under

9 “(i) facilitate the Secretary’s ability to
10 complete the Secretary’s review; and

13 “(B) the sponsor authorized such consulta-
14 tion.

15 “(2) *LIMITATION.*—*The requirements of this sub-*
16 *section shall apply only in instances where the con-*
17 *sultation is undertaken solely under the authority of*
18 *this section. The requirements of this subsection shall*
19 *not apply to any consultation initiated under any*
20 *other authority.*”.

21 **SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIP-**
22 **TION DRUG CONTAINER LABELS BY VISUALLY**
23 **IMPAIRED AND BLIND CONSUMERS.**

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1 (1) *IN GENERAL.*—*The Architectural and Trans-*
2 *portation Barriers Compliance Board (referred to in*
3 *this section as the “Access Board”)* shall convene a
4 *stakeholder working group (referred to in this section*
5 *as the “working group”)* to develop best practices on
6 *access to information on prescription drug container*
7 *labels for individuals who are blind or visually im-*
8 *paired.*

9 (2) *MEMBERS.*—*The working group shall be*
10 *comprised of representatives of national organizations*
11 *representing blind and visually impaired individuals,*
12 *national organizations representing the elderly, and*
13 *industry groups representing stakeholders, including*
14 *retail, mail-order, and independent community phar-*
15 *macies, who would be impacted by such best practices.*
16 *Representation within the working group shall be di-*
17 *vided equally between consumer and industry advo-*
18 *cates.*

19 (3) *BEST PRACTICES.*—

20 (A) *IN GENERAL.*—*The working group shall*
21 *develop, not later than 1 year after the date of*
22 *the enactment of this Act, best practices for phar-*
23 *macies to ensure that blind and visually im-*
24 *paired individuals have safe, consistent, reliable,*

1 *and independent access to the information on*
2 *prescription drug container labels.*

3 *(B) PUBLIC AVAILABILITY.—The best prac-*
4 *tices developed under subparagraph (A) may be*
5 *made publicly available, including through the*
6 *Internet Web sites of the working group partici-*
7 *pant organizations, and through other means, in*
8 *a manner that provides access to interested indi-*
9 *viduals, including individuals with disabilities.*

10 *(C) LIMITATIONS.—The best practices devel-*
11 *oped under subparagraph (A) shall not be con-*
12 *strued as accessibility guidelines or standards of*
13 *the Access Board, and shall not confer any rights*
14 *or impose any obligations on working group par-*
15 *ticipants or other persons. Nothing in this sec-*
16 *tion shall be construed to limit or condition any*
17 *right, obligation, or remedy available under the*
18 *Americans with Disabilities Act of 1990 (42*
19 *U.S.C. 12101 et seq.) or any other Federal or*
20 *State law requiring effective communication,*
21 *barrier removal, or nondiscrimination on the*
22 *basis of disability.*

23 *(4) CONSIDERATIONS.—In developing and*
24 *issuing the best practices under paragraph (3)(A), the*
25 *working group shall consider—*

1 (A) *the use of—*

2 (i) *Braille;*

3 (ii) *auditory means, such as—*

4 (I) *“talking bottles” that provide*
5 *audible container label information;*

6 (II) *digital voice recorders at-*
7 *tached to the prescription drug con-*
8 *tainer; and*

9 (III) *radio frequency identifica-*
10 *tion tags;*

11 (iii) *enhanced visual means, such as—*

12 (I) *large font labels or large font*
13 *“duplicate” labels that are affixed or*
14 *matched to a prescription drug con-*
15 *tainer;*

16 (II) *high-contrast printing; and*

17 (III) *sans-serif font; and*

18 (iv) *other relevant alternatives as de-*
19 *termined by the working group;*

20 (B) *whether there are technical, financial,*
21 *manpower, or other factors unique to pharmacies*
22 *with 20 or fewer retail locations which may pose*
23 *significant challenges to the adoption of the best*
24 *practices; and*

1 (C) such other factors as the working group
2 determines to be appropriate.

3 (5) *INFORMATION CAMPAIGN.*—Upon completion
4 of development of the best practices under subsection
5 (a)(3), the National Council on Disability, in con-
6 sultation with the working group, shall conduct an
7 informational and educational campaign designed to
8 inform individuals with disabilities, pharmacists,
9 and the public about such best practices.

10 (6) *FACA WAIVER.*—The Federal Advisory Com-
11 mittee Act (5 U.S.C. App.) shall not apply to the
12 working group.

13 (b) *GAO STUDY.*—

14 (1) *IN GENERAL.*—Beginning 18 months after
15 the completion of the development of best practices
16 under subsection (a)(3)(A), the Comptroller General of
17 the United States shall conduct a review of the extent
18 to which pharmacies are utilizing such best practices,
19 and the extent to which barriers to accessible informa-
20 tion on prescription drug container labels for blind
21 and visually impaired individuals continue.

22 (2) *REPORT.*—Not later than September 30,
23 2016, the Comptroller General of the United States
24 shall submit to Congress a report on the review con-
25 ducted under paragraph (1). Such report shall in-

1 *clude recommendations about how best to reduce the*
2 *barriers experienced by blind and visually impaired*
3 *individuals to independently accessing information*
4 *on prescription drug container labels.*

5 *(c) DEFINITIONS.—In this section—*

6 *(1) the term “pharmacy” includes a pharmacy*
7 *that receives prescriptions and dispenses prescription*
8 *drugs through an Internet Web site or by mail;*

9 *(2) the term “prescription drug” means a drug*
10 *subject to section 503(b)(1) of the Federal Food, Drug,*
11 *and Cosmetic Act (21 U.S.C. 353(b)(1)); and*

12 *(3) the term “prescription drug container label”*
13 *means the label with the directions for use that is af-*
14 *fixed to the prescription drug container by the phar-*
15 *macist and dispensed to the consumer.*

16 **SEC. 905. RISK-BENEFIT FRAMEWORK.**

17 *Section 505(d) (21 U.S.C. 355(d)) is amended by add-*
18 *ing at the end the following: “The Secretary shall imple-*
19 *ment a structured risk-benefit assessment framework in the*
20 *new drug approval process to facilitate the balanced consid-*
21 *eration of benefits and risks, a consistent and systematic*
22 *approach to the discussion and regulatory decisionmaking,*
23 *and the communication of the benefits and risks of new*
24 *drugs. Nothing in the preceding sentence shall alter the cri-*

1 *teria for evaluating an application for premarket approval*
 2 *of a drug.”.*

3 **SEC. 906. GRANTS AND CONTRACTS FOR THE DEVELOP-**
 4 **MENT OF ORPHAN DRUGS.**

5 (a) *QUALIFIED TESTING DEFINITION.*—Section
 6 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.
 7 360ee(b)(1)(A)(ii)) is amended by striking “after the date
 8 such drug is designated under section 526 of such Act and”.

9 (b) *AUTHORIZATION OF APPROPRIATIONS.*—Section
 10 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amend-
 11 ed to read as follows:

12 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—For
 13 grants and contracts under subsection (a), there is author-
 14 ized to be appropriated \$30,000,000 for each of fiscal years
 15 2013 through 2017.”.

16 **SEC. 907. REPORTING OF INCLUSION OF DEMOGRAPHIC**
 17 **SUBGROUPS IN CLINICAL TRIALS AND DATA**
 18 **ANALYSIS IN APPLICATIONS FOR DRUGS, BIO-**
 19 **LOGICS, AND DEVICES.**

20 (a) *REPORT.*—

21 (1) *IN GENERAL.*—Not later than 1 year after
 22 the date of enactment of this Act, the Secretary, act-
 23 ing through the Commissioner, shall publish on the
 24 Internet Web site of the Food and Drug Administra-
 25 tion a report, consistent with the regulations of the

1 *Food and Drug Administration pertaining to the pro-*
2 *tection of sponsors' confidential commercial informa-*
3 *tion as of the date of enactment of this Act, address-*
4 *ing the extent to which clinical trial participation*
5 *and the inclusion of safety and effectiveness data by*
6 *demographic subgroups including sex, age, race, and*
7 *ethnicity, is included in applications submitted to the*
8 *Food and Drug Administration, and shall provide*
9 *such publication to Congress.*

10 (2) *CONTENTS OF REPORT.*—*The report described*
11 *in paragraph (1) shall contain the following:*

12 (A) *A description of existing tools to ensure*
13 *that data to support demographic analyses are*
14 *submitted in applications for drugs, biological*
15 *products, and devices, and that these analyses*
16 *are conducted by applicants consistent with ap-*
17 *plicable Food and Drug Administration require-*
18 *ments and Guidance for Industry. The report*
19 *shall address how the Food and Drug Adminis-*
20 *tration makes available information about dif-*
21 *ferences in safety and effectiveness of medical*
22 *products according to demographic subgroups,*
23 *such as sex, age, racial, and ethnic subgroups, to*
24 *health care providers, researchers, and patients.*

1 (B) *An analysis of the extent to which de-*
2 *mographic data subset analyses on sex, age, race,*
3 *and ethnicity is presented in applications for*
4 *new drug applications for new molecular entities*
5 *under section 505 of the Federal Food, Drug,*
6 *and Cosmetic Act (21 U.S.C. 355), in biologics*
7 *license applications under section 351 of the*
8 *Public Health Service Act (42 U.S.C. 262), and*
9 *in premarket approval applications under sec-*
10 *tion 515 of the Federal Food, Drug, and Cos-*
11 *metic Act (21 U.S.C. 360e) for products ap-*
12 *proved or licensed by the Food and Drug Admin-*
13 *istration, consistent with applicable require-*
14 *ments and Guidance for Industry, and consistent*
15 *with the regulations of the Food and Drug Ad-*
16 *ministration pertaining to the protection of*
17 *sponsors' confidential commercial information as*
18 *of the date of enactment of this Act.*

19 (C) *An analysis of the extent to which de-*
20 *mographic subgroups, including sex, age, racial,*
21 *and ethnic subgroups, are represented in clinical*
22 *studies to support applications for approved or*
23 *licensed new molecular entities, biological prod-*
24 *ucts, and devices.*

1 (D) *An analysis of the extent to which a*
2 *summary of product safety and effectiveness data*
3 *by demographic subgroups including sex, age,*
4 *race, and ethnicity is readily available to the*
5 *public in a timely manner by means of the prod-*
6 *uct labeling or the Food and Drug Administra-*
7 *tion's Internet Web site.*

8 (b) *ACTION PLAN.*—

9 (1) *IN GENERAL.*—*Not later than 1 year after*
10 *the publication of the report described in subsection*
11 *(a), the Secretary, acting through the Commissioner,*
12 *shall publish an action plan on the Internet Web site*
13 *of the Food and Drug Administration, and provide*
14 *such publication to Congress.*

15 (2) *CONTENT OF ACTION PLAN.*—*The plan de-*
16 *scribed in paragraph (1) shall include—*

17 (A) *recommendations, as appropriate, to*
18 *improve the completeness and quality of analyses*
19 *of data on demographic subgroups in summaries*
20 *of product safety and effectiveness data and in*
21 *labeling;*

22 (B) *recommendations, as appropriate, on*
23 *the inclusion of such data, or the lack of avail-*
24 *ability of such data in labeling;*

1 (C) recommendations, as appropriate, to
2 otherwise improve the public availability of such
3 data to patients, health care providers, and re-
4 searchers; and

5 (D) a determination with respect to each
6 recommendation identified in subparagraphs (A)
7 through (C) that distinguishes between product
8 types referenced in subsection (a)(2)(B) insofar
9 as the applicability of each such recommendation
10 to each type of product.

11 (c) *DEFINITIONS.*—*In this section:*

12 (1) The term “Commissioner” means the Com-
13 missioner of Food and Drugs.

14 (2) The term “device” has the meaning given
15 such term in section 201(h) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 321(h)).

17 (3) The term “drug” has the meaning given such
18 term in section 201(g) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 321(g)).

20 (4) The term “biological product” has the mean-
21 ing given such term in section 351(i) of the Public
22 Health Service Act (42 U.S.C. 262(i)).

23 (5) The term “Secretary” means the Secretary of
24 Health and Human Services.

1 **SEC. 908. RARE PEDIATRIC DISEASE PRIORITY REVIEW**
 2 **VOUCHER INCENTIVE PROGRAM.**

3 *Subchapter B of chapter V (21 U.S.C. 360aa et seq.)*
 4 *is amended by adding at the end the following:*

5 **“SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
 6 **FOR RARE PEDIATRIC DISEASES.**

7 *“(a) DEFINITIONS.—In this section:*

8 *“(1) PRIORITY REVIEW.—The term ‘priority re-*
 9 *view’, with respect to a human drug application as*
 10 *defined in section 735(1), means review and action by*
 11 *the Secretary on such application not later than 6*
 12 *months after receipt by the Secretary of such applica-*
 13 *tion, as described in the Manual of Policies and Pro-*
 14 *cedures of the Food and Drug Administration and*
 15 *goals identified in the letters described in section*
 16 *101(b) of the Prescription Drug User Fee Amend-*
 17 *ments of 2012.*

18 *“(2) PRIORITY REVIEW VOUCHER.—The term*
 19 *‘priority review voucher’ means a voucher issued by*
 20 *the Secretary to the sponsor of a rare pediatric dis-*
 21 *ease product application that entitles the holder of*
 22 *such voucher to priority review of a single human*
 23 *drug application submitted under section 505(b)(1) or*
 24 *section 351(a) of the Public Health Service Act after*
 25 *the date of approval of the rare pediatric disease*
 26 *product application.*

1 “(3) *RARE PEDIATRIC DISEASE.*—*The term ‘rare*
 2 *pediatric disease’ means a disease that meets each of*
 3 *the following criteria:*

4 “(A) *The disease primarily affects individ-*
 5 *uals aged from birth to 18 years, including age*
 6 *groups often called neonates, infants, children,*
 7 *and adolescents.*

8 “(B) *The disease is a rare disease or condi-*
 9 *tion, within the meaning of section 526.*

10 “(4) *RARE PEDIATRIC DISEASE PRODUCT APPLI-*
 11 *CATION.*—*The term ‘rare pediatric disease product*
 12 *application’ means a human drug application, as de-*
 13 *finied in section 735(1), that—*

14 “(A) *is for a drug or biological product—*

15 “(i) *that is for the prevention or treat-*
 16 *ment of a rare pediatric disease; and*

17 “(ii) *that contains no active ingredient*
 18 *(including any ester or salt of the active in-*
 19 *gredient) that has been previously approved*
 20 *in any other application under section*
 21 *505(b)(1), 505(b)(2), or 505(j) of this Act or*
 22 *section 351(a) or 351(k) of the Public*
 23 *Health Service Act;*

1 “(B) is submitted under section 505(b)(1) of
2 this Act or section 351(a) of the Public Health
3 Service Act;

4 “(C) the Secretary deems eligible for pri-
5 ority review;

6 “(D) that relies on clinical data derived
7 from studies examining a pediatric population
8 and dosages of the drug intended for that popu-
9 lation;

10 “(E) that does not seek approval for an
11 adult indication in the original rare pediatric
12 disease product application; and

13 “(F) is approved after the date of the enact-
14 ment of the Prescription Drug User Fee Amend-
15 ments of 2012.

16 “(b) *PRIORITY REVIEW VOUCHER.*—

17 “(1) *IN GENERAL.*—The Secretary shall award a
18 priority review voucher to the sponsor of a rare pedi-
19 atric disease product application upon approval by
20 the Secretary of such rare pediatric disease product
21 application.

22 “(2) *TRANSFERABILITY.*—

23 “(A) *IN GENERAL.*—The sponsor of a rare
24 pediatric disease product application that re-
25 ceives a priority review voucher under this sec-

tion may transfer (including by sale) the entitlement to such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

“(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.

“(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012.

“(4) NOTIFICATION.—

“(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a le-

1 *gally binding commitment to pay for the user fee*
2 *to be assessed in accordance with this section.*

3 “(B) *TRANSFER AFTER NOTICE.*—*The spon-*
4 *sor of a human drug application that provides*
5 *notification of the intent of such sponsor to use*
6 *the voucher for the human drug application*
7 *under subparagraph (A) may transfer the vouch-*
8 *er after such notification is provided, if such*
9 *sponsor has not yet submitted the human drug*
10 *application described in the notification.*

11 “(5) *TERMINATION OF AUTHORITY.*—*The Sec-*
12 *retary may not award any priority review vouchers*
13 *under paragraph (1) after the last day of the 1-year*
14 *period that begins on the date that the Secretary*
15 *awards the third rare pediatric disease priority*
16 *voucher under this section.*

17 “(c) *PRIORITY REVIEW USER FEE.*—

18 “(1) *IN GENERAL.*—*The Secretary shall establish*
19 *a user fee program under which a sponsor of a*
20 *human drug application that is the subject of a pri-*
21 *ority review voucher shall pay to the Secretary a fee*
22 *determined under paragraph (2). Such fee shall be in*
23 *addition to any fee required to be submitted by the*
24 *sponsor under chapter VII.*

1 “(2) *FEE AMOUNT.*—*The amount of the priority*
2 *review user fee shall be determined each fiscal year by*
3 *the Secretary, based on the difference between—*

4 “(A) *the average cost incurred by the Food*
5 *and Drug Administration in the review of a*
6 *human drug application subject to priority re-*
7 *view in the previous fiscal year; and*

8 “(B) *the average cost incurred by the Food*
9 *and Drug Administration in the review of a*
10 *human drug application that is not subject to*
11 *priority review in the previous fiscal year.*

12 “(3) *ANNUAL FEE SETTING.*—*The Secretary shall*
13 *establish, before the beginning of each fiscal year be-*
14 *ginning after September 30, 2012, the amount of the*
15 *priority review user fee for that fiscal year.*

16 “(4) *PAYMENT.*—

17 “(A) *IN GENERAL.*—*The priority review*
18 *user fee required by this subsection shall be due*
19 *upon the notification by a sponsor of the intent*
20 *of such sponsor to use the voucher, as specified*
21 *in subsection (b)(4)(A). All other user fees associ-*
22 *ated with the human drug application shall be*
23 *due as required by the Secretary or under appli-*
24 *cable law.*

1 “(B) *COMPLETE APPLICATION.*—An appli-
 2 cation described under subparagraph (A) for
 3 which the sponsor requests the use of a priority
 4 review voucher shall be considered incomplete if
 5 the fee required by this subsection and all other
 6 applicable user fees are not paid in accordance
 7 with the Secretary’s procedures for paying such
 8 fees.

9 “(C) *NO WAIVERS, EXEMPTIONS, REDUC-*
 10 *TIONS, OR REFUNDS.*—The Secretary may not
 11 grant a waiver, exemption, reduction, or refund
 12 of any fees due and payable under this section.

13 “(5) *OFFSETTING COLLECTIONS.*—Fees collected
 14 pursuant to this subsection for any fiscal year—

15 “(A) shall be deposited and credited as off-
 16 setting collections to the account providing ap-
 17 propriations to the Food and Drug Administra-
 18 tion; and

19 “(B) shall not be collected for any fiscal
 20 year except to the extent provided in advance in
 21 appropriations Acts.

22 “(d) *DESIGNATION PROCESS.*—

23 “(1) *IN GENERAL.*—Upon the request of the man-
 24 ufacturer or the sponsor of a new drug, the Secretary
 25 may designate—

1 “(A) *the new drug as a drug for a rare pe-*
 2 *diatric disease; and*

3 “(B) *the application for the new drug as a*
 4 *rare pediatric disease product application.*

5 “(2) *REQUEST FOR DESIGNATION.*—*The request*
 6 *for a designation under paragraph (1) shall be made*
 7 *at the same time a request for designation of orphan*
 8 *disease status under section 526 or fast-track designa-*
 9 *tion under section 506 is made. Requesting designa-*
 10 *tion under this subsection is not a prerequisite to re-*
 11 *ceiving a priority review voucher under this section.*

12 “(3) *DETERMINATION BY SECRETARY.*—*Not later*
 13 *than 60 days after a request is submitted under para-*
 14 *graph (1), the Secretary shall determine whether—*

15 “(A) *the disease or condition that is the*
 16 *subject of such request is a rare pediatric disease;*
 17 *and*

18 “(B) *the application for the new drug is a*
 19 *rare pediatric disease product application.*

20 “(e) *MARKETING OF RARE PEDIATRIC DISEASE PROD-*
 21 *UCTS.*—

22 “(1) *REVOCATION.*—*The Secretary may revoke*
 23 *any priority review voucher awarded under sub-*
 24 *section (b) if the rare pediatric disease product for*
 25 *which such voucher was awarded is not marketed in*

1 *the United States within the 365-day period begin-*
2 *ning on the date of the approval of such drug under*
3 *section 505 of this Act or section 351 of the Public*
4 *Health Service Act.*

5 “(2) *POSTAPPROVAL PRODUCTION REPORT.*—*The*
6 *sponsor of an approved rare pediatric disease product*
7 *shall submit a report to the Secretary not later than*
8 *5 years after the approval of the applicable rare pedi-*
9 *atric disease product application. Such report shall*
10 *provide the following information, with respect to*
11 *each of the first 4 years after approval of such prod-*
12 *uct:*

13 “(A) *The estimated population in the*
14 *United States suffering from the rare pediatric*
15 *disease.*

16 “(B) *The estimated demand in the United*
17 *States for such rare pediatric disease product.*

18 “(C) *The actual amount of such rare pedi-*
19 *atric disease product distributed in the United*
20 *States.*

21 “(f) *NOTICE AND REPORT.*—

22 “(1) *NOTICE OF ISSUANCE OF VOUCHER AND AP-*
23 *PROVAL OF PRODUCTS UNDER VOUCHER.*—*The Sec-*
24 *retary shall publish a notice in the Federal Register*
25 *and on the Internet Web site of the Food and Drug*

1 *Administration not later than 30 days after the oc-*
2 *currence of each of the following:*

3 “(A) *The Secretary issues a priority review*
4 *voucher under this section.*

5 “(B) *The Secretary approves a drug pursu-*
6 *ant to an application submitted under section*
7 *505(b) of this Act or section 351(a) of the Public*
8 *Health Service Act for which the sponsor of the*
9 *application used a priority review voucher under*
10 *this section.*

11 “(2) *NOTIFICATION.—If, after the last day of the*
12 *1-year period that begins on the date that the Sec-*
13 *retary awards the third rare pediatric disease pri-*
14 *ority voucher under this section, a sponsor of an ap-*
15 *plication submitted under section 505(b) of this Act*
16 *or section 351(a) of the Public Health Service Act for*
17 *a drug uses a priority review voucher under this sec-*
18 *tion for such application, the Secretary shall submit*
19 *to the Committee on Energy and Commerce of the*
20 *House of Representatives and the Committee on*
21 *Health, Education, Labor, and Pensions of the Senate*
22 *a document—*

23 “(A) *notifying such Committees of the use of*
24 *such voucher; and*

1 “(B) *identifying the drug for which such*
2 *priority review voucher is used.*

3 “(g) *ELIGIBILITY FOR OTHER PROGRAMS.—Nothing*
4 *in this section precludes a sponsor who seeks a priority re-*
5 *view voucher under this section from participating in any*
6 *other incentive program, including under this Act.*

7 “(h) *RELATION TO OTHER PROVISIONS.—The provi-*
8 *sions of this section shall supplement, not supplant, any*
9 *other provisions of this Act or the Public Health Service*
10 *Act that encourage the development of drugs for tropical*
11 *diseases and rare pediatric diseases.*

12 “(i) *GAO STUDY AND REPORT.—*

13 “(1) *STUDY.—*

14 “(A) *IN GENERAL.—Beginning on the date*
15 *that the Secretary awards the third rare pedi-*
16 *atric disease priority voucher under this section,*
17 *the Comptroller General of the United States*
18 *shall conduct a study of the effectiveness of*
19 *awarding rare pediatric disease priority vouch-*
20 *ers under this section in the development of*
21 *human drug products that treat or prevent such*
22 *diseases.*

23 “(B) *CONTENTS OF STUDY.—In conducting*
24 *the study under subparagraph (A), the Comp-*
25 *troller General shall examine the following:*

1 “(i) *The indications for which each*
 2 *rare disease product for which a priority re-*
 3 *view voucher was awarded was approved*
 4 *under section 505 or section 351 of the Pub-*
 5 *lic Health Service Act.*

6 “(ii) *Whether, and to what extent, an*
 7 *unmet need related to the treatment or pre-*
 8 *vention of a rare pediatric disease was met*
 9 *through the approval of such a rare disease*
 10 *product.*

11 “(iii) *The value of the priority review*
 12 *voucher if transferred.*

13 “(iv) *Identification of each drug for*
 14 *which a priority review voucher was used.*

15 “(v) *The length of the period of time*
 16 *between the date on which a priority review*
 17 *voucher was awarded and the date on which*
 18 *it was used.*

19 “(2) *REPORT.—Not later than 1 year after the*
 20 *date under paragraph (1)(A), the Comptroller Gen-*
 21 *eral shall submit to the Committee on Energy and*
 22 *Commerce of the House of Representatives and the*
 23 *Committee on Health, Education, Labor, and Pen-*
 24 *sions of the Senate, a report containing the results of*
 25 *the study under paragraph (1).”.*

1 ***TITLE X—DRUG SHORTAGES***

2 ***SEC. 1001. DISCONTINUANCE OR INTERRUPTION IN THE***
 3 ***PRODUCTION OF LIFE-SAVING DRUGS.***

4 (a) *IN GENERAL.*—Section 506C (21 U.S.C. 356c) is
 5 amended to read as follows:

6 ***“SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE***
 7 ***PRODUCTION OF LIFE-SAVING DRUGS.***

8 “(a) *IN GENERAL.*—A manufacturer of a drug—

9 “(1) that is—

10 “(A) life-supporting;

11 “(B) life-sustaining; or

12 “(C) intended for use in the prevention or
 13 *treatment of a debilitating disease or condition,*
 14 *including any such drug used in emergency med-*
 15 *ical care or during surgery; and*

16 “(2) that is not a radio pharmaceutical drug
 17 *product or any other product as designated by the*
 18 *Secretary,*

19 *shall notify the Secretary, in accordance with subsection*
 20 *(b), of a permanent discontinuance in the manufacture of*
 21 *the drug or an interruption of the manufacture of the drug*
 22 *that is likely to lead to a meaningful disruption in the sup-*
 23 *ply of that drug in the United States, and the reasons for*
 24 *such discontinuance or interruption.*

1 “(b) *TIMING.*—A notice required under 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, through such means
9 as the Secretary deems appropriate, information on the dis-
10 continuation or interruption of the manufacture of the
11 drugs described in subsection (a) to appropriate organiza-
12 tions, including physician, health provider, and patient or-
13 ganizations, as described in section 506E.

14 “(d) *CONFIDENTIALITY.*—Nothing in this section shall
15 be construed as authorizing the Secretary to disclose any
16 information that is a trade secret or confidential informa-
17 tion subject to section 552(b)(4) of title 5, United States
18 Code, or section 1905 of title 18, United States Code.

19 “(e) *COORDINATION WITH ATTORNEY GENERAL.*—Not
20 later than 30 days after the receipt of a notification de-
21 scribed in subsection (a), the Secretary shall—

22 “(1) *determine whether the notification pertains*
23 *to a controlled substance subject to a production quota*
24 *under section 306 of the Controlled Substances Act;*
25 *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 in-
6 crease the aggregate and individual production
7 quotas under section 306 of the Controlled Sub-
8 stances Act applicable to such controlled sub-
9 stance and any ingredient therein to a level the
10 Secretary deems necessary to address a shortage
11 of a controlled substance based on the best avail-
12 able 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 At-
16 torney General shall provide to the Secretary a
17 written response detailing the basis for the Attor-
18 ney General’s determination.

19 *The Secretary shall make the written response pro-*
20 *vided under subparagraph (C) available to the public*
21 *on the Internet Web site of the Food and Drug Ad-*
22 *ministration.*

23 “(f) *FAILURE TO MEET REQUIREMENTS.*—If a person
24 *fails to submit information required under subsection (a)*
25 *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 Secretary
6 a written response to such letter setting forth the basis
7 for noncompliance and providing information re-
8 quired 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 Internet Web site of the Food and Drug Ad-
14 ministration, with appropriate redactions made to
15 protect information described in subsection (d), except
16 that, 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 re-
20 quirements of this paragraph shall not apply.

21 “(g) *EXPEDITED INSPECTIONS AND REVIEWS.*—If,
22 based on notifications described in subsection (a) or any
23 other relevant information, the Secretary concludes that
24 there is, or is likely to be, a drug shortage of a drug de-
25 scribed in subsection (a), the Secretary may—

1 “(1) expedite the review of a supplement to a
2 new drug application submitted under section 505(b),
3 an abbreviated new drug application submitted under
4 section 505(j), or a supplement to such an application
5 submitted under section 505(j) that could help miti-
6 gate or prevent such shortage; or

7 “(2) expedite an inspection or reinspection of an
8 establishment that could help mitigate or prevent such
9 drug shortage.

10 “(h) *DEFINITIONS.*—For purposes of this section—

11 “(1) the term ‘drug’—

12 “(A) means a drug (as defined in section
13 201(g)) that is intended for human use and that
14 is subject to section 503(b)(1); and

15 “(B) does not include biological products
16 (as defined in section 351 of the Public Health
17 Service Act), unless otherwise provided by the
18 Secretary in the regulations promulgated under
19 subsection (i);

20 “(2) the term ‘drug shortage’ or ‘shortage’, with
21 respect to a drug, means a period of time when the
22 demand or projected demand for the drug within the
23 United States exceeds the supply of the drug; and

24 “(3) the term ‘meaningful disruption’—

1 “(A) means a change in production that is
 2 reasonably likely to lead to a reduction in the
 3 supply of a drug by a manufacturer that is more
 4 than negligible and affects the ability of the
 5 manufacturer to fill orders or meet expected de-
 6 mand for its product; and

7 “(B) does not include interruptions in man-
 8 ufacturing due to matters such as routine main-
 9 tenance or insignificant changes in manufac-
 10 turing so long as the manufacturer expects to re-
 11 sume operations in a short period of time.

12 “(i) *REGULATIONS.*—

13 “(1) *IN GENERAL.*—Not later than 18 months
 14 after the date of enactment of the Food and Drug Ad-
 15 ministration Safety and Innovation Act, the Sec-
 16 retary shall adopt a final regulation implementing
 17 this section.

18 “(2) *CONTENTS.*—Such regulation shall define,
 19 for purposes of this section, the terms ‘life-supporting’,
 20 ‘life-sustaining’, and ‘intended for use in the preven-
 21 tion or treatment of a debilitating disease or condi-
 22 tion’.

23 “(3) *INCLUSION OF BIOLOGICAL PRODUCTS.*—

24 “(A) *IN GENERAL.*—The Secretary may by
 25 regulation apply this section to biological prod-

1 *ucts (as defined in section 351 of the Public*
 2 *Health Service Act), including plasma products*
 3 *derived from human plasma protein and their*
 4 *recombinant analogs, if the Secretary determines*
 5 *such inclusion would benefit the public health.*
 6 *Such regulation shall take into account any sup-*
 7 *ply reporting programs and shall aim to reduce*
 8 *duplicative notification.*

9 *“(B) RULE FOR VACCINES.—If the Sec-*
 10 *retary applies this section to vaccines pursuant*
 11 *to subparagraph (A), the Secretary shall—*

12 *“(i) consider whether the notification*
 13 *requirement under subsection (a) may be*
 14 *satisfied by submitting a notification to the*
 15 *Centers for Disease Control and Prevention*
 16 *under the vaccine shortage notification pro-*
 17 *gram of such Centers; and*

18 *“(ii) explain the determination made*
 19 *by the Secretary under clause (i) in the reg-*
 20 *ulation.*

21 *“(4) PROCEDURE.—In promulgating a regula-*
 22 *tion implementing this section, the Secretary shall—*

23 *“(A) issue a notice of proposed rulemaking*
 24 *that includes the proposed regulation;*

1 “(B) provide a period of not less than 60
2 days for comments on the proposed regulation;
3 and

4 “(C) publish the final regulation not less
5 than 30 days before the regulation’s effective
6 date.

7 “(5) *RESTRICTIONS*.—Notwithstanding any other
8 provision of Federal law, in implementing this sec-
9 tion, the Secretary shall only promulgate regulations
10 as described in paragraph (4).”.

11 (b) *EFFECT OF NOTIFICATION*.—The submission of a
12 notification to the Secretary of Health and Human Services
13 (referred to in this title as the “Secretary”) for purposes
14 of complying with the requirement in section 506C(a) of
15 the Federal Food, Drug, and Cosmetic Act (as amended by
16 subsection (a)) shall not be construed—

17 (1) as an admission that any product that is the
18 subject of such notification violates any provision of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 301 *et seq.*); or

21 (2) as evidence of an intention to promote or
22 market the product for an indication or use for which
23 the product has not been approved by the Secretary.

1 **SEC. 1002. ANNUAL REPORTING ON DRUG SHORTAGES.**

2 Chapter V (21 U.S.C. 351 et seq.) is amended by in-
3 serting after section 506C, as amended by section 1001 of
4 this Act, the following:

5 **“SEC. 506C–1. ANNUAL REPORTING ON DRUG SHORTAGES.**

6 “(a) *ANNUAL REPORTS TO CONGRESS.*—Not later than
7 the end of calendar year 2013, and not later than the end
8 of each calendar year thereafter, the Secretary shall submit
9 to the Committee on Energy and Commerce of the House
10 of Representatives and the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate a report on drug
12 shortages that—

13 “(1) specifies the number of manufacturers that
14 submitted a notification to the Secretary under sec-
15 tion 506C(a) during such calendar year;

16 “(2) describes the communication between the
17 field investigators of the Food and Drug Administra-
18 tion and the staff of the Center for Drug Evaluation
19 and Research’s Office of Compliance and Drug Short-
20 age Program, including the Food and Drug Adminis-
21 tration’s procedures for enabling and ensuring such
22 communication;

23 “(3)(A) lists the major actions taken by the Sec-
24 retary to prevent or mitigate the drug shortages de-
25 scribed in paragraph (7);

1 “(B) in the list under subparagraph (A), in-
2 cludes—

3 “(i) the number of applications and supple-
4 ments for which the Secretary expedited review
5 under section 506C(g)(1) during such calendar
6 year; and

7 “(ii) the number of establishment inspec-
8 tions or reinspections that the Secretary expe-
9 dited under section 506C(g)(2) during such cal-
10 endar year;

11 “(4) describes the coordination between the Food
12 and Drug Administration and the Drug Enforcement
13 Administration on efforts to prevent or alleviate drug
14 shortages;

15 “(5) identifies the number of and describes the
16 instances in which the Food and Drug Administra-
17 tion exercised regulatory flexibility and discretion to
18 prevent or alleviate a drug shortage;

19 “(6) lists the names of manufacturers that were
20 issued letters under section 506C(f); and

21 “(7) specifies the number of drug shortages oc-
22 curring during such calendar year, as identified by
23 the Secretary.

24 “(b) *TREND ANALYSIS.*—The Secretary is authorized
25 to retain a third party to conduct a study, if the Secretary

1 *believes such a study would help clarify the causes, trends,*
 2 *or solutions related to drug shortages.*

3 “(c) *DEFINITION.*—*In this section, the term ‘drug*
 4 *shortage’ or ‘shortage’ has the meaning given such term in*
 5 *section 506C.’.*”

6 **SEC. 1003. COORDINATION; TASK FORCE AND STRATEGIC**
 7 **PLAN.**

8 *Chapter V (21 U.S.C. 351 et seq.) is amended by in-*
 9 *serting after section 506C–1, as added by section 1002 of*
 10 *this Act, the following:*

11 **“SEC. 506D. COORDINATION; TASK FORCE AND STRATEGIC**
 12 **PLAN.**

13 “(a) *TASK FORCE AND STRATEGIC PLAN.*—

14 “(1) *IN GENERAL.*—

15 “(A) *TASK FORCE.*—*As soon as practicable*
 16 *after the date of enactment of the Food and Drug*
 17 *Administration Safety and Innovation Act, the*
 18 *Secretary shall establish a task force to develop*
 19 *and implement a strategic plan for enhancing*
 20 *the Secretary’s response to preventing and miti-*
 21 *gating drug shortages.*

22 “(B) *STRATEGIC PLAN.*—*The strategic plan*
 23 *described in subparagraph (A) shall include—*

1 “(i) plans for enhanced interagency
2 and intra-agency coordination, communica-
3 tion, and decisionmaking;

4 “(ii) plans for ensuring that drug
5 shortages are considered when the Secretary
6 initiates a regulatory action that could pre-
7 cipitate a drug shortage or exacerbate an
8 existing drug shortage;

9 “(iii) plans for effective communica-
10 tion with outside stakeholders, including
11 who the Secretary should alert about poten-
12 tial or actual drug shortages, how the com-
13 munication should occur, and what types of
14 information should be shared;

15 “(iv) plans for considering the impact
16 of drug shortages on research and clinical
17 trials; and

18 “(v) an examination of whether to es-
19 tablish a ‘qualified manufacturing partner
20 program’, as described in subparagraph
21 (C).

22 “(C) DESCRIPTION OF PROGRAM.—In con-
23 ducting the examination of a ‘qualified manufac-
24 turing partner program’ under subparagraph
25 (B)(v), the Secretary—

1 “(i) shall take into account that—

2 “(I) a ‘qualified manufacturer’,
3 for purposes of such program, would
4 need to have the capability and capac-
5 ity to supply products determined or
6 anticipated to be in shortage; and

7 “(II) in examining the capability
8 and capacity to supply products in
9 shortage, the ‘qualified manufacturer’
10 could have a site that manufactures a
11 drug listed under section 506E or have
12 the capacity to produce drugs in re-
13 sponse to a shortage within a rapid
14 timeframe; and

15 “(ii) shall examine whether incentives
16 are necessary to encourage the participation
17 of ‘qualified manufacturers’ in such a pro-
18 gram.

19 “(D) CONSULTATION.—In carrying out this
20 paragraph, the task force shall ensure consulta-
21 tion with the appropriate offices within the Food
22 and Drug Administration, including the Office
23 of the Commissioner, the Center for Drug Eval-
24 uation and Research, the Office of Regulatory
25 Affairs, and employees within the Department of

1 *Health and Human Services with expertise re-*
2 *garding drug shortages. The Secretary shall en-*
3 *gage external stakeholders and experts as appro-*
4 *priate.*

5 “(2) *TIMING.*—*Not later than 1 year after the*
6 *date of enactment of the Food and Drug Administra-*
7 *tion Safety and Innovation Act, the task force shall—*

8 “(A) *publish the strategic plan described in*
9 *paragraph (1); and*

10 “(B) *submit such plan to Congress.*

11 “(b) *COMMUNICATION.*—*The Secretary shall ensure*
12 *that, prior to any enforcement action or issuance of a warn-*
13 *ing letter that the Secretary determines could reasonably*
14 *be anticipated to lead to a meaningful disruption in the*
15 *supply in the United States of a drug described under sec-*
16 *tion 506C(a), there is communication with the appropriate*
17 *office of the Food and Drug Administration with expertise*
18 *regarding drug shortages regarding whether the action or*
19 *letter could cause, or exacerbate, a shortage of the drug.*

20 “(c) *ACTION.*—*If the Secretary determines, after the*
21 *communication described in subsection (b), that an enforce-*
22 *ment action or a warning letter could reasonably cause or*
23 *exacerbate a shortage of a drug described under section*
24 *506C(a), then the Secretary shall evaluate the risks associ-*
25 *ated with the impact of such shortage upon patients and*

1 *those risks associated with the violation involved before tak-*
 2 *ing such action or issuing such letter, unless there is immi-*
 3 *nent risk of serious adverse health consequences or death*
 4 *to humans.*

5 “(d) *REPORTING BY OTHER ENTITIES.*—*The Secretary*
 6 *shall identify or establish a mechanism by which health care*
 7 *providers and other third-party organizations may report*
 8 *to the Secretary evidence of a drug shortage.*

9 “(e) *REVIEW AND CONSTRUCTION.*—*No determination,*
 10 *finding, action, or omission of the Secretary under this sec-*
 11 *tion shall—*

12 “(1) *be subject to judicial review; or*

13 “(2) *be construed to establish a defense to an en-*
 14 *forcement action by the Secretary.*

15 “(f) *SUNSET.*—*Subsections (a), (b), (c), and (e) shall*
 16 *cease to be effective on the date that is 5 years after the*
 17 *date of enactment of the Food and Drug Administration*
 18 *Safety and Innovation Act.”.*

19 **SEC. 1004. DRUG SHORTAGE LIST.**

20 *Chapter V (21 U.S.C. 351 et seq.) is amended by in-*
 21 *serting after section 506D, as added by section 1003 of this*
 22 *Act, the following:*

1 **“SEC. 506E. DRUG SHORTAGE LIST.**

2 “(a) *ESTABLISHMENT.*—*The Secretary shall maintain*
3 *an up-to-date list of drugs that are determined by the Sec-*
4 *retary to be in shortage in the United States.*

5 “(b) *CONTENTS.*—*For each drug on such list, the Sec-*
6 *retary shall include the following information:*

7 “(1) *The name of the drug in shortage, including*
8 *the National Drug Code number for such drug.*

9 “(2) *The name of each manufacturer of such*
10 *drug.*

11 “(3) *The reason for the shortage, as determined*
12 *by the Secretary, selecting from the following cat-*
13 *egories:*

14 “(A) *Requirements related to complying*
15 *with good manufacturing practices.*

16 “(B) *Regulatory delay.*

17 “(C) *Shortage of an active ingredient.*

18 “(D) *Shortage of an inactive ingredient*
19 *component.*

20 “(E) *Discontinuation of the manufacture of*
21 *the drug.*

22 “(F) *Delay in shipping of the drug.*

23 “(G) *Demand increase for the drug.*

24 “(4) *The estimated duration of the shortage as*
25 *determined by the Secretary.*

26 “(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 INFOR-*
5 *MATION.*—Nothing in this section alters or amends
6 section 1905 of title 18, United States Code, or section
7 552(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) or section 506C(c) if the Secretary determines that
12 disclosure of such information would adversely affect
13 the public health (such as by increasing the possi-
14 bility of hoarding or other disruption of the avail-
15 ability of drug products to patients).”.

16 **SEC. 1005. 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 following:

19 “(h)(1) Not later than 30 days after the receipt of a
20 request described in paragraph (2), the Attorney General
21 shall—

22 “(A) complete review of such request; and

23 “(B)(i) as necessary to address a shortage of a
24 controlled substance, increase the aggregate and indi-
25 vidual production quotas under this section applica-

1 *ble to such controlled substance and any ingredient*
 2 *therein to the level requested; or*

3 *“(ii) if the Attorney General determines that the*
 4 *level requested is not necessary to address a shortage*
 5 *of a controlled substance, the Attorney General shall*
 6 *provide a written response detailing the basis for the*
 7 *Attorney General’s determination.*

8 *The Secretary shall make the written response provided*
 9 *under subparagraph (B)(ii) available to the public on the*
 10 *Internet Web site of the Food and Drug Administration.*

11 *“(2) A request is described in this paragraph if—*

12 *“(A) the request pertains to a controlled sub-*
 13 *stance on the list of drugs in shortage maintained*
 14 *under section 506E of the Federal Food, Drug, and*
 15 *Cosmetic Act;*

16 *“(B) the request is submitted by the manufac-*
 17 *turer of the controlled substance; and*

18 *“(C) the controlled substance is in schedule II.”.*

19 **SEC. 1006. ATTORNEY GENERAL REPORT ON DRUG SHORT-**
 20 **AGES.**

21 *Not later than 6 months after the date of the enactment*
 22 *of this Act, and annually thereafter, the Attorney General*
 23 *shall submit to the Committee on Energy and Commerce*
 24 *of the House of Representatives and the Committee on the*
 25 *Judiciary of the Senate a report on drug shortages that—*

1 (1) identifies the number of requests received
 2 under section 306(h) of the Controlled Substances Act
 3 (as added by section 1005 of this Act), the average re-
 4 view time for such requests, the number of requests
 5 granted and denied under such section, and, for each
 6 of the requests denied under such section, the basis for
 7 such denial;

8 (2) describes the coordination between the Drug
 9 Enforcement Administration and Food and Drug Ad-
 10 ministration on efforts to prevent or alleviate drug
 11 shortages; and

12 (3) identifies drugs containing a controlled sub-
 13 stance subject to section 306 of the Controlled Sub-
 14 stances Act when such a drug is determined by the
 15 Secretary to be in shortage.

16 **SEC. 1007. HOSPITAL REPACKAGING OF DRUGS IN SHORT-**
 17 **AGE.**

18 Chapter V (21 U.S.C. 351 et seq.) is amended by in-
 19 serting after section 506E, as added by section 1004 of this
 20 Act, the following:

21 **“SEC. 506F. HOSPITAL REPACKAGING OF DRUGS IN SHORT-**
 22 **AGE.**

23 “(a) *DEFINITIONS.*—In this section:

1 “(1) *DRUG*.—The term ‘drug’ excludes any con-
2 trolled substance (as such term is defined in section
3 102 of the Controlled Substances Act).

4 “(2) *HEALTH SYSTEM*.—The term ‘health system’
5 means a collection of hospitals that are owned and
6 operated by the same entity and that share access to
7 databases with drug order information for their pa-
8 tients.

9 “(3) *REPACKAGE*.—For the purposes of this sec-
10 tion only, the term ‘repackage’, with respect to a
11 drug, means to divide the volume of a drug into
12 smaller amounts in order to—

13 “(A) extend the supply of a drug in re-
14 sponse to the placement of the drug on a drug
15 shortage list under section 506E; and

16 “(B) facilitate access to the drug by hos-
17 pitals within the same health system.

18 “(b) *EXCLUSION FROM REGISTRATION*.—Notwith-
19 standing any other provision of this Act, a hospital shall
20 not be considered an establishment for which registration
21 is required under section 510 solely because it repackages
22 a drug and transfers it to another hospital within the same
23 health system in accordance with the conditions in sub-
24 section (c)—

1 “(1) during any period in which the drug is list-
2 ed on the drug shortage list under section 506E; or

3 “(2) during the 60-day period following any pe-
4 riod described in paragraph (1).

5 “(c) *CONDITIONS.*—Subsection (b) shall only apply to
6 a hospital, with respect to the repackaging of a drug for
7 transfer to another hospital within the same health system,
8 if the following conditions are met:

9 “(1) *DRUG FOR INTRASYSTEM USE ONLY.*—In no
10 case may a drug that has been repackaged in accord-
11 ance with this section be sold or otherwise distributed
12 by the health system or a hospital within the system
13 to an entity or individual that is not a hospital with-
14 in such health system.

15 “(2) *COMPLIANCE WITH STATE RULES.*—Repack-
16 aging of a drug under this section shall be done in
17 compliance with applicable State requirements of
18 each State in which the drug is repackaged and re-
19 ceived.

20 “(d) *TERMINATION.*—This section shall not apply on
21 or after the date on which the Secretary issues final guid-
22 ance that clarifies the policy of the Food and Drug Admin-
23 istration regarding hospital pharmacies repackaging and
24 safely transferring repackaged drugs to other hospitals
25 within the same health system during a drug shortage.”.

1 **SEC. 1008. STUDY ON DRUG SHORTAGES.**

2 (a) *STUDY.*—*The Comptroller General of the United*
3 *States shall conduct a study to examine the cause of drug*
4 *shortages and formulate recommendations on how to pre-*
5 *vent or alleviate such shortages.*

6 (b) *CONSIDERATION.*—*In conducting the study under*
7 *this section, the Comptroller General shall consider the fol-*
8 *lowing questions:*

9 (1) *What are the dominant characteristics of*
10 *drugs that have gone into a drug shortage over the*
11 *preceding 3 years?*

12 (2) *Are there systemic high-risk factors (such as*
13 *drug pricing structure, including Federal reimburse-*
14 *ments, or the number of manufacturers producing a*
15 *drug product) that have led to the concentration of*
16 *drug shortages in certain drug products that have*
17 *made such products vulnerable to drug shortages?*

18 (3) *Is there a reason why drug shortages have oc-*
19 *curred primarily in the sterile injectable market and*
20 *in certain therapeutic areas?*

21 (4)(A) *How have regulations, guidance docu-*
22 *ments, regulatory practices, policies, and other ac-*
23 *tions of Federal departments and agencies (including*
24 *the effectiveness of interagency and intra-agency co-*
25 *ordination, communication, strategic planning, and*

1 *decisionmaking), including those used to enforce stat-*
2 *utory requirements, affected drug shortages?*

3 *(B) Do any such regulations, guidances, policies,*
4 *or practices cause, exacerbate, prevent, or mitigate*
5 *drug shortages?*

6 *(C) How can regulations, guidances, policies, or*
7 *practices be modified, streamlined, expanded, or dis-*
8 *continued in order to reduce or prevent such drug*
9 *shortages?*

10 *(D) What effect would the changes described in*
11 *subparagraph (C) have on the public health?*

12 *(5) How does hoarding affect drug shortages?*

13 *(6) How would incentives alleviate or prevent*
14 *drug shortages?*

15 *(7) To what extent are health care providers, in-*
16 *cluding hospitals and physicians responding to drug*
17 *shortages, able to adjust care effectively to compensate*
18 *for such shortages, and what impediments exist that*
19 *hinder provider ability to adjust to such shortages?*

20 *(8)(A) Have drug shortages led market partici-*
21 *pants to stockpile affected drugs or sell such drugs at*
22 *inflated prices?*

23 *(B) What has been the impact of any such ac-*
24 *tivities described in subparagraph (A) on Federal rev-*

1 *enue, and are there any economic factors that have*
 2 *exacerbated or created a market for such activities?*

3 *(C) Is there a need for any additional reporting*
 4 *or enforcement actions to address such activities?*

5 *(9)(A) How have the activities under section*
 6 *506D of the Federal Food, Drug, and Cosmetic Act*
 7 *(as added by section 1003 of this Act) improved the*
 8 *efforts of the Food and Drug Administration to miti-*
 9 *gate and prevent drug shortages?*

10 *(B) Is there a need to continue the task force and*
 11 *strategic plan under such section 506D, or are there*
 12 *any other recommendations to increase communica-*
 13 *tion and coordination inside the Food and Drug Ad-*
 14 *ministration, between the Food and Drug Adminis-*
 15 *tration and other agencies, and between the Food and*
 16 *Drug Administration and stakeholders?*

17 *(c) CONSULTATION WITH STAKEHOLDERS.—In con-*
 18 *ducting the study under this section, the Comptroller Gen-*
 19 *eral shall consult with relevant stakeholders, including phy-*
 20 *sicians, pharmacists, hospitals, patients, drug manufactur-*
 21 *ers, and other health providers.*

22 *(d) REPORT.—Not later than 18 months after the date*
 23 *of the enactment of this Act, the Comptroller General shall*
 24 *submit a report to the Committee on Energy and Commerce*
 25 *of the House of Representatives and the Committee on*

1 *Health, Education, Labor, and Pensions of the Senate on*
 2 *the results of the study under this section.*

3 ***TITLE XI—OTHER PROVISIONS***

4 ***Subtitle A—Reauthorizations***

5 ***SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO*** 6 ***EXCLUSIVITY OF CERTAIN DRUGS CON-*** 7 ***TAINING SINGLE ENANTIOMERS.***

8 (a) *IN GENERAL.*—Section 505(u)(4) (21 U.S.C.
 9 355(u)(4)) is amended by striking “2012” and inserting
 10 “2017”.

11 (b) *AMENDMENT.*—Section 505(u)(1)(A)(ii)(II) (21
 12 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting “clin-
 13 ical” after “any”.

14 ***SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUB-*** 15 ***LIC-PRIVATE PARTNERSHIPS.***

16 Subsection (f) of section 566 (21 U.S.C. 360bbb–5) is
 17 amended to read as follows:

18 “(f) *AUTHORIZATION OF APPROPRIATIONS.*—To carry
 19 out this section, there is authorized to be appropriated
 20 \$6,000,000 for each of fiscal years 2013 through 2017.”.

21 ***Subtitle B—Medical Gas Product*** 22 ***Regulation***

23 ***SEC. 1111. REGULATION OF MEDICAL GASES.***

24 Chapter V (21 U.S.C. 351 et seq.) is amended by add-
 25 ing at the end the following:

1 **“Subchapter G—Medical Gases**

2 **“SEC. 575. DEFINITIONS.**

3 *“In this subchapter:*

4 *“(1) The term ‘designated medical gas’ means*
 5 *any of the following:*

6 *“(A) Oxygen that meets the standards set*
 7 *forth in an official compendium.*

8 *“(B) Nitrogen that meets the standards set*
 9 *forth in an official compendium.*

10 *“(C) Nitrous oxide that meets the standards*
 11 *set forth in an official compendium.*

12 *“(D) Carbon dioxide that meets the stand-*
 13 *ards set forth in an official compendium.*

14 *“(E) Helium that meets the standards set*
 15 *forth in an official compendium.*

16 *“(F) Carbon monoxide that meets the stand-*
 17 *ards set forth in an official compendium.*

18 *“(G) Medical air that meets the standards*
 19 *set forth in an official compendium.*

20 *“(H) Any other medical gas deemed appro-*
 21 *priate by the Secretary, after taking into account*
 22 *any investigational new drug application or in-*
 23 *vestigational new animal drug application for*
 24 *the same medical gas submitted in accordance*
 25 *with regulations applicable to such applications*

1 *in title 21 of the Code of Federal Regulations,*
 2 *unless any period of exclusivity under section*
 3 *505(c)(3)(E)(ii) or section 505(j)(5)(F)(ii), or*
 4 *the extension of any such period under section*
 5 *505A, applicable to such medical gas has not ex-*
 6 *pired.*

7 “(2) The term ‘medical gas’ means a drug that—

8 “(A) is manufactured or stored in a lique-

9 *fied, nonliquefied, or cryogenic state; and*

10 “(B) is administered as a gas.

11 **“SEC. 576. REGULATION OF MEDICAL GASES.**

12 “(a) CERTIFICATION OF DESIGNATED MEDICAL

13 *GASES.—*

14 “(1) SUBMISSION.—*Beginning 180 days after the*

15 *date of enactment of this section, any person may file*

16 *with the Secretary a request for certification of a*

17 *medical gas as a designated medical gas. Any such re-*

18 *quest shall contain the following information:*

19 “(A) *A description of the medical gas.*

20 “(B) *The name and address of the sponsor.*

21 “(C) *The name and address of the facility*

22 *or facilities where the medical gas is or will be*

23 *manufactured.*

1 “(D) *Any other information deemed appro-*
 2 *priate by the Secretary to determine whether the*
 3 *medical gas is a designated medical gas.*

4 “(2) *GRANT OF CERTIFICATION.—The certifi-*
 5 *cation requested under paragraph (1) is deemed to be*
 6 *granted unless, within 60 days of the filing of such*
 7 *request, the Secretary finds that—*

8 “(A) *the medical gas subject to the certifi-*
 9 *cation is not a designated medical gas;*

10 “(B) *the request does not contain the infor-*
 11 *mation required under paragraph (1) or other-*
 12 *wise lacks sufficient information to permit the*
 13 *Secretary to determine that the medical gas is a*
 14 *designated medical gas; or*

15 “(C) *denying the request is necessary to*
 16 *protect the public health.*

17 “(3) *EFFECT OF CERTIFICATION.—*

18 “(A) *IN GENERAL.—*

19 “(i) *APPROVED USES.—A designated*
 20 *medical gas for which a certification is*
 21 *granted under paragraph (2) is deemed,*
 22 *alone or in combination, as medically ap-*
 23 *propriate, with another designated medical*
 24 *gas or gases for which a certification or cer-*
 25 *tifications have been granted, to have in ef-*

1 *fect an approved application under section*
2 *505 or 512, subject to all applicable post-*
3 *approval requirements, for the following in-*
4 *dications for use:*

5 *“(I) In the case of oxygen, the*
6 *treatment or prevention of hypoxemia*
7 *or hypoxia.*

8 *“(II) In the case of nitrogen, use*
9 *in hypoxic challenge testing.*

10 *“(III) In the case of nitrous oxide,*
11 *analgesia.*

12 *“(IV) In the case of carbon diox-*
13 *ide, use in extracorporeal membrane*
14 *oxygenation therapy or respiratory*
15 *stimulation.*

16 *“(V) In the case of helium, the*
17 *treatment of upper airway obstruction*
18 *or increased airway resistance.*

19 *“(VI) In the case of medical air,*
20 *to reduce the risk of hyperoxia.*

21 *“(VII) In the case of carbon mon-*
22 *oxide, use in lung diffusion testing.*

23 *“(VIII) Any other indication for*
24 *use for a designated medical gas or*
25 *combination of designated medical*

1 *gases deemed appropriate by the Sec-*
2 *retary, unless any period of exclusivity*
3 *under clause (iii) or (iv) of section*
4 *505(c)(3)(E), clause (iii) or (iv) of sec-*
5 *tion 505(j)(5)(F), or section 527, or the*
6 *extension of any such period under sec-*
7 *tion 505A, applicable to such indica-*
8 *tion for use for such gas or combina-*
9 *tion of gases has not expired.*

10 “(ii) *LABELING.*—*The requirements of*
11 *sections 503(b)(4) and 502(f) are deemed to*
12 *have been met for a designated medical gas*
13 *if the labeling on final use container for*
14 *such medical gas bears—*

15 “(I) *the information required by*
16 *section 503(b)(4);*

17 “(II) *a warning statement con-*
18 *cerning the use of the medical gas as*
19 *determined by the Secretary by regula-*
20 *tion; and*

21 “(III) *appropriate directions and*
22 *warnings concerning storage and han-*
23 *dling.*

24 “(B) *INAPPLICABILITY OF EXCLUSIVITY*

25 *PROVISIONS.—*

1 “(i) *NO EXCLUSIVITY FOR A CERTIFIED*
 2 *MEDICAL GAS.*—No designated medical gas
 3 deemed under subparagraph (A)(i) to have
 4 in effect an approved application is eligible
 5 for any period of exclusivity under section
 6 505(c), 505(j), or 527, or the extension of
 7 any such period under section 505A, on the
 8 basis of such deemed approval.

9 “(ii) *EFFECT ON CERTIFICATION.*—No
 10 period of exclusivity under section 505(c),
 11 505(j), or section 527, or the extension of
 12 any such period under section 505A, with
 13 respect to an application for a drug product
 14 shall prohibit, limit, or otherwise affect the
 15 submission, grant, or effect of a certification
 16 under this section, except as provided in
 17 subsection (a)(3)(A)(i)(VIII) and section
 18 575(1)(H).

19 “(4) *WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.*—

21 “(A) *WITHDRAWAL, SUSPENSION OF APPROVAL.*—Nothing in this subchapter limits the
 22 Secretary’s authority to withdraw or suspend
 23 approval of a drug product, including a des-
 24 ignated medical gas deemed under this section to
 25

1 *have in effect an approved application under sec-*
 2 *tion 505 or section 512 of this Act.*

3 “(B) *REVOCATION OF CERTIFICATION.*—*The*
 4 *Secretary may revoke the grant of a certification*
 5 *under paragraph (2) if the Secretary determines*
 6 *that the request for certification contains any*
 7 *material omission or falsification.*

8 “(b) *PRESCRIPTION REQUIREMENT.*—

9 “(1) *IN GENERAL.*—*A designated medical gas*
 10 *shall be subject to the requirements of section*
 11 *503(b)(1) unless the Secretary exercises the authority*
 12 *provided in section 503(b)(3) to remove such medical*
 13 *gas from the requirements of section 503(b)(1), the gas*
 14 *is approved for use without a prescription pursuant*
 15 *to an application under section 505 or 512, or the use*
 16 *in question is authorized pursuant to another provi-*
 17 *sion of this Act relating to use of medical products in*
 18 *emergencies.*

19 “(2) *OXYGEN.*—

20 “(A) *NO PRESCRIPTION REQUIRED FOR*
 21 *CERTAIN USES.*—*Notwithstanding paragraph*
 22 *(1), oxygen may be provided without a prescrip-*
 23 *tion for the following uses:*

1 “(i) *For use in the event of depressuri-*
 2 *zation or other environmental oxygen defi-*
 3 *ciency.*

4 “(ii) *For oxygen deficiency or for use*
 5 *in emergency resuscitation, when adminis-*
 6 *tered by properly trained personnel.*

7 “(B) *LABELING.—For oxygen provided pur-*
 8 *suant to subparagraph (A), the requirements of*
 9 *section 503(b)(4) shall be deemed to have been*
 10 *met if its labeling bears a warning that the oxy-*
 11 *gen can be used for emergency use only and for*
 12 *all other medical applications a prescription is*
 13 *required.*

14 **“SEC. 577. INAPPLICABILITY OF DRUG FEES TO DES-**
 15 **IGNATED MEDICAL GASES.**

16 *“A designated medical gas, alone or in combination*
 17 *with another designated gas or gases (as medically appro-*
 18 *priate) deemed under section 576 to have in effect an ap-*
 19 *proved application shall not be assessed fees under section*
 20 *736(a) on the basis of such deemed approval.”.*

21 **SEC. 1112. CHANGES TO REGULATIONS.**

22 *(a) REPORT.—Not later than 18 months after the date*
 23 *of the enactment of this Act, the Secretary, after obtaining*
 24 *input from medical gas manufacturers and any other inter-*
 25 *ested members of the public, shall—*

1 (1) *determine whether any changes to the Fed-*
2 *eral drug regulations are necessary for medical gases;*
3 *and*

4 (2) *submit to the Committee on Health, Edu-*
5 *cation, Labor, and Pensions of the Senate and the*
6 *Committee on Energy and Commerce of the House of*
7 *Representatives a report regarding any such changes.*

8 (b) *REGULATIONS.—If the Secretary determines under*
9 *subsection (a) that changes to the Federal drug regulations*
10 *are necessary for medical gases, the Secretary shall issue*
11 *final regulations revising the Federal drug regulations with*
12 *respect to medical gases not later than 48 months after the*
13 *date of the enactment of this Act.*

14 (c) *DEFINITIONS.—In this section:*

15 (1) *The term “Federal drug regulations” means*
16 *regulations in title 21 of the Code of Federal Regula-*
17 *tions pertaining to drugs.*

18 (2) *The term “medical gas” has the meaning*
19 *given to such term in section 575 of the Federal Food,*
20 *Drug, and Cosmetic Act, as added by section 1111 of*
21 *this Act.*

22 (3) *The term “Secretary” means the Secretary of*
23 *Health and Human Services, acting through the Com-*
24 *missioner of Food and Drugs.*

1 **SEC. 1113. RULES OF CONSTRUCTION.**

2 *Nothing in this subtitle and the amendments made by*
3 *this subtitle applies with respect to—*

4 *(1) a drug that is approved prior to May 1,*
5 *2012, pursuant to an application submitted under*
6 *section 505 or 512 of the Federal Food, Drug, and*
7 *Cosmetic Act (21 U.S.C. 355, 360b);*

8 *(2) any gas listed in subparagraphs (A) through*
9 *(G) of section 575(1) of the Federal Food, Drug, and*
10 *Cosmetic Act, as added by section 1111 of this Act,*
11 *or any combination of any such gases, for an indica-*
12 *tion that—*

13 *(A) is not included in, or is different from,*
14 *those specified in subclauses (I) through (VII) of*
15 *section 576(a)(3)(A)(i) of such Act; and*

16 *(B) is approved on or after May 1, 2012,*
17 *pursuant to an application submitted under sec-*
18 *tion 505 or 512; or*

19 *(3) any designated medical gas added pursuant*
20 *to subparagraph (H) of section 575(1) of such Act for*
21 *an indication that—*

22 *(A) is not included in, or is different from,*
23 *those originally added pursuant to subparagraph*
24 *(H) of section 575(1) and section*
25 *576(a)(3)(A)(i)(VIII); and*

1 (B) is approved on or after May 1, 2012,
 2 pursuant to an application submitted under sec-
 3 tion 505 or 512 of such Act.

4 ***Subtitle C—Miscellaneous***
 5 ***Provisions***

6 ***SEC. 1121. GUIDANCE DOCUMENT REGARDING PRODUCT***
 7 ***PROMOTION USING THE INTERNET.***

8 *Not later than 2 years after the date of enactment of*
 9 *this Act, the Secretary of Health and Human Services shall*
 10 *issue guidance that describes Food and Drug Administra-*
 11 *tion policy regarding the promotion, using the Internet (in-*
 12 *cluding social media), of medical products that are regu-*
 13 *lated by such Administration.*

14 ***SEC. 1122. COMBATING PRESCRIPTION DRUG ABUSE.***

15 *(a) IN GENERAL.—To combat the significant rise in*
 16 *prescription drug abuse and the consequences of such abuse,*
 17 *the Secretary of Health and Human Services (referred to*
 18 *in this section as the “Secretary”), in coordination with*
 19 *other Federal agencies, as appropriate, shall review current*
 20 *Federal initiatives and identify gaps and opportunities*
 21 *with respect to—*

22 *(1) ensuring the safe use of prescription drugs*
 23 *with the potential for abuse; and*

24 *(2) the treatment of prescription drug*
 25 *dependence.*

1 (b) *REPORT.*—Not later than 1 year after the date of
2 enactment of this Act, the Secretary shall post on the De-
3 partment of Health and Human Service’s Internet Web site
4 a report on the findings of the review under subsection (a).
5 Such report shall include findings and recommendations
6 on—

7 (1) *how best to leverage and build upon existing*
8 *Federal and federally funded data sources, such as*
9 *prescription drug monitoring program data and the*
10 *sentinel initiative of the Food and Drug Administra-*
11 *tion under section 505(k)(3) of the Federal Food,*
12 *Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as it*
13 *relates to collection of information relevant to adverse*
14 *events, patient safety, and patient outcomes, to create*
15 *a centralized data clearinghouse and early warning*
16 *tool;*

17 (2) *how best to develop and disseminate widely*
18 *best practices models and suggested standard require-*
19 *ments to States for achieving greater interoperability*
20 *and effectiveness of prescription drug monitoring pro-*
21 *grams, especially with respect to provider participa-*
22 *tion, producing standardized data on adverse events,*
23 *patient safety, and patient outcomes; and*

24 (3) *how best to develop provider, pharmacist,*
25 *and patient education tools and a strategy to widely*

1 *disseminate such tools and assess the efficacy of such*
 2 *tools.*

3 *(c) GUIDANCE ON ABUSE-DETERRENT PRODUCTS.—*
 4 *Not later than 6 months after the date of enactment of this*
 5 *Act, the Secretary shall promulgate guidance on the devel-*
 6 *opment of abuse-deterrent drug products.*

7 **SEC. 1123. OPTIMIZING GLOBAL CLINICAL TRIALS.**

8 *Subchapter E of chapter V (21 U.S.C. 360bbb et seq.),*
 9 *as amended by section 903 of this Act, is further amended*
 10 *by adding at the end the following:*

11 **“SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.**

12 *“(a) IN GENERAL.—The Secretary shall—*

13 *“(1) work with other regulatory authorities of*
 14 *similar standing, medical research companies, and*
 15 *international organizations to foster and encourage*
 16 *uniform, scientifically driven clinical trial standards*
 17 *with respect to medical products around the world;*
 18 *and*

19 *“(2) enhance the commitment to provide con-*
 20 *sistent parallel scientific advice to manufacturers*
 21 *seeking simultaneous global development of new med-*
 22 *ical products in order to—*

23 *“(A) enhance medical product development;*

24 *“(B) facilitate the use of foreign data; and*

1 “(C) *minimize the need to conduct duplica-*
 2 *tive clinical studies, preclinical studies, or non-*
 3 *clinical studies.*

4 “(b) *MEDICAL PRODUCT.—In this section, the term*
 5 *‘medical product’ means a drug, as defined in subsection*
 6 *(g) of section 201, a device, as defined in subsection (h)*
 7 *of such section, or a biological product, as defined in section*
 8 *351(i) of the Public Health Service Act.*

9 “(c) *SAVINGS CLAUSE.—Nothing in this section shall*
 10 *alter the criteria for evaluating the safety or effectiveness*
 11 *of a medical product under this Act.*

12 **“SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM**
 13 **OUTSIDE THE UNITED STATES.**

14 “(a) *IN GENERAL.—In determining whether to ap-*
 15 *prove, license, or clear a drug or device pursuant to an ap-*
 16 *plication submitted under this chapter, the Secretary shall*
 17 *accept data from clinical investigations conducted outside*
 18 *of the United States, including the European Union, if the*
 19 *applicant demonstrates that such data are adequate under*
 20 *applicable standards to support approval, licensure, or*
 21 *clearance of the drug or device in the United States.*

22 “(b) *NOTICE TO SPONSOR.—If the Secretary finds*
 23 *under subsection (a) that the data from clinical investiga-*
 24 *tions conducted outside the United States, including in the*
 25 *European Union, are inadequate for the purpose of making*

1 *a determination on approval, clearance, or licensure of a*
 2 *drug or device pursuant to an application submitted under*
 3 *this chapter, the Secretary shall provide written notice to*
 4 *the sponsor of the application of such finding and include*
 5 *the rationale for such finding.”.*

6 **SEC. 1124. ADVANCING REGULATORY SCIENCE TO PRO-**
 7 **MOTE PUBLIC HEALTH INNOVATION.**

8 *(a) IN GENERAL.—Not later than 1 year after the date*
 9 *of enactment of this Act, the Secretary of Health and*
 10 *Human Services (referred to in this section as the “Sec-*
 11 *retary”)* shall develop a strategy and implementation plan
 12 *for advancing regulatory science for medical products in*
 13 *order to promote the public health and advance innovation*
 14 *in regulatory decisionmaking.*

15 *(b) REQUIREMENTS.—The strategy and implementa-*
 16 *tion plan developed under subsection (a) shall be consistent*
 17 *with the user fee performance goals in the Prescription*
 18 *Drug User Fee Agreement commitment letter, the Generic*
 19 *Drug User Fee Agreement commitment letter, and the Bio-*
 20 *similar User Fee Agreement commitment letter transmitted*
 21 *by the Secretary to Congress on January 13, 2012, and the*
 22 *Medical Device User Fee Agreement commitment letter*
 23 *transmitted by the Secretary to Congress on April 20, 2012,*
 24 *and shall—*

1 (1) *identify a clear vision of the fundamental*
2 *role of efficient, consistent, and predictable, science-*
3 *based decisions throughout regulatory decisionmaking*
4 *of the Food and Drug Administration with respect to*
5 *medical products;*

6 (2) *identify the regulatory science priorities of*
7 *the Food and Drug Administration directly related to*
8 *fulfilling the mission of the agency with respect to de-*
9 *cisionmaking concerning medical products and allo-*
10 *cation of resources toward such regulatory science pri-*
11 *orities;*

12 (3) *identify regulatory and scientific gaps that*
13 *impede the timely development and review of, and*
14 *regulatory certainty with respect to, the approval, li-*
15 *cence, or clearance of medical products, including*
16 *with respect to companion products and new tech-*
17 *nologies, and facilitating the timely introduction and*
18 *adoption of new technologies and methodologies in a*
19 *safe and effective manner;*

20 (4) *identify clear, measurable metrics by which*
21 *progress on the priorities identified under paragraph*
22 *(2) and gaps identified under paragraph (3) will be*
23 *measured by the Food and Drug Administration, in-*
24 *cluding metrics specific to the integration and adop-*
25 *tion of advances in regulatory science described in*

1 paragraph (5) and improving medical product deci-
2 sionmaking, in a predictable and science-based man-
3 ner; and

4 (5) set forth how the Food and Drug Administra-
5 tion will ensure that advances in regulatory science
6 for medical products are adopted, as appropriate, on
7 an ongoing basis and in an manner integrated across
8 centers, divisions, and branches of the Food and Drug
9 Administration, including by senior managers and
10 reviewers, including through the—

11 (A) development, updating, and consistent
12 application of guidance documents that support
13 medical product decisionmaking; and

14 (B) adoption of the tools, methods, and
15 processes under section 566 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

17 (c) *PERFORMANCE REPORTS.*—The annual perform-
18 ance reports submitted to Congress under sections 736B(a)
19 (as amended by section 104 of this Act), 738A(a) (as
20 amended by section 204 of this Act), 744C(a) (as added by
21 section 303 of this Act), and 744I(a) (as added by section
22 403 of this Act) of the Federal Food, Drug, and Cosmetic
23 Act for each of fiscal years 2014 and 2016, shall include
24 a report from the Secretary on the progress made with re-
25 spect to—

1 (1) *advancing the regulatory science priorities*
2 *identified under paragraph (2) of subsection (b) and*
3 *resolving the gaps identified under paragraph (3) of*
4 *such subsection, including reporting on specific*
5 *metrics identified under paragraph (4) of such sub-*
6 *section;*

7 (2) *the integration and adoption of advances in*
8 *regulatory science as set forth in paragraph (5) of*
9 *such subsection; and*

10 (3) *the progress made in advancing the regu-*
11 *latory science goals outlined in the Prescription Drug*
12 *User Fee Agreement commitment letter, the Generic*
13 *Drug User Fee Agreement commitment letter, and the*
14 *Biosimilar User Fee Agreement commitment letter*
15 *transmitted by the Secretary to Congress on January*
16 *13, 2012, and the Medical Device User Fee Agreement*
17 *transmitted by the Secretary to Congress on April 20,*
18 *2012.*

19 (d) *MEDICAL PRODUCT.*—*In this section, the term*
20 *“medical product” means a drug, as defined in subsection*
21 *(g) of section 201 of the Federal Food, Drug, and Cosmetic*
22 *Act (21 U.S.C. 321), a device, as defined in subsection (h)*
23 *of such section, or a biological product, as defined in section*
24 *351(i) of the Public Health Service Act.*

1 **SEC. 1125. INFORMATION TECHNOLOGY.**

2 (a) *HHS REPORT*.—Not later than 1 year after the
3 date of enactment of this Act, the Secretary of Health and
4 Human Services shall—

5 (1) report to Congress on—

6 (A) the milestones and a completion date
7 for developing and implementing a comprehen-
8 sive information technology strategic plan to
9 align the information technology systems mod-
10 ernization projects with the strategic goals of the
11 Food and Drug Administration, including re-
12 sults-oriented goals, strategies, milestones, per-
13 formance measures;

14 (B) efforts to finalize and approve a com-
15 prehensive inventory of the information tech-
16 nology systems of the Food and Drug Adminis-
17 tration that includes information describing each
18 system, such as costs, system function or pur-
19 pose, and status information, and incorporate
20 use of the system portfolio into the information
21 investment management process of the Food and
22 Drug Administration;

23 (C) the ways in which the Food and Drug
24 Administration uses the plan described in sub-
25 paragraph (A) to guide and coordinate the mod-
26 ernization projects and activities of the Food and

1 *Drug Administration, including the interdepend-*
2 *encies among projects and activities; and*

3 *(D) the extent to which the Food and Drug*
4 *Administration has fulfilled or is implementing*
5 *recommendations of the Government Account-*
6 *ability Office with respect to the Food and Drug*
7 *Administration and information technology; and*
8 *(2) develop—*

9 *(A) a documented enterprise architecture*
10 *program management plan that includes the*
11 *tasks, activities, and timeframes associated with*
12 *developing and using the architecture and ad-*
13 *dresses how the enterprise architecture program*
14 *management will be performed in coordination*
15 *with other management disciplines, such as orga-*
16 *nizational strategic planning, capital planning*
17 *and investment control, and performance man-*
18 *agement; and*

19 *(B) a skills inventory, needs assessment,*
20 *gap analysis, and initiatives to address skills*
21 *gaps as part of a strategic approach to informa-*
22 *tion technology human capital planning.*

23 *(b) GAO REPORT.—Not later than January 1, 2016,*
24 *the Comptroller General of the United States shall issue a*
25 *report regarding the strategic plan described in subsection*

1 (a)(1)(A) and related actions carried out by the Food and
 2 Drug Administration. Such report shall assess the progress
 3 the Food and Drug Administration has made on—

4 (1) the development and implementation of a
 5 comprehensive information technology strategic plan,
 6 including the results-oriented goals, strategies, mile-
 7 stones, and performance measures identified in sub-
 8 section (a)(1)(A);

9 (2) the effectiveness of the comprehensive infor-
 10 mation technology strategic plan described in sub-
 11 section (a)(1)(A), including the results-oriented goals
 12 and performance measures; and

13 (3) the extent to which the Food and Drug Ad-
 14 ministration has fulfilled recommendations of the
 15 Government Accountability Office with respect to such
 16 agency and information technology.

17 **SEC. 1126. NANOTECHNOLOGY.**

18 (a) *IN GENERAL.*—The Secretary of Health and
 19 Human Services (referred to in this section as the “Sec-
 20 retary”) shall intensify and expand activities related to en-
 21 hancing scientific knowledge regarding nanomaterials in-
 22 cluded or intended for inclusion in products regulated
 23 under the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 24 301 et seq.) or other statutes administered by the Food and
 25 Drug Administration, to address issues relevant to the regu-

1 *lation of those products, including the potential toxicology*
2 *of such nanomaterials, the potential benefit of new therapies*
3 *derived from nanotechnology, the effects of such nanomate-*
4 *rials on biological systems, and the interaction of such*
5 *nanomaterials with biological systems.*

6 (b) *ACTIVITIES.—In conducting activities related to*
7 *nanotechnology, the Secretary may—*

8 (1) *assess scientific literature and data on gen-*
9 *eral nanomaterials interactions with biological sys-*
10 *tems and on specific nanomaterials of concern to the*
11 *Food and Drug Administration;*

12 (2) *in cooperation with other Federal agencies,*
13 *develop and organize information using databases*
14 *and models that will facilitate the identification of*
15 *generalized principles and characteristics regarding*
16 *the behavior of classes of nanomaterials with biologi-*
17 *cal systems;*

18 (3) *promote Food and Drug Administration pro-*
19 *grams and participate in collaborative efforts, to fur-*
20 *ther the understanding of the science of novel prop-*
21 *erties of nanomaterials that might contribute to tox-*
22 *icity;*

23 (4) *promote and participate in collaborative ef-*
24 *forts to further the understanding of measurement*
25 *and detection methods for nanomaterials;*

1 (5) collect, synthesize, interpret, and disseminate
 2 scientific information and data related to the inter-
 3 actions of nanomaterials with biological systems;

4 (6) build scientific expertise on nanomaterials
 5 within the Food and Drug Administration, including
 6 field and laboratory expertise, for monitoring the pro-
 7 duction and presence of nanomaterials in domestic
 8 and imported products regulated under this Act;

9 (7) ensure ongoing training, as well as dissemi-
 10 nation of new information within the centers of the
 11 Food and Drug Administration, and more broadly
 12 across the Food and Drug Administration, to ensure
 13 timely, informed consideration of the most current
 14 science pertaining to nanomaterials;

15 (8) encourage the Food and Drug Administra-
 16 tion to participate in international and national con-
 17 sensus standards activities pertaining to nanomate-
 18 rials; and

19 (9) carry out other activities that the Secretary
 20 determines are necessary and consistent with the pur-
 21 poses described in paragraphs (1) through (8).

22 **SEC. 1127. ONLINE PHARMACY REPORT TO CONGRESS.**

23 Not later than 1 year after the date of enactment of
 24 this Act, the Comptroller General of the United States shall
 25 submit to the Committee on Health, Education, Labor, and

1 *Pensions of the Senate and the Committee on Energy and*
2 *Commerce of the House of Representatives a report that de-*
3 *scribes any problems posed by pharmacy Internet Web sites*
4 *that violate Federal or State law, including—*

5 (1) *the methods by which Internet Web sites are*
6 *used to sell prescription drugs in violation of Federal*
7 *or State law or established industry standards;*

8 (2) *the harmful health effects that patients expe-*
9 *rience when they consume prescription drugs pur-*
10 *chased through such pharmacy Internet Web sites;*

11 (3) *efforts by the Federal Government and State*
12 *and local governments to investigate and prosecute*
13 *the owners or operators of pharmacy Internet Web*
14 *sites, to address the threats such Web sites pose, and*
15 *to protect patients;*

16 (4) *the level of success that Federal, State, and*
17 *local governments have experienced in investigating*
18 *and prosecuting such cases;*

19 (5) *whether the law, as in effect on the date of*
20 *the report, provides sufficient authorities to Federal,*
21 *State, and local governments to investigate and pros-*
22 *ecute the owners and operators of pharmacy Internet*
23 *Web sites that violate Federal or State law or estab-*
24 *lished industry standards;*

1 (6) *additional authorities that could assist Fed-*
 2 *eral, State, and local governments in investigating*
 3 *and prosecuting the owners and operators of phar-*
 4 *macy Internet Web sites that violate Federal or State*
 5 *law or established industry standards;*

6 (7) *laws, policies, and activities that would edu-*
 7 *cate consumers about how to distinguish pharmacy*
 8 *Internet Web sites that comply with Federal and*
 9 *State laws and established industry standards from*
 10 *those pharmacy Internet Web sites that do not comply*
 11 *with such laws and standards; and*

12 (8) *activities that private sector actors are tak-*
 13 *ing to address the prevalence of illegitimate pharmacy*
 14 *Internet Web sites, and any policies to encourage fur-*
 15 *ther activities.*

16 **SEC. 1128. REPORT ON SMALL BUSINESSES.**

17 *Not later than 1 year after the date of enactment of*
 18 *this Act, the Commissioner of Food and Drugs shall submit*
 19 *a report to Congress that includes—*

20 (1) *a listing of and staffing levels of all small*
 21 *business offices at the Food and Drug Administration,*
 22 *including the small business liaison program;*

23 (2) *the status of partnership efforts between the*
 24 *Food and Drug Administration and the Small Busi-*
 25 *ness Administration;*

1 (3) a summary of outreach efforts to small busi-
 2 nesses and small business associations, including
 3 availability of toll-free telephone help lines;

4 (4) with respect to the program under the Or-
 5 phan Drug Act (Public Law 97–414), the number of
 6 applications made by small businesses and number of
 7 applications approved for research grants and the
 8 number of companies receiving protocol assistance for
 9 the development of drugs for rare diseases and dis-
 10 orders;

11 (5) the number of small businesses submitting
 12 applications and receiving approval for unsolicited
 13 grant applications from the Food and Drug Adminis-
 14 tration;

15 (6) the number of small businesses submitting
 16 applications and receiving approval for solicited
 17 grant applications from the Food and Drug Adminis-
 18 tration; and

19 (7) barriers small businesses encounter in the
 20 drug and medical device approval process.

21 **SEC. 1129. PROTECTIONS FOR THE COMMISSIONED CORPS**
 22 **OF THE PUBLIC HEALTH SERVICE ACT.**

23 (a) *IN GENERAL.*—Section 221(a) of the Public Health
 24 Service Act (42 U.S.C. 213a(a)) is amended by adding at
 25 the end the following:

1 “(18) *Section 1034, Protected Communications;*
 2 *Prohibition of Retaliatory Personnel Actions.*”.

3 (b) *CONFORMING AMENDMENT.*—*Section 221(b) of the*
 4 *Public Health Service Act (42 U.S.C. 213a(b)) is amended*
 5 *by adding at the end the following: “For purposes of para-*
 6 *graph (18) of subsection (a), the term ‘Inspector General’*
 7 *in section 1034 of such title 10 shall mean the Inspector*
 8 *General of the Department of Health and Human Serv-*
 9 *ices.”.*

10 **SEC. 1130. COMPLIANCE DATE FOR RULE RELATING TO**
 11 **SUNSCREEN DRUG PRODUCTS FOR OVER-**
 12 **THE-COUNTER HUMAN USE.**

13 *In accordance with the final rule issued by the Com-*
 14 *missioner of Food and Drug entitled “Labeling and Effec-*
 15 *tiveness Testing; Sunscreen Drug Products for Over-the-*
 16 *Counter Human Use; Delay of Compliance Dates” (77 Fed.*
 17 *Reg. 27591 (May 11, 2012)), a product subject to the final*
 18 *rule issued by the Commissioner entitled “Labeling and Ef-*
 19 *fectiveness Testing; Sunscreen Drug Products for Over-the-*
 20 *Counter Human Use” (76 Fed. Reg. 35620 (June 17,*
 21 *2011)), shall comply with such rule not later than—*

- 22 (1) *December 17, 2013, for products subject to*
 23 *such rule with annual sales of less than \$25,000 and*
 24 (2) *December 17, 2012, for all other products*
 25 *subject to such rule.*

1 **SEC. 1131. STRATEGIC INTEGRATED MANAGEMENT PLAN.**

2 *Not later than 1 year after the date of enactment of*
3 *this Act, the Secretary of Health and Human Services shall*
4 *submit to Congress a strategic integrated management plan*
5 *for the Center for Drug Evaluation and Research, the Cen-*
6 *ter for Biologics Evaluation and Research, and the Center*
7 *for Devices and Radiological Health. Such strategic man-*
8 *agement plan shall—*

9 *(1) identify strategic institutional goals, prior-*
10 *ities, and mechanisms to improve efficiency, for the*
11 *Center for Drug Evaluation and Research, the Center*
12 *for Biologics Evaluation and Research, and the Cen-*
13 *ter for Devices and Radiological Health;*

14 *(2) describe the actions the Secretary will take to*
15 *recruit, retain, train, and continue to develop the*
16 *workforce at the Center for Drug Evaluation and Re-*
17 *search, the Center for Biologics Evaluation and Re-*
18 *search, and the Center for Devices and Radiological*
19 *Health to fulfill the public health mission of the Food*
20 *and Drug Administration; and*

21 *(3) identify results-oriented, outcome-based meas-*
22 *ures that the Secretary will use to measure the*
23 *progress of achieving the strategic goals, priorities,*
24 *and mechanisms identified under paragraph (1) and*
25 *the effectiveness of the actions identified under para-*
26 *graph (2), including metrics to ensure that managers*

1 *and reviewers of the Center for Drug Evaluation and*
 2 *Research, the Center for Biologics Evaluation and Re-*
 3 *search, and the Center for Devices and Radiological*
 4 *Health are familiar with and appropriately and con-*
 5 *sistently apply the requirements under the Federal*
 6 *Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),*
 7 *including new requirements under parts 2, 3, 7, and*
 8 *8 of subchapter C of title VII of the Federal Food,*
 9 *Drug, and Cosmetic Act (21 U.S.C. 379f et seq.).*

10 **SEC. 1132. ASSESSMENT AND MODIFICATION OF REMS.**

11 *(a) ASSESSMENT AND MODIFICATION OF APPROVED*
 12 *STRATEGY.—Section 505–1(g) (21 U.S.C. 355–1(g)) is*
 13 *amended—*

14 *(1) in paragraph (1), by striking “, and propose*
 15 *a modification to,”;*

16 *(2) in paragraph (2)—*

17 *(A) in the matter before subparagraph*
 18 *(A)—*

19 *(i) by striking “, subject to paragraph*
 20 *(5),”;* *and*

21 *(ii) by striking “, and may propose a*
 22 *modification to,”;*

23 *(B) in subparagraph (C), by striking “new*
 24 *safety or effectiveness information indicates*
 25 *that” and all that follows and inserting the fol-*

1 *lowing: “an assessment is needed to evaluate*
 2 *whether the approved strategy should be modified*
 3 *to—*

4 *“(i) ensure the benefits of the drug out-*
 5 *weigh the risks of the drug; or*

6 *“(ii) minimize the burden on the*
 7 *health care delivery system of complying*
 8 *with the strategy.”; and*

9 *(C) by striking subparagraph (D);*

10 *(3) in paragraph (3), by striking “for a drug*
 11 *shall include—” and all that follows and inserting*
 12 *the following “for a drug shall include, with respect*
 13 *to each goal included in the strategy, an assessment*
 14 *of the extent to which the approved strategy, includ-*
 15 *ing each element of the strategy, is meeting the goal*
 16 *or whether 1 or more such goals or such elements*
 17 *should be modified.”; and*

18 *(4) by amending paragraph (4) to read as fol-*
 19 *lows:*

20 *“(4) MODIFICATION.—*

21 *“(A) ON INITIATIVE OF RESPONSIBLE PER-*
 22 *SON.—After the approval of a risk evaluation*
 23 *and mitigation strategy by the Secretary, the re-*
 24 *sponsible person may, at any time, submit to the*
 25 *Secretary a proposal to modify the approved*

1 *strategy. Such proposal may propose the addi-*
 2 *tion, modification, or removal of any goal or ele-*
 3 *ment of the approved strategy and shall include*
 4 *an adequate rationale to support such proposed*
 5 *addition, modification, or removal of any goal or*
 6 *element of the strategy.*

7 *“(B) ON INITIATIVE OF SECRETARY.—After*
 8 *the approval of a risk evaluation and mitigation*
 9 *strategy by the Secretary, the Secretary may, at*
 10 *any time, require a responsible person to submit*
 11 *a proposed modification to the strategy within*
 12 *120 days or within such reasonable time as the*
 13 *Secretary specifies, if the Secretary, in consulta-*
 14 *tion with the offices described in subsection*
 15 *(c)(2), determines that 1 or more goals or ele-*
 16 *ments should be added, modified, or removed*
 17 *from the approved strategy to—*

18 *“(i) ensure the benefits of the drug out-*
 19 *weigh the risks of the drug; or*

20 *“(ii) minimize the burden on the*
 21 *health care delivery system of complying*
 22 *with the strategy.”.*

23 *(b) REVIEW OF PROPOSED STRATEGIES; REVIEW OF*
 24 *ASSESSMENTS AND MODIFICATIONS OF APPROVED STRATE-*

1 *GIES.—Section 505–1(h) (21 U.S.C. 355–1(h)) is amend-*
 2 *ed—*

3 *(1) in the subsection heading by inserting “AND*
 4 *MODIFICATIONS” after “REVIEW OF ASSESSMENTS”;*

5 *(2) in paragraph (1)—*

6 *(A) by inserting “and proposed modifica-*
 7 *tion to” after “under subsection (a) and each as-*
 8 *essment of”; and*

9 *(B) by inserting “, and, if necessary,*
 10 *promptly initiate discussions with the respon-*
 11 *sible person about such proposed strategy, assess-*
 12 *ment, or modification” after “subsection (g)”;*

13 *(3) by striking paragraph (2);*

14 *(4) by redesignating paragraphs (3) through (9)*
 15 *as paragraphs (2) through (8), respectively;*

16 *(5) in paragraph (2), as redesignated by para-*
 17 *graph (4)—*

18 *(A) by amending subparagraph (A) to read*
 19 *as follows:*

20 *“(A) IN GENERAL.—*

21 *“(i) TIMEFRAME.—Unless the dispute*
 22 *resolution process described under para-*
 23 *graph (3) or (4) applies, and, except as pro-*
 24 *vided in clause (ii) or clause (iii) below, the*
 25 *Secretary, in consultation with the offices*

1 *described in subsection (c)(2), shall review*
2 *and act on the proposed risk evaluation and*
3 *mitigation strategy for a drug or any pro-*
4 *posed modification to any required strategy*
5 *within 180 days of receipt of the proposed*
6 *strategy or modification.*

7 “(ii) *MINOR MODIFICATIONS.—The*
8 *Secretary shall review and act on a pro-*
9 *posed minor modification, as defined by the*
10 *Secretary in guidance, within 60 days of*
11 *receipt of such modification.*

12 “(iii) *REMS MODIFICATION DUE TO*
13 *SAFETY LABEL CHANGES.—Not later than*
14 *60 days after the Secretary receives a pro-*
15 *posed modification to an approved risk*
16 *evaluation and mitigation strategy to con-*
17 *form the strategy to approved safety label*
18 *changes, including safety labeling changes*
19 *initiated by the sponsor in accordance with*
20 *FDA regulatory requirements, or to a safety*
21 *label change that the Secretary has directed*
22 *the holder of the application to make pursu-*
23 *ant to section 505(o)(4), the Secretary shall*
24 *review and act on such proposed modifica-*
25 *tion to the approved strategy.*

1 “(iv) *GUIDANCE.—The Secretary shall*
 2 *establish, through guidance, that responsible*
 3 *persons may implement certain modifica-*
 4 *tions to an approved risk evaluation and*
 5 *mitigation strategy following notification to*
 6 *the Secretary.*”; and

7 (B) by amending subparagraph (C) to read
 8 as follows:

9 “(C) *PUBLIC AVAILABILITY.—Upon acting*
 10 *on a proposed risk evaluation and mitigation*
 11 *strategy or proposed modification to a risk eval-*
 12 *uation and mitigation strategy under subpara-*
 13 *graph (A), the Secretary shall make publicly*
 14 *available an action letter describing the actions*
 15 *taken by the Secretary under such subparagraph*
 16 *(A).*”;

17 (6) in paragraph (4), as redesignated by para-
 18 graph (4)—

19 (A) in subparagraph (A)(i)—

20 (i) by striking “Not earlier than 15
 21 days, and not later than 35 days, after dis-
 22 cussions under paragraph (2) have begun,
 23 the” and inserting “The”; and

24 (ii) by inserting “, after the sponsor is
 25 required to make a submission under sub-

1 section (a)(2) or (g),” before “request in
2 writing”; and

3 (B) in subparagraph (I)—

4 (i) by striking clauses (i) and (ii); and

5 (ii) by striking “if the Secretary—”

6 and inserting “if the Secretary has com-

7 plied with the timing requirements of sched-

8 uling review by the Drug Safety Oversight

9 Board, providing a written recommenda-

10 tion, and issuing an action letter under

11 subparagraphs (B), (F), and (G), respec-

12 tively.”;

13 (7) in paragraph (5), as redesignated by para-

14 graph (4)—

15 (A) in subparagraph (A), by striking “any

16 of subparagraphs (B) through (D)” and insert-

17 ing “subparagraph (B) or (C)”; and

18 (B) in subparagraph (C), by striking

19 “paragraph (4) or (5)” and inserting “para-

20 graph (3) or (4)”; and

21 (8) in paragraph (8), as redesignated by para-

22 graph (4), by striking “paragraphs (7) and (8)” and

23 inserting “paragraphs (6) and (7).”.

24 (c) *GUIDANCE*.—Not later than 1 year after the date

25 of enactment of this Act, the Secretary of Health and

1 *Human Services shall issue guidance that, for purposes of*
 2 *section 505–1(h)(2)(A) of the Federal Food, Drug, and Cos-*
 3 *metic Act (21 U.S.C. 355–1(h)(2)(A)), describes the types*
 4 *of modifications to approved risk evaluation and mitigation*
 5 *strategies that shall be considered to be minor modifications*
 6 *of such strategies.*

7 **SEC. 1133. EXTENSION OF PERIOD FOR FIRST APPLICANT**
 8 **TO OBTAIN TENTATIVE APPROVAL WITHOUT**
 9 **FORFEITING 180-DAY-EXCLUSIVITY PERIOD.**

10 (a) *EXTENSION.*—

11 (1) *IN GENERAL.*—*If a first applicant files an*
 12 *application during the 30-month period ending on the*
 13 *date of enactment of this Act and such application*
 14 *initially contains a certification described in para-*
 15 *graph (2)(A)(vii)(IV) of section 505(j) of the Federal*
 16 *Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), or*
 17 *if a first applicant files an application and the appli-*
 18 *cation is amended during such period to first contain*
 19 *such a certification, the phrase “30 months” in para-*
 20 *graph (5)(D)(i)(IV) of such section shall, with respect*
 21 *to such application, be read as meaning—*

22 (A) *during the period beginning on the date*
 23 *of enactment of this Act, and ending on Sep-*
 24 *tember 30, 2015, “40 months”; and*

1 (B) during the period beginning on October
 2 1, 2015, and ending on September 30, 2016, “36
 3 months”.

4 (2) CONFORMING AMENDMENT.—In the case of
 5 an application to which an extended period under
 6 paragraph (1) applies, the reference to the 30-month
 7 period under section 505(q)(1)(G) of the Federal
 8 Food, Drug, and Cosmetic Act (21 U.S.C.
 9 355(q)(1)(G)) shall be read to be the applicable period
 10 under paragraph (1).

11 (b) PERIOD FOR OBTAINING TENTATIVE APPROVAL OF
 12 CERTAIN APPLICATIONS.—If an application is filed on or
 13 before the date of enactment of this Act and such applica-
 14 tion is amended during the period beginning on the day
 15 after the date of enactment of this Act and ending on Sep-
 16 tember 30, 2017, to first contain a certification described
 17 in paragraph (2)(A)(vii)(IV) of section 505(j) of the Federal
 18 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), the date
 19 of the filing of such amendment (rather than the date of
 20 the filing of such application) shall be treated as the begin-
 21 ning of the 30-month period described in paragraph
 22 (5)(D)(i)(IV) of such section 505(j).

23 (c) DEFINITIONS.—For the purposes of this section, the
 24 terms “application” and “first applicant” mean applica-
 25 tion and first applicant, as such terms are used in section

1 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and Cos-
 2 metic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)).

3 **SEC. 1134. DEADLINE FOR DETERMINATION ON CERTAIN**
 4 **PETITIONS.**

5 (a) *IN GENERAL.*—Section 505 (21 U.S.C. 355) is
 6 amended by adding at the end the following:

7 “(w) *DEADLINE FOR DETERMINATION ON CERTAIN*
 8 *PETITIONS.*—The Secretary shall issue a final, substantive
 9 determination on a petition submitted pursuant to sub-
 10 section (b) of section 314.161 of title 21, Code of Federal
 11 Regulations (or any successor regulations), no later than
 12 270 days after the date the petition is submitted.”.

13 (b) *APPLICATION.*—The amendment made by sub-
 14 section (a) shall apply to any petition that is submitted
 15 pursuant to subsection (b) of section 314.161 of title 21,
 16 Code of Federal Regulations (or any successor regulations),
 17 on or after the date of enactment of this Act.

18 **SEC. 1135. FINAL AGENCY ACTION RELATING TO PETITIONS**
 19 **AND CIVIL ACTIONS.**

20 Section 505(q) (21 U.S.C. 355(q)) is amended—

21 (1) in paragraph (1)—

22 (A) in subparagraph (A), by striking “sub-
 23 section (b)(2) or (j)” and inserting “subsection
 24 (b)(2) or (j) of this section or section 351(k) of
 25 the Public Health Service Act”; and

1 (B) in subparagraph (F), by striking “180
2 days” and inserting “150 days”;

3 (2) in paragraph (2)(A)—

4 (A) in the subparagraph heading, by strik-
5 ing “180” and inserting “150”; and

6 (B) in clause (i), by striking “180-day” and
7 inserting “150-day”;

8 (3) in paragraph (4)—

9 (A) by redesignating subparagraphs (A)
10 and (B) as clauses (i) and (ii), respectively, and
11 moving such clauses, as so redesignated, 2 ems to
12 the right;

13 (B) by striking “This subsection does not
14 apply to—” and inserting the following:

15 “(A) This subsection does not apply to—”;

16 and

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

18 “(B) Paragraph (2) does not apply to a pe-
19 tition addressing issues concerning an applica-
20 tion submitted pursuant to section 351(k) of the
21 Public Health Service Act.”; and

22 (4) in paragraph (5), by striking “subsection
23 (b)(2) or (j)” inserting “subsection (b)(2) or (j) of the
24 Act or 351(k) of the Public Health Service Act”.

1 **SEC. 1136. ELECTRONIC SUBMISSION OF APPLICATIONS.**

2 *Subchapter D of chapter VII (21 U.S.C. 379k et seq.)*
 3 *is amended by inserting after section 745 the following:*

4 **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

5 *“(a) DRUGS AND BIOLOGICS.—*

6 *“(1) IN GENERAL.—Beginning no earlier than*
 7 *24 months after the issuance of a final guidance*
 8 *issued after public notice and opportunity for com-*
 9 *ment, submissions under subsection (b), (i), or (j) of*
 10 *section 505 of this Act or subsection (a) or (k) of sec-*
 11 *tion 351 of the Public Health Service Act shall be*
 12 *submitted in such electronic format as specified by the*
 13 *Secretary in such guidance.*

14 *“(2) GUIDANCE CONTENTS.—In the guidance*
 15 *under paragraph (1), the Secretary may—*

16 *“(A) provide a timetable for establishment*
 17 *by the Secretary of further standards for elec-*
 18 *tronic submission as required by such para-*
 19 *graph; and*

20 *“(B) set forth criteria for waivers of and ex-*
 21 *emptions from the requirements of this sub-*
 22 *section.*

23 *“(3) EXCEPTION.—This subsection shall not*
 24 *apply to submissions described in section 561.*

25 *“(b) DEVICES.—*

1 “(1) *IN GENERAL.*—Beginning after the issuance
 2 of final guidance implementing this paragraph,
 3 presubmissions and submissions for devices under sec-
 4 tion 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f),
 5 520(g), 520(m), or 564 of this Act or section 351 of
 6 the Public Health Service Act, and any supplements
 7 to such presubmissions or submissions, shall include
 8 an electronic copy of such presubmissions or submis-
 9 sions.

10 “(2) *GUIDANCE CONTENTS.*—In the guidance
 11 under paragraph (1), the Secretary may—

12 “(A) provide standards for the electronic
 13 copy required under such paragraph; and

14 “(B) set forth criteria for waivers of and ex-
 15 emptions from the requirements of this sub-
 16 section.”.

17 **SEC. 1137. PATIENT PARTICIPATION IN MEDICAL PRODUCT**
 18 **DISCUSSIONS.**

19 Subchapter E of chapter V (21 U.S.C. 360bbb et seq.),
 20 as amended by section 1123 of this Act, is further amended
 21 by adding at the end the following:

22 **“SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PROD-**
 23 **UCT DISCUSSION.**

24 “(a) *IN GENERAL.*—The Secretary shall develop and
 25 implement strategies to solicit the views of patients during

1 *the medical product development process and consider the*
2 *perspectives of patients during regulatory discussions, in-*
3 *cluding by—*

4 “(1) *fostering participation of a patient rep-*
5 *resentative who may serve as a special government*
6 *employee in appropriate agency meetings with med-*
7 *ical product sponsors and investigators; and*

8 “(2) *exploring means to provide for identifica-*
9 *tion of patient representatives who do not have any,*
10 *or have minimal, financial interests in the medical*
11 *products industry.*

12 “(b) *PROTECTION OF PROPRIETARY INFORMATION.—*
13 *Nothing in this section shall be construed to alter the protec-*
14 *tions offered by laws, regulations, or policies governing dis-*
15 *closure of confidential commercial or trade secret informa-*
16 *tion and any other information exempt from disclosure pur-*
17 *suant to section 552(b) of title 5, United States Code, as*
18 *such laws, regulations, or policies would apply to consulta-*
19 *tion with individuals and organizations prior to the date*
20 *of enactment of this section.*

21 “(c) *OTHER CONSULTATION.—Nothing in this section*
22 *shall be construed to limit the ability of the Secretary to*
23 *consult with individuals and organizations as authorized*
24 *prior to the date of enactment of this section.*

1 “(d) *NO RIGHT OR OBLIGATION.*—Nothing in this sec-
 2 tion shall be construed to create a legal right for a consulta-
 3 tion on any matter or require the Secretary to meet with
 4 any particular expert or stakeholder. Nothing in this section
 5 shall be construed to alter agreed upon goals and procedures
 6 identified in the letters described in section 101(b) of the
 7 Prescription Drug User Fee Amendments of 2012. Nothing
 8 in this section is intended to increase the number of review
 9 cycles as in effect before the date of enactment of this section.

10 “(e) *FINANCIAL INTEREST.*—In this section, the term
 11 ‘financial interest’ means a financial interest under section
 12 208(a) of title 18, United States Code.”.

13 **SEC. 1138. ENSURING ADEQUATE INFORMATION REGARD-**
 14 **ING PHARMACEUTICALS FOR ALL POPU-**
 15 **LATIONS, PARTICULARLY UNDERREP-**
 16 **RESENTED SUBPOPULATIONS, INCLUDING**
 17 **RACIAL SUBGROUPS.**

18 (a) *COMMUNICATION PLAN.*—The Secretary of Health
 19 and Human Services (referred to in this section as the “Sec-
 20 retary”), acting through the Commissioner of Food and
 21 Drugs, shall review and modify, as necessary, the Food and
 22 Drug Administration’s communication plan to inform and
 23 educate health care providers and patients on the benefits
 24 and risks of medical products, with particular focus on

1 *underrepresented subpopulations, including racial sub-*
2 *groups.*

3 (b) *CONTENT.—The communication plan described*
4 *under subsection (a)—*

5 (1) *shall take into account—*

6 (A) *the goals and principles set forth in the*
7 *Strategic Action Plan to Reduce Racial and*
8 *Ethnic Health Disparities issued by the Depart-*
9 *ment of Health and Human Services;*

10 (B) *the nature of the medical product; and*

11 (C) *health and disease information avail-*
12 *able from other agencies within such Depart-*
13 *ment, as well as any new means of commu-*
14 *nicating health and safety benefits and risks re-*
15 *lated to medical products;*

16 (2) *taking into account the nature of the medical*
17 *product, shall address the best strategy for commu-*
18 *nicating safety alerts, labeled indications for the med-*
19 *ical products, changes to the label or labeling of med-*
20 *ical products (including black-box warnings, health*
21 *advisories, health and safety benefits and risks), par-*
22 *ticular actions to be taken by health care professionals*
23 *and patients, any information identifying particular*
24 *subpopulations, and any other relevant information*
25 *as determined appropriate to enhance communica-*

1 *tion, including varied means of electronic commu-*
 2 *nication; and*

3 *(3) shall include a process for implementation of*
 4 *any improvements or other modifications determined*
 5 *to be necessary.*

6 *(c) ISSUANCE AND POSTING OF COMMUNICATION*
 7 *PLAN.—*

8 *(1) COMMUNICATION PLAN.—Not later than 1*
 9 *year after the date of enactment of this Act, the Sec-*
 10 *retary, acting through the Commissioner of Food and*
 11 *Drugs, shall issue the communication plan described*
 12 *under this section.*

13 *(2) POSTING OF COMMUNICATION PLAN ON THE*
 14 *OFFICE OF MINORITY HEALTH WEB SITE.—The Sec-*
 15 *retary, acting through the Commissioner of Food and*
 16 *Drugs, shall publicly post the communication plan on*
 17 *the Internet Web site of the Office of Minority Health*
 18 *of the Food and Drug Administration, and provide*
 19 *links to any other appropriate Internet Web site, and*
 20 *seek public comment on the communication plan.*

21 **SEC. 1139. SCHEDULING OF HYDROCODONE.**

22 *(a) IN GENERAL.—Not later than 60 days after the*
 23 *date of enactment of this Act, if practicable, the Secretary*
 24 *of Health and Human Services (referred to in this section*
 25 *as the “Secretary”) shall hold a public meeting to solicit*

1 *advice and recommendations to assist in conducting a sci-*
2 *entific and medical evaluation in connection with a sched-*
3 *uling recommendation to the Drug Enforcement Adminis-*
4 *tration regarding drug products containing hydrocodone,*
5 *combined with other analgesics or as an antitussive.*

6 (b) *STAKEHOLDER INPUT.*—*In conducting the evalua-*
7 *tion under subsection (a), the Secretary shall solicit input*
8 *from a variety of stakeholders including patients, health*
9 *care providers, harm prevention experts, the National Insti-*
10 *tute on Drug Abuse, the Centers for Disease Control and*
11 *Prevention, and the Drug Enforcement Administration re-*
12 *garding the health benefits and risks, including the poten-*
13 *tial for abuse and the impact of up-scheduling of these prod-*
14 *ucts.*

15 (c) *TRANSCRIPT.*—*The transcript of any public meet-*
16 *ing conducted pursuant to this section shall be published*
17 *on the Internet Web site of the Food and Drug Administra-*
18 *tion.*

19 **SEC. 1140. STUDY ON DRUG LABELING BY ELECTRONIC**
20 **MEANS.**

21 (a) *STUDY.*—*The Comptroller General of the United*
22 *States shall conduct a study on the benefits and efficiencies*
23 *of electronic patient labeling of prescription drugs, as a*
24 *complete or partial substitute for patient labeling in paper*
25 *form. The study shall address the implementation costs to*

1 *the different levels of the distribution system, logistical bar-*
 2 *riers to utilizing a system of electronic patient labeling, and*
 3 *any anticipated public health impact of movement to elec-*
 4 *tronic labeling.*

5 (b) *REPORT.*—*Not later than 1 year after the date of*
 6 *enactment of this Act, the Comptroller General shall submit*
 7 *to Congress a report on the results of the study under sub-*
 8 *section (a).*

9 **SEC. 1141. RECOMMENDATIONS ON INTEROPERABILITY**
 10 **STANDARDS.**

11 (a) *IN GENERAL.*—*The Secretary of Health and*
 12 *Human Services may facilitate, and, as appropriate, may*
 13 *consult with the Attorney General to facilitate, the develop-*
 14 *ment of recommendations on interoperability standards to*
 15 *inform and facilitate the exchange of prescription drug in-*
 16 *formation across State lines by States receiving grant funds*
 17 *under—*

18 (1) *the Harold Rogers Prescription Drug Moni-*
 19 *toring Program established under the Departments of*
 20 *Commerce, Justice, and State, the Judiciary, and Re-*
 21 *lated Agencies Appropriations Act, 2002 (Public Law*
 22 *107–77; 115 Stat. 748); and*

23 (2) *the Controlled Substance Monitoring Pro-*
 24 *gram established under section 399O of the Public*
 25 *Health Service Act (42 U.S.C. 280g–3).*

1 (b) *REQUIREMENTS.*—*The Secretary of Health and*
2 *Human Services shall consider the following in facilitating*
3 *the development of recommendations on interoperability of*
4 *prescription drug monitoring programs under subsection*
5 *(a)—*

6 (1) *open standards that are freely available,*
7 *without cost and without restriction, in order to pro-*
8 *mote broad implementation;*

9 (2) *the use of exchange intermediaries, or hubs,*
10 *as necessary to facilitate interstate interoperability by*
11 *accommodating State-to-hub, hub-to-hub, and direct*
12 *State-to-State communication;*

13 (3) *the support of transmissions that are fully*
14 *secured as required, using industry standard methods*
15 *of encryption, to ensure that protected health infor-*
16 *mation and personally identifiable information are*
17 *not compromised at any point during such trans-*
18 *mission;*

19 (4) *access control methodologies to share pro-*
20 *ected information solely in accordance with State*
21 *laws and regulations; and*

22 (5) *consider model interoperability standards de-*
23 *veloped by the Alliance of States with Prescription*
24 *Monitoring Programs.*

25 (c) *REPORT.*—

1 (1) *IN GENERAL.*—Not later than 1 year after
2 the date of enactment of this Act, the Secretary of
3 Health and Human Services shall submit to the Com-
4 mittee on Health, Education, Labor, and Pensions of
5 the Senate and the Committee on Energy and Com-
6 merce of the House of Representatives a report on en-
7 hancing the interoperability of State prescription
8 drug monitoring programs with other technologies
9 and databases used for detecting and reducing fraud,
10 diversion, and abuse of prescription drugs.

11 (2) *CONTENTS.*—The report required under
12 paragraph (1) shall include—

13 (A) an assessment of legal, technical, fiscal,
14 privacy, or security challenges that have an im-
15 pact on interoperability;

16 (B) a discussion of how State prescription
17 drug monitoring programs could increase the
18 production and distribution of unsolicited re-
19 ports to prescribers and dispensers of prescrip-
20 tion drugs, law enforcement officials, and health
21 professional licensing agencies, including the en-
22 hancement of such reporting through interoper-
23 ability with other States and relevant technology
24 and databases;

1 (C) any recommendations for addressing
 2 challenges that impact interoperability of State
 3 prescription drug monitoring programs in order
 4 to reduce fraud, diversion, and abuse of prescrip-
 5 tion drugs; and

6 (D) an assessment of the extent to which
 7 providers use prescription drug management
 8 programs in delivering care and preventing pre-
 9 scription drug abuse.

10 **SEC. 1142. CONFLICTS OF INTEREST.**

11 (a) *IN GENERAL.*—Section 712 (21 U.S.C. 379d–1) is
 12 amended—

13 (1) by striking subsections (b) and (c) and in-
 14 serting the following subsections:

15 “(b) *RECRUITMENT FOR ADVISORY COMMITTEES.*—

16 “(1) *IN GENERAL.*—The Secretary shall—

17 “(A) develop and implement strategies on
 18 effective outreach to potential members of advi-
 19 sory committees at universities, colleges, other
 20 academic research centers, professional and med-
 21 ical societies, and patient and consumer groups;

22 “(B) seek input from professional medical
 23 and scientific societies to determine the most ef-
 24 fective informational and recruitment activities;

1 “(C) *at least every 180 days, request refer-*
 2 *als for potential members of advisory commit-*
 3 *tees from a variety of stakeholders, including—*

4 “(i) *product developers, patient groups,*
 5 *and disease advocacy organizations; and*

6 “(ii) *relevant—*

7 “(I) *professional societies;*

8 “(II) *medical societies;*

9 “(III) *academic organizations;*

10 *and*

11 “(IV) *governmental organizations;*

12 *and*

13 “(D) *in carrying out subparagraphs (A)*
 14 *and (B), take into account the levels of activity*
 15 *(including the numbers of annual meetings) and*
 16 *the numbers of vacancies of the advisory commit-*
 17 *tees.*

18 “(2) *RECRUITMENT ACTIVITIES.—The recruit-*
 19 *ment activities under paragraph (1) may include—*

20 “(A) *advertising the process for becoming*
 21 *an advisory committee member at medical and*
 22 *scientific society conferences;*

23 “(B) *making widely available, including by*
 24 *using existing electronic communications chan-*
 25 *nels, the contact information for the Food and*

1 *Drug Administration point of contact regarding*
 2 *advisory committee nominations; and*

3 “(C) *developing a method through which an*
 4 *entity receiving funding from the National Insti-*
 5 *tutes of Health, the Agency for Healthcare Re-*
 6 *search and Quality, the Centers for Disease Con-*
 7 *trol and Prevention, or the Veterans Health Ad-*
 8 *ministration can identify a person whom the*
 9 *Food and Drug Administration can contact re-*
 10 *garding the nomination of individuals to serve*
 11 *on advisory committees.*

12 “(3) *EXPERTISE.—In carrying out this sub-*
 13 *section, the Secretary shall seek to ensure that the*
 14 *Secretary has access to the most current expert advice.*

15 “(c) *DISCLOSURE OF DETERMINATIONS AND CERTIFI-*
 16 *CATIONS.—Notwithstanding section 107(a)(2) of the Ethics*
 17 *in Government Act of 1978, the following shall apply:*

18 “(1) *15 OR MORE DAYS IN ADVANCE.—As soon as*
 19 *practicable, but (except as provided in paragraph (2))*
 20 *not later than 15 days prior to a meeting of an advi-*
 21 *sory committee to which a written determination as*
 22 *referred to in section 208(b)(1) of title 18, United*
 23 *States Code, or a written certification as referred to*
 24 *in section 208(b)(3) of such title, applies, the Sec-*
 25 *retary shall disclose (other than information exempted*

1 *from disclosure under section 552 or section 552a of*
2 *title 5, United States Code (popularly known as the*
3 *Freedom of Information Act and the Privacy Act of*
4 *1974, respectively)) on the Internet Web site of the*
5 *Food and Drug Administration—*

6 *“(A) the type, nature, and magnitude of the*
7 *financial interests of the advisory committee*
8 *member to which such determination or certifi-*
9 *cation applies; and*

10 *“(B) the reasons of the Secretary for such*
11 *determination or certification, including, as ap-*
12 *propriate, the public health interest in having*
13 *the expertise of the member with respect to the*
14 *particular matter before the advisory committee.*

15 *“(2) LESS THAN 30 DAYS IN ADVANCE.—In the*
16 *case of a financial interest that becomes known to the*
17 *Secretary less than 30 days prior to a meeting of an*
18 *advisory committee to which a written determination*
19 *as referred to in section 208(b)(1) of title 18, United*
20 *States Code, or a written certification as referred to*
21 *in section 208(b)(3) of such title applies, the Sec-*
22 *retary shall disclose (other than information exempted*
23 *from disclosure under section 552 or 552a of title 5,*
24 *United States Code) on the Internet Web site of the*
25 *Food and Drug Administration, the information de-*

1 scribed in subparagraphs (A) and (B) of paragraph
 2 (1) as soon as practicable after the Secretary makes
 3 such determination or certification, but in no case
 4 later than the date of such meeting.”;

5 (2) in subsection (d), by striking “subsection
 6 (c)(3)” and inserting “subsection (c)”;

7 (3) by amending subsection (e) to read as fol-
 8 lows:

9 “(e) *ANNUAL REPORT.*—

10 “(1) *IN GENERAL.*—Not later than February 1 of
 11 each year, the Secretary shall submit to the Com-
 12 mittee on Appropriations and the Committee on
 13 Health, Education, Labor, and Pensions of the Sen-
 14 ate, and the Committee on Appropriations and the
 15 Committee on Energy and Commerce of the House of
 16 Representatives, a report that describes—

17 “(A) with respect to the fiscal year that
 18 ended on September 30 of the previous year, the
 19 number of persons nominated for participation
 20 at meetings for each advisory committee, the
 21 number of persons so nominated, and willing to
 22 serve, the number of vacancies on each advisory
 23 committee, and the number of persons contacted
 24 for service as members on each advisory com-
 25 mittee meeting for each advisory committee who

1 *did not participate because of the potential for*
2 *such participation to constitute a disqualifying*
3 *financial interest under section 208 of title 18,*
4 *United States Code;*

5 “(B) *with respect to such year, the number*
6 *of persons contacted for services as members for*
7 *each advisory committee meeting for each advi-*
8 *sory committee who did not participate because*
9 *of reasons other than the potential for such par-*
10 *ticipation to constitute a disqualifying financial*
11 *interest under section 208 of title 18, United*
12 *States Code;*

13 “(C) *with respect to such year, the number*
14 *of members attending meetings for each advisory*
15 *committee; and*

16 “(D) *with respect to such year, the aggre-*
17 *gate number of disclosures required under sub-*
18 *section (d) and the percentage of individuals to*
19 *whom such disclosures did not apply who served*
20 *on such committee.*

21 “(2) *PUBLIC AVAILABILITY.—Not later than 30*
22 *days after submitting any report under paragraph*
23 *(1) to the committees specified in such paragraph, the*
24 *Secretary shall make each such report available to the*
25 *public.”;*

1 (4) in subsection (f), by striking “shall review
2 guidance” and all that follows through the end of the
3 subsection and inserting the following: “shall—

4 “(1) review guidance of the Food and Drug Ad-
5 ministration with respect to advisory committees re-
6 garding disclosure of conflicts of interest and the ap-
7 plication of section 208 of title 18, United States
8 Code; and

9 “(2) update such guidance as necessary to ensure
10 that the Food and Drug Administration receives ap-
11 propriate access to needed scientific expertise, with
12 due consideration of the requirements of such section
13 208.”; and

14 (5) by adding at the end the following:

15 “(g) *GUIDANCE ON REPORTED DISCLOSED FINANCIAL*
16 *INTEREST OR INVOLVEMENT.*—The Secretary shall issue
17 guidance that describes how the Secretary reviews the finan-
18 cial interests and involvement of advisory committee mem-
19 bers that are disclosed under subsection (c) but that the Sec-
20 retary determines not to meet the definition of a disquali-
21 fying interest under section 208 of title 18, United States
22 Code for the purposes of participating in a particular mat-
23 ter.”.

24 (b) *APPLICABILITY.*—The amendments made by sub-
25 section (a) apply beginning on October 1, 2012.

1 **SEC. 1143. NOTIFICATION OF FDA INTENT TO REGULATE**
 2 **LABORATORY-DEVELOPED TESTS.**

3 (a) *IN GENERAL.*—*The Food and Drug Administra-*
 4 *tion may not issue any draft or final guidance on the regu-*
 5 *lation of laboratory-developed tests under the Federal Food,*
 6 *Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) without,*
 7 *at least 60 days prior to such issuance—*

8 (1) *notifying the Committee on Energy and*
 9 *Commerce of the House of Representatives and the*
 10 *Committee on Health, Education, Labor, and Pen-*
 11 *sions of the Senate of the Administration’s intent to*
 12 *take such action; and*

13 (2) *including in such notification the antici-*
 14 *pated details of such action.*

15 (b) *SUNSET.*—*Subsection (a) shall cease to have force*
 16 *or effect on the date that is 5 years after the date of enact-*
 17 *ment of this Act.*

18 ***Subtitle D—Synthetic Drugs***

19 **SEC. 1151. SHORT TITLE.**

20 *This subtitle may be cited as the “Synthetic Drug*
 21 *Abuse Prevention Act of 2012”.*

22 **SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE**
 23 ***I OF THE CONTROLLED SUBSTANCES ACT.***

24 (a) *CANNABIMIMETIC AGENTS.*—*Schedule I, as set*
 25 *forth in section 202(c) of the Controlled Substances Act (21*

1 *U.S.C. 812(c)) is amended by adding at the end the fol-*
2 *lowing:*

3 “(d)(1) *Unless specifically exempted or unless listed in*
4 *another schedule, any material, compound, mixture, or*
5 *preparation which contains any quantity of*
6 *cannabimimetic agents, or which contains their salts, iso-*
7 *mers, and salts of isomers whenever the existence of such*
8 *salts, isomers, and salts of isomers is possible within the*
9 *specific chemical designation.*

10 “(2) *In paragraph (1):*

11 “(A) *The term ‘cannabimimetic agents’ means*
12 *any substance that is a cannabinoid receptor type 1*
13 *(CB1 receptor) agonist as demonstrated by binding*
14 *studies and functional assays within any of the fol-*
15 *lowing structural classes:*

16 “(i) *2-(3-hydroxycyclohexyl)phenol with*
17 *substitution at the 5-position of the phenolic ring*
18 *by alkyl or alkenyl, whether or not substituted on*
19 *the cyclohexyl ring to any extent.*

20 “(ii) *3-(1-naphthoyl)indole or 3-(1-*
21 *naphthylmethane)indole by substitution at the*
22 *nitrogen atom of the indole ring, whether or not*
23 *further substituted on the indole ring to any ex-*
24 *tent, whether or not substituted on the naphthoyl*
25 *or naphthyl ring to any extent.*

1 “(iii) 3-(1-naphthoyl)pyrrole by substi-
 2 tution at the nitrogen atom of the pyrrole ring,
 3 whether or not further substituted in the pyrrole
 4 ring to any extent, whether or not substituted on
 5 the naphthoyl ring to any extent.

6 “(iv) 1-(1-naphthylmethylene)indene by sub-
 7 stitution of the 3-position of the indene ring,
 8 whether or not further substituted in the indene
 9 ring to any extent, whether or not substituted on
 10 the naphthyl ring to any extent.

11 “(v) 3-phenylacetylindole or 3-benzoylindole
 12 by substitution at the nitrogen atom of the indole
 13 ring, whether or not further substituted in the
 14 indole ring to any extent, whether or not sub-
 15 stituted on the phenyl ring to any extent.

16 “(B) Such term includes—

17 “(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-
 18 hydroxycyclohexyl]-phenol (CP-47,497);

19 “(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-
 20 hydroxycyclohexyl]-phenol (cannabicyclohexanol
 21 or CP-47,497 C8-homolog);

22 “(iii) 1-pentyl-3-(1-naphthoyl)indole
 23 (JWH-018 and AM678);

24 “(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-
 25 073);

- 1 “(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–
- 2 019);
- 3 “(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naph-
- 4 thoyl)indole (JWH–200);
- 5 “(vii) 1-pentyl-3-(2-
- 6 methoxyphenylacetyl)indole (JWH–250);
- 7 “(viii) 1-pentyl-3-[1-(4-
- 8 methoxynaphthoyl)]indole (JWH–081);
- 9 “(ix) 1-pentyl-3-(4-methyl-1-naph-
- 10 thoyl)indole (JWH–122);
- 11 “(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole
- 12 (JWH–398);
- 13 “(xi) 1-(5-fluoropentyl)-3-(1-naph-
- 14 thoyl)indole (AM2201);
- 15 “(xii) 1-(5-fluoropentyl)-3-(2-
- 16 iodobenzoyl)indole (AM694);
- 17 “(xiii) 1-pentyl-3-[(4-methoxy)-ben-
- 18 zoyl]indole (SR–19 and RCS–4);
- 19 “(xiv) 1-cyclohexylethyl-3-(2-
- 20 methoxyphenylacetyl)indole (SR–18 and RCS–
- 21 8); and
- 22 “(xv) 1-pentyl-3-(2-
- 23 chlorophenylacetyl)indole (JWH–203).”.

1 (b) *OTHER DRUGS.*—Schedule I of section 202(c) of
 2 the Controlled Substances Act (21 U.S.C. 812(c)) is amend-
 3 ed in subsection (c) by adding at the end the following:

4 “(18) 4-methylmethcathinone (Mephedrone).

5 “(19) 3,4-methylenedioxypropylvalerone (MDPV).

6 “(20) 2-(2,5-Dimethoxy-4-
 7 ethylphenyl)ethanamine (2C-E).

8 “(21) 2-(2,5-Dimethoxy-4-
 9 methylphenyl)ethanamine (2C-D).

10 “(22) 2-(4-Chloro-2,5-
 11 dimethoxyphenyl)ethanamine (2C-C).

12 “(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine
 13 (2C-I).

14 “(24) 2-[4-(Ethylthio)-2,5-
 15 dimethoxyphenyl]ethanamine (2C-T-2).

16 “(25) 2-[4-(Isopropylthio)-2,5-
 17 dimethoxyphenyl]ethanamine (2C-T-4).

18 “(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-
 19 H).

20 “(27) 2-(2,5-Dimethoxy-4-nitro-
 21 phenyl)ethanamine (2C-N).

22 “(28) 2-(2,5-Dimethoxy-4-(n)-
 23 propylphenyl)ethanamine (2C-P).”.

1 **SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT**
2 **HAZARDS TO PUBLIC SAFETY EXPANSION.**

3 *Section 201(h)(2) of the Controlled Substances Act (21*
4 *U.S.C. 811(h)(2)) is amended—*

5 *(1) by striking “one year” and inserting “2*
6 *years”; and*

7 *(2) by striking “six months” and inserting “1*
8 *year”.*

Attest:

Clerk.

112TH CONGRESS
2^D SESSION

S. 3187

AMENDMENT