

Calendar No. 120

110TH CONGRESS
1ST SESSION

S. 1082

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 10, 2007

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 24, 2007

Reported by Mr. KENNEDY, with an amendment and an amendment to the title

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

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

3 **SECTION 1. SHORT TITLE; REFERENCES IN ACT.**

4 (a) ~~SHORT TITLE.~~—This Act may be cited as the
5 ~~“Prescription Drug User Fee Amendments of 2007”.~~

1 (b) REFERENCES IN ACT.—Except as otherwise spec-
2 ified, whenever in this Act an amendment is expressed in
3 terms of an amendment to a section or other provision,
4 the reference shall be considered to be made to a section
5 or other provision of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 301 et seq.).

7 **SEC. 2. DRUG FEES.**

8 Section 735 (21 U.S.C. 379g) is amended—

9 (1) by striking the section designation and all
10 that follows through “For purposes of this sub-
11 chapter:” and inserting the following:

12 **“SEC. 735. DRUG FEES.**

13 “(a) PURPOSE.—It is the purpose of this part that
14 the fees authorized under this part be dedicated toward
15 expediting the drug development process, the process for
16 the review of human drug applications, and postmarket
17 drug safety, as set forth in the goals identified for pur-
18 poses of this subchapter in the letters from the Secretary
19 to the Chairman of the Committee on Health, Education,
20 Labor, and Pensions of the Senate and the Chairman of
21 the Committee on Energy and Commerce of the House
22 of Representatives, as set forth in the Congressional
23 Record.

24 “(b) REPORTS.—

1 “(1) PERFORMANCE REPORT.—For fiscal years
2 2008 through 2012, not later than 120 days after
3 the end of each fiscal year during which fees are col-
4 lected under this part, the Secretary shall prepare
5 and submit to the Committee on Health, Education,
6 Labor, and Pensions of the Senate and the Com-
7 mittee on Energy and Commerce of the House of
8 Representatives, a report concerning the progress of
9 the Food and Drug Administration in achieving the
10 goals identified in the letters described in subsection
11 (a) during such fiscal year and the future plans of
12 the Food and Drug Administration for meeting the
13 goals. The report for a fiscal year shall include infor-
14 mation on all previous cohorts for which the Sec-
15 retary has not given a complete response on all
16 human drug applications and supplements in the co-
17 hort.

18 “(2) FISCAL REPORT.—For fiscal years 2008
19 through 2012, not later than 120 days after the end
20 of each fiscal year during which fees are collected
21 under this part, the Secretary shall prepare and sub-
22 mit to the Committee on Health, Education, Labor,
23 and Pensions of the Senate and the Committee on
24 Energy and Commerce of the House of Representa-
25 tives, a report on the implementation of the author-

1 ity for such fees during such fiscal year and the use,
 2 by the Food and Drug Administration, of the fees
 3 collected during such fiscal year for which the report
 4 is made.

5 “(3) PUBLIC AVAILABILITY.—The Secretary
 6 shall make the reports required under paragraphs
 7 (1) and (2) available to the public on the Internet
 8 website of the Food and Drug Administration.

9 “(e) REAUTHORIZATION.—

10 “(1) CONSULTATION.—In developing rec-
 11 ommendations to present to Congress with respect to
 12 the goals, and plans for meeting the goals, for the
 13 process for the review of human drug applications
 14 for the first 5 fiscal years after fiscal year 2012, and
 15 for the reauthorization of this part for such fiscal
 16 years, the Secretary shall consult with—

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

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

21 “(C) scientific and academic experts;

22 “(D) health care professionals;

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

25 “(F) the regulated industry.

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

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

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

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

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

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

18 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
19 Not later than January 15, 2012, the Secretary
20 shall transmit to Congress the revised recommenda-
21 tions under paragraph (2), a summary of the views
22 and comments received under such paragraph, and
23 any changes made to the recommendations in re-
24 sponse to such views and comments.

25 “(d) DEFINITIONS.—For purposes of this part:”;

- 1 (2) in subsection (d)—
- 2 (A) in paragraph (1)—
- 3 (i) in subparagraph (A), by striking
- 4 “505(b)(1),” and inserting “505(b), or”;
- 5 (ii) by striking subparagraph (B);
- 6 (iii) by redesignating subparagraph
- 7 (C) as subparagraph (B); and
- 8 (iv) in the matter following subpara-
- 9 graph (B), as so redesignated, by striking
- 10 “subparagraph (C)” and inserting “sub-
- 11 paragraph (B)”;
- 12 (B) in paragraph (3)(C), by—
- 13 (i) striking “the list” and inserting
- 14 “the list (not including the discontinued
- 15 section of such list)”;
- 16 (ii) striking “a list” and inserting “a
- 17 list (not including the discontinued section
- 18 of such a list)”;
- 19 (C) in paragraph (4), by inserting before
- 20 the period at the end the following: “(such as
- 21 capsules, tablets, and lyophilized products be-
- 22 fore reconstitution)”;
- 23 (D) by amending paragraph (6)(F) to read
- 24 as follows:

1 “(F) In the case of drugs approved under
2 human drug applications or supplements,
3 postmarket safety activities, including—

4 “(i) collecting, developing, and review-
5 ing safety information on approved drugs
6 (including adverse event reports);

7 “(ii) developing and using improved
8 adverse event data collection systems (in-
9 cluding information technology systems);
10 and

11 “(iii) developing and using improved
12 analytical tools to assess potential safety
13 problems (including by accessing external
14 data bases).”;

15 (E) in paragraph (8)—

16 (i) by striking “April of the preceding
17 fiscal year” and inserting “October of the
18 preceding fiscal year”; and

19 (ii) by striking “April 1997” and in-
20 serting “October 1996”;

21 (F) by redesignating paragraph (9) as
22 paragraph (10); and

23 (G) by inserting after paragraph (8) the
24 following:

1 “(9) The term ‘person’ includes an affiliate
2 thereof.”.

3 **SEC. 3. AUTHORITY TO ASSESS AND USE DRUG FEES.**

4 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
5 379h(a)) is amended—

6 (1) in the matter preceding paragraph (1), by
7 striking “2003” and inserting “2008”;

8 (2) in paragraph (1)—

9 (A) in subparagraph (D)—

10 (i) in the heading, by inserting “OR
11 WITHDRAWN BEFORE FILING” after “RE-
12 FUND OF FEE IF APPLICATION REFUSED
13 FOR FILING”; and

14 (ii) by inserting before the period at
15 the end the following: “or withdrawn with-
16 out a waiver before filing”;

17 (B) by redesignating subparagraphs (E)
18 and (F) as subparagraphs (F) and (G), respec-
19 tively; and

20 (C) by inserting after subparagraph (D)
21 the following:

22 “(E) FEE FOR APPLICATION PREVIOUSLY
23 REFUSED FOR FILING OR WITHDRAWN BEFORE
24 FILING.—An application or supplement that
25 has been refused for filing or that was with-

1 drawn before filing, if filed under protest or re-
2 submitted, shall be subject to the fee under sub-
3 paragraph (A) (unless an exception under sub-
4 paragraph (C) or (F) applies or the fee is
5 waived or reduced under subsection (d)), with-
6 out regard to previous payment of such a fee
7 and the refund of 75 percent of that fee under
8 subparagraph (D).”; and
9 ~~(3)~~ in paragraph ~~(2)~~—

10 (A) in subparagraph (A), by striking “sub-
11 paragraph (B)” and inserting “subparagraphs
12 (B) and (C)”; and

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

14 “(C) SPECIAL RULES FOR COMPOUNDED
15 POSITRON EMISSION TOMOGRAPHY DRUGS.—

16 “(i) IN GENERAL.—Except as pro-
17 vided in clause (ii), each person who is
18 named as the applicant in an approved
19 human drug application for a compounded
20 positron emission tomography drug shall
21 be subject under subparagraph (A) to one-
22 quarter of an annual establishment fee
23 with respect to each such establishment
24 identified in the application as producing

1 compounded positron emission tomography
2 drugs under the approved application.

3 “(ii) ~~EXCEPTION FROM ANNUAL ES-~~
4 ~~TABLISHMENT FEE.~~—Each person who is
5 named as the applicant in an application
6 described in clause (i) shall not be assessed
7 an annual establishment fee for a fiscal
8 year if the person certifies to the Sec-
9 retary, at a time specified by the Secretary
10 and using procedures specified by the Sec-
11 retary, that—

12 “(I) the person is a not-for-profit
13 medical center that has only 1 estab-
14 lishment for the production of com-
15 pounded positron emission tomog-
16 raphy drugs; and

17 “(II) at least 95 percent of the
18 total number of doses of each com-
19 pounded positron emission tomog-
20 raphy drug produced by such estab-
21 lishment during such fiscal year will
22 be used within the medical center.”.

23 (b) ~~FEE REVENUE AMOUNTS.~~—Section 736(b) (21
24 U.S.C. 379h(b)) is amended to read as follows:

1 “(b) FEE REVENUE AMOUNTS.—Except as provided
2 in subsections (c), (d), (f), and (g), fees under subsection
3 (a) shall be established to generate the following revenue
4 amounts, in each fiscal year beginning with fiscal year
5 2008 and continuing through fiscal year 2012:
6 \$392,783,000, plus an adjustment for workload on
7 \$354,893,000 of this amount. Such adjustment shall be
8 made in accordance with the workload adjustment provi-
9 sions in effect for fiscal year 2007, except that instead
10 of commercial investigational new drug applications sub-
11 mitted to the Secretary, all commercial investigational new
12 drug applications with a submission during the previous
13 12-month period shall be used in the determination. One-
14 third of the revenue amount shall be derived from applica-
15 tion fees, one-third from establishment fees, and one-third
16 from product fees.”.

17 (c) ADJUSTMENTS TO FEES.—

18 (1) INFLATION ADJUSTMENT.—Section
19 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

20 (A) in the matter preceding subparagraph
21 (A) by striking “The revenues established in
22 subsection (b)” and inserting “Beginning with
23 fiscal year 2009, the revenues established in
24 subsection (b)”;

1 (B) in subparagraph (A) by striking “or”
2 at the end;

3 (C) in subparagraph (B) by striking the
4 period at the end and inserting “, or,”;

5 (D) by inserting after subparagraph (B)
6 the following:

7 “(C) the average annual change in the
8 cost, per full-time equivalent position of the
9 Food and Drug Administration, of all personnel
10 compensation and benefits paid with respect to
11 such positions, for the first 5 fiscal years of the
12 previous 6 fiscal years.”; and

13 (E) in the matter following subparagraph
14 (C) (as added by this paragraph), by striking
15 “fiscal year 2003” and inserting “fiscal year
16 2008”.

17 (2) WORKLOAD ADJUSTMENT.—Section
18 736(e)(2) (21 U.S.C. 379h(e)(2)) is amended—

19 (A) in the matter preceding subparagraph
20 (A,) by striking “2004” and inserting “2009”;

21 (B) in the first sentence of subparagraph
22 (A)—

23 (i) by striking “, commercial inves-
24 tigation new drug applications” and in-

1 serting “(adjusted for changes in review
2 activities)”; and

3 (ii) by inserting before the period at
4 the end “, and the change in the number
5 of commercial investigational new drug ap-
6 plications with a submission during the
7 previous 12-month period (adjusted for
8 changes in review activities)”;

9 (C) in subparagraph (B), by adding at the
10 end the following new sentence: “Further, any
11 adjustment for changes in review activities
12 made in setting fees and fee revenue amounts
13 for fiscal year 2009 may not result in the total
14 workload adjustment being more than 2 per-
15 centage points higher than it would be absent
16 the adjustment for changes in review activi-
17 ties.”; and

18 (D) by adding at the end the following:

19 “(C) The Secretary shall contract with an
20 independent accounting firm to study the ad-
21 justment for changes in review activities applied
22 in setting fees for fiscal year 2009 and to make
23 recommendations, if warranted, on future
24 changes in the methodology for calculating the
25 adjustment for changes in review activity. After

1 review of the recommendations by the inde-
2 pendent accounting firm, the Secretary shall
3 make appropriate changes to the workload ad-
4 justment methodology in setting fees for fiscal
5 years 2010 through 2012. If the study is not
6 conducted, no adjustment for changes in review
7 activities shall be made after fiscal year 2009.”.

8 ~~(3) RENT AND RENT-RELATED COST ADJUST-~~
9 ~~MENT.—Section 736(e) (21 U.S.C. 379h(e)) is~~
10 ~~amended—~~

11 (A) by redesignating paragraphs ~~(3)~~, ~~(4)~~,
12 and ~~(5)~~ as paragraphs ~~(4)~~, ~~(5)~~, and ~~(6)~~, respec-
13 tively; and

14 (B) by inserting after paragraph ~~(2)~~ the
15 following:

16 “~~(3) RENT AND RENT-RELATED COST ADJUST-~~
17 ~~MENT.—Beginning in fiscal year 2010, the Secretary~~
18 ~~shall, before making the adjustments under para-~~
19 ~~graphs (1) and (2), reduce the fee amounts estab-~~
20 ~~lished in subsection (b), if actual costs paid for rent~~
21 ~~and rent-related expenses are less than \$11,721,000.~~
22 ~~The reductions made under this paragraph, if any,~~
23 ~~shall not exceed the amounts by which costs fell~~
24 ~~below \$11,721,000, and shall not exceed~~
25 ~~\$11,721,000 in any fiscal year.”.~~

1 (4) FINAL YEAR ADJUSTMENT.—Section 736(c)
2 (~~21 U.S.C. 379h(e)~~) is amended—

3 (A) in paragraph (4), as redesignated by
4 this subsection—

5 (i) by striking “2007” each place it
6 appears and inserting “2012”; and

7 (ii) by striking “2008” and inserting
8 “2013”; and

9 (B) in paragraph (5), as redesignated by
10 this subsection, by striking “2002” and insert-
11 ing “2007”.

12 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
13 (~~21 U.S.C. 379h(d)~~) is amended—

14 (1) in paragraph (1), in the matter preceding
15 subparagraph (A), by—

16 (A) inserting “to a person who is named as
17 the applicant” after “The Secretary shall
18 grant”;

19 (B) inserting “to that person” after “a
20 waiver from or a reduction of one or more fees
21 assessed”; and

22 (C) striking “finds” and inserting “deter-
23 mines”;

24 (2) by redesignating paragraphs (2) and (3) as
25 paragraphs (3) and (4), respectively;

1 (3) by inserting after paragraph (1) the fol-
2 lowing:

3 “(2) EVALUATION.—For the purpose of deter-
4 mining whether to grant a waiver or reduction of a
5 fee under paragraph (1), the Secretary shall con-
6 sider only the circumstances and assets of the appli-
7 cant and any affiliate of the applicant.”; and

8 (4) in paragraph (4), as redesignated by this
9 subsection, in subparagraph (A), by inserting before
10 the period at the end “, and that does not have a
11 drug product that has been approved under a human
12 drug application and introduced or delivered for in-
13 troduction into interstate commerce”.

14 (e) CREDITING AND AVAILABILITY OF FEES.—

15 (1) AUTHORIZATION OF APPROPRIATIONS.—
16 Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amend-
17 ed to read as follows:

18 “(3) AUTHORIZATION OF APPROPRIATIONS.—
19 There are authorized to be appropriated for fees
20 under this section such sums as are authorized to be
21 assessed and collected under this section in each of
22 fiscal years 2008 through 2012.”.

23 (2) OFFSET.—Section 736(g)(4) (21 U.S.C.
24 379h(g)(4)) is amended to read as follows:

1 “(4) OFFSET.—If the cumulative amount of
2 fees collected during fiscal years 2008, 2009, and
3 2010, plus the amount estimated to be collected for
4 fiscal year 2011, exceeds the amount of fees speci-
5 fied in aggregate in appropriation Acts for such fis-
6 cal years, the aggregate amount in excess shall be
7 credited to the appropriation account of the Food
8 and Drug Administration as provided in paragraph
9 (1), and shall be subtracted from the amount of fees
10 that would otherwise be authorized to be collected
11 under this section pursuant to appropriation Acts
12 for fiscal year 2012.”.

13 (f) CONFORMING AMENDMENTS.—

14 (1) Section 736(a) (21 U.S.C. 379h(a)), as
15 amended by this section, is amended—

16 (A) in paragraph (1)(A), by striking “sub-
17 section (e)(4)” each place it appears and insert-
18 ing “subsection (e)(5)”;

19 (B) in paragraph (2), by striking “sub-
20 section (e)(4)” and inserting “subsection
21 (e)(5)”; and

22 (C) in paragraph (3), by striking “sub-
23 section (e)(4)” and inserting “subsection
24 (e)(5)”.

1 (2) Section 736A(h)(3), as added by section 4
 2 of this Act, is amended by striking “735(3)” and in-
 3 serting “735(d)(3)”.

4 **SEC. 4. AUTHORITY TO ASSESS AND USE PRESCRIPTION**
 5 **DRUG ADVERTISING FEES.**

6 Chapter VII, subchapter C, part 2 (21 U.S.C. 379g
 7 et seq.) is amended by adding after section 736 the fol-
 8 lowing new section:

9 **“SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE**
 10 **ADVISORY REVIEW OF PRESCRIPTION DRUG**
 11 **ADVERTISING.**

12 “(a) ~~TYPES OF DIRECT-TO-CONSUMER TELEVISION~~
 13 ~~ADVERTISEMENT REVIEW FEES.~~—Beginning in fiscal
 14 year 2008, the Secretary shall assess and collect fees in
 15 accordance with this section as follows:

16 “(1) ~~ADVISORY REVIEW FEE.~~—

17 “(A) ~~IN GENERAL.~~—Except as provided in
 18 subparagraph (B), each person that on or after
 19 October 1, 2007, submits a proposed direct-to-
 20 consumer television advertisement for advisory
 21 review by the Secretary prior to its initial public
 22 dissemination shall be subject to a fee estab-
 23 lished under subsection (c)(3).

24 “(B) ~~EXCEPTION FOR REQUIRED SUBMIS-~~
 25 ~~SIONS.~~—A direct-to-consumer television adver-

1 tisement that is required to be submitted to the
2 Secretary prior to initial public dissemination
3 shall not be assessed a fee unless the sponsor
4 designates it as a submission for advisory re-
5 view.

6 “(C) PAYMENT.—The fee required by sub-
7 paragraph (A) shall be due no later than Octo-
8 ber 1 of the fiscal year in which the direct-to-
9 consumer television advertisement shall be sub-
10 mitted to the Secretary for advisory review.

11 “(D) MODIFICATION OF ADVISORY REVIEW
12 FEE.—

13 “(i) LATE PAYMENT.—If, on or before
14 November 1 of the fiscal year in which the
15 fees are due, a person has not paid all fees
16 that were due and payable for advisory re-
17 views identified in response to the Federal
18 Register notice described in subsection
19 (c)(3)(A), the fees shall be regarded as
20 late. Such fees shall be due and payable 20
21 days before any direct-to-consumer tele-
22 vision advertisement is submitted by such
23 person to the Secretary for advisory re-
24 view. Notwithstanding any other provision
25 of this section, such fees shall be due and

1 payable for each of those advisory reviews
2 in the amount of 150 percent of the advi-
3 sory review fee established for that fiscal
4 year pursuant to subsection (c)(3).

5 “(ii) LATE NOTICE OF SUBMISSION.—

6 If any person submits any direct-to-con-
7 sumer television advertisements for advi-
8 sory review that are in excess of the num-
9 ber identified by that person in response to
10 the Federal Register notice described in
11 subsection (c)(3)(A), that person must pay
12 a fee for each of those advisory reviews in
13 the amount of 150 percent of the advisory
14 review fee established for that fiscal year
15 pursuant to subsection (c)(3). Fees under
16 this subparagraph shall be due 20 days be-
17 fore the direct-to-consumer television ad-
18 vertisement is submitted by such person to
19 the Secretary for advisory review.

20 “(E) LIMITS.—

21 “(i) IN GENERAL.—The payment of a
22 fee under this paragraph for a fiscal year
23 entitles the person that pays the fee to ac-
24 ceptance for advisory review by the Sec-
25 retary of 1 direct-to-consumer television

1 advertisement and acceptance of 1 resub-
2 mission for advisory review of the same ad-
3 vertisement. The advertisement shall be
4 submitted for review in the fiscal year for
5 which the fee was assessed, except that a
6 person may carry over no more than 1
7 paid advisory review submission to the next
8 fiscal year. Resubmissions may be sub-
9 mitted without regard to the fiscal year of
10 the initial advisory review submission.

11 “(ii) NO REFUND.—Except as pro-
12 vided by subsection (f), fees paid under
13 this paragraph shall not be refunded.

14 “(iii) NO WAIVER, EXEMPTION, OR
15 REDUCTION.—The Secretary shall not
16 grant a waiver, exemption, or reduction of
17 any fees due or payable under this section.

18 “(iv) NON-TRANSFERABILITY.—The
19 right to an advisory review is not transfer-
20 able, except to a successor in interest.

21 “(2) OPERATING RESERVE FEE.—

22 “(A) IN GENERAL.—Each person that, on
23 or after October 1, 2007, is assessed an advi-
24 sory review fee under paragraph (1) shall be
25 subject to an operating reserve fee established

1 under subsection (d)(2) only in the first fiscal
2 year in which an advisory review fee is assessed.

3 “(B) PAYMENT.—Except as provided in
4 subparagraph (C), the fee required by subpara-
5 graph (A) shall be due no later than October 1
6 of the first fiscal year in which the person is re-
7 quired to pay an advisory review fee under
8 paragraph (1).

9 “(C) LATE NOTICE OF SUBMISSION.—If, in
10 the first fiscal year of a person’s participation
11 in the Program, that person submits any direct-
12 to-consumer television advertisements for advi-
13 sory review that are in excess of the number
14 identified by that person in response to the
15 Federal Register notice described in subsection
16 (c)(3)(A), that person must pay an operating
17 reserve fee for each of those advisory reviews
18 equal to the advisory review fee for each sub-
19 mission established under paragraph (1)(D)(ii).
20 Fees required by this subparagraph shall be in
21 addition to the fees required under subpara-
22 graph (B), if any. Fees under this subpara-
23 graph shall be due 20 days before any direct-
24 to-consumer television advertisement is sub-

1 mitted by such person to the Secretary for advi-
2 sory review.

3 “(b) ~~ADVISORY REVIEW FEE REVENUE AMOUNTS.—~~

4 Fees under subsection (a)(1) shall be established to gen-
5 erate revenue amounts of \$6,250,000 for each of fiscal
6 years 2008 through 2012, as adjusted pursuant to sub-
7 section (c).

8 “(c) ~~ADJUSTMENTS.—~~

9 “(1) ~~INFLATION ADJUSTMENT.—~~Beginning
10 with fiscal year 2009, the revenues established in
11 subsection (b) shall be adjusted by the Secretary by
12 notice, published in the Federal Register, for a fiscal
13 year to reflect the greater of—

14 “(A) the total percentage change that oc-
15 curred in the Consumer Price Index for all
16 urban consumers (all items; United States city
17 average), for the 12-month period ending June
18 30 preceding the fiscal year for which fees are
19 being established;

20 “(B) the total percentage change for the
21 previous fiscal year in basic pay under the Gen-
22 eral Schedule in accordance with section 5332
23 of title 5, as adjusted by any locality-based
24 comparability payment pursuant to section

1 5304 of such title for Federal employees sta-
2 tioned in the District of Columbia; or

3 “~~(C)~~ the average annual change in the
4 cost, per full-time equivalent position of the
5 Food and Drug Administration, of all personnel
6 compensation and benefits paid with respect to
7 such positions, for the first 5 fiscal years of the
8 previous 6 fiscal years.

9 The adjustment made each fiscal year by this sub-
10 section shall be added on a compounded basis to the
11 sum of all adjustments made each fiscal year after
12 fiscal year 2008 under this subsection.

13 “~~(2)~~ WORKLOAD ADJUSTMENT.—

14 “~~(A)~~ IN GENERAL.—Beginning with fiscal
15 year 2009, after the fee revenues established in
16 subsection (b) of this section are adjusted for a
17 fiscal year for inflation in accordance with para-
18 graph (1), the fee revenues shall be adjusted
19 further for such fiscal year to reflect changes in
20 the workload of the Secretary with respect to
21 the submission of proposed direct-to-consumer
22 television advertisements for advisory review
23 prior to initial broadcast.

24 “~~(B)~~ DETERMINATION OF WORKLOAD AD-
25 JUSTMENT.—

1 “(i) IN GENERAL.—The workload ad-
2 justment under this paragraph for a fiscal
3 year shall be determined by the Sec-
4 retary—

5 “(I) based upon the number of
6 direct-to-consumer television adver-
7 tisements identified pursuant to para-
8 graph (3)(A) for that fiscal year, ex-
9 cluding allowable previously paid carry
10 over submissions; and

11 “(II) by multiplying the number
12 of such advertisements projected for
13 that fiscal year that exceeds 150 by
14 \$27,600 (adjusted each year begin-
15 ning with fiscal year 2009 for infla-
16 tion in accordance with paragraph
17 (1)).

18 “(ii) PUBLICATION IN FEDERAL REG-
19 ISTER.—The Secretary shall publish in the
20 Federal Register the fee revenues and fees
21 resulting from the adjustment and the sup-
22 porting methodologies.

23 “(C) LIMITATION.—Under no cir-
24 cumstances shall the adjustment result in fee
25 revenues for a fiscal year that are less than the

1 fee revenues established for the prior fiscal
2 year.

3 ~~“(3) ANNUAL FEE SETTING.—~~

4 ~~“(A) NUMBER OF ADVERTISEMENTS.—The~~
5 Secretary shall, 120 days before the start of
6 each fiscal year, publish a notice in the Federal
7 Register requesting any person to notify the
8 Secretary within 30 days of the number of di-
9 rect-to-consumer television advertisements the
10 person intends to submit for advisory review by
11 the Secretary in the next fiscal year. Notifica-
12 tion to the Secretary of the number of adver-
13 tisements a person intends to submit for advi-
14 sory review prior to initial broadcast shall be a
15 legally binding commitment by that person to
16 pay the annual advisory review fee for that
17 number of submissions on or before October 1
18 of the fiscal year in which the advertisement is
19 intended to be submitted. A person shall at the
20 same time also notify the Secretary if such per-
21 son intends to use a paid submission from the
22 previous fiscal year under subsection
23 (a)(1)(E)(i). If such person does not so notify
24 the Secretary, all submissions for advisory re-
25 view shall be subject to advisory review fees.

1 “(B) ANNUAL FEE.—The Secretary shall,
2 60 days before the start of each fiscal year, es-
3 tablish, for the next fiscal year, the direct-to-
4 consumer television advertisement advisory re-
5 view fee under subsection (a)(1), based on the
6 revenue amounts established under subsection
7 (b); the adjustments provided under this sub-
8 section and the number of direct-to-consumer
9 television advertisements identified pursuant to
10 subparagraph (A), excluding allowable pre-
11 viously paid carry over submissions. The annual
12 advisory review fee shall be established by divid-
13 ing the fee revenue for a fiscal year (as ad-
14 justed pursuant to this subsection) by the num-
15 ber of direct-to-consumer television advertise-
16 ments identified pursuant to subparagraph (A),
17 excluding allowable previously paid carry over
18 submissions.

19 “(C) FISCAL YEAR 2008 FEE LIMIT.—Not-
20 withstanding subsection (b), the fee established
21 under subparagraph (B) for fiscal year 2008
22 may not be more than \$82,000 per submission
23 for advisory review.

24 “(D) ANNUAL FEE LIMIT.—Notwith-
25 standing subsection (b), the fee established

1 under subparagraph (B) for a fiscal year after
2 fiscal year 2008 may not be more than 50 per-
3 cent more than the fee established for the prior
4 fiscal year.

5 “(E) LIMIT.—The total amount of fees ob-
6 ligated for a fiscal year may not exceed the
7 total costs for such fiscal year for the resources
8 allocated for the process for the advisory review
9 of prescription drug advertising.

10 “(d) OPERATING RESERVES.—

11 “(1) IN GENERAL.—The Secretary shall estab-
12 lish in the Food and Drug Administration salaries
13 and expenses appropriation account without fiscal
14 year limitation a Direct-to-Consumer Advisory Re-
15 view Operating Reserve, of at least \$6,250,000 in
16 fiscal year 2008, to continue the Program in the
17 event the fees collected in any subsequent fiscal year
18 pursuant to subsection (e)(3) do not generate the fee
19 revenue amount established for that fiscal year.

20 “(2) FEE SETTING.—The Secretary shall estab-
21 lish the operating reserve fee under subsection
22 (a)(2)(A) for each person required to pay the fee by
23 multiplying the number of direct-to-consumer tele-
24 vision advertisements identified by that person pur-
25 suant to subsection (e)(3)(A) by the advisory review

1 fee established pursuant to subsection (c)(3) for that
2 fiscal year. In no case shall the operating reserve fee
3 assessed be less than the operating reserve fee as-
4 sessed if the person had first participated in the
5 Program in fiscal year 2008.

6 “(3) USE OF OPERATING RESERVE.—The Sec-
7 retary may use funds from the reserves under this
8 subsection only to the extent necessary in any fiscal
9 year to make up the difference between the fee rev-
10 enue amount established for that fiscal year under
11 subsection (b) and the amount of fees collected for
12 that fiscal year pursuant to subsection (a), or to pay
13 costs of ending the Program if it is terminated pur-
14 suant to subsection (f) or if it is not reauthorized
15 after fiscal year 2012.

16 “(4) REFUND OF OPERATING RESERVES.—
17 Within 120 days of the end of fiscal year 2012, or
18 if the Program is terminated pursuant to subsection
19 (f), the Secretary, after setting aside sufficient oper-
20 ating reserve amounts to terminate the Program,
21 shall refund all amounts remaining in the operating
22 reserve on a pro rata basis to each person that paid
23 an operating reserve fee assessment. In no event
24 shall the refund to any person exceed the total

1 amount of operating reserve fees paid by such per-
2 son pursuant to subsection (a)(2).

3 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
4 standing any other law or regulation of the Secretary, a
5 submission for advisory review of a direct-to-consumer tel-
6 evision advertisement submitted by a person subject to
7 fees under subsection (a) shall be considered incomplete
8 and shall not be accepted for review by the Secretary until
9 all fees owed by such person under this section have been
10 paid.

11 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
12 GRAM.—

13 “(1) FIRST FISCAL YEAR.—If on November 1,
14 2007, or 120 days after enactment of the Prescrip-
15 tion Drug User Fee Amendments of 2007, whichever
16 is later, the Secretary has received less than
17 \$11,250,000 in advisory review fees and operating
18 reserve fees combined, the Program shall be termi-
19 nated and all collected fees shall be refunded.

20 “(2) SUBSEQUENT FISCAL YEARS.—Beginning
21 in fiscal year 2009, if, on November 1 of a fiscal
22 year, the combination of the operating reserves, an-
23 nual fee revenues from that fiscal year, and unobli-
24 gated fee revenues from prior fiscal years is less
25 than \$9,000,000, adjusted for inflation (in accord-

1 ance with subsection (c)(1)), the Program shall be
2 terminated, and the Secretary shall notify all partici-
3 pants, retain any money from the unused advisory
4 review fees and the operating reserves needed to ter-
5 minate the Program, and refund the remainder of
6 the unused fees and operating reserves. To the ex-
7 tent required to terminate the Program, the Sec-
8 retary shall first use unobligated advisory review fee
9 revenues from prior fiscal years, then the operating
10 reserves, and then unused advisory review fees from
11 the relevant fiscal year.

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

13 “(1) IN GENERAL.—Fees authorized under sub-
14 section (a) shall be collected and available for obliga-
15 tion only to the extent and in the amount provided
16 in advance in appropriations Acts. Such fees are au-
17 thorized to remain available until expended. Such
18 sums as may be necessary may be transferred from
19 the Food and Drug Administration salaries and ex-
20 penses appropriation account without fiscal year lim-
21 itation to such appropriation account for salaries
22 and expenses with such fiscal year limitation. The
23 sums transferred shall be available solely for the
24 process for the advisory review of prescription drug
25 advertising.

1 “(2) COLLECTIONS AND APPROPRIATION
2 ACTS.—The fees authorized by this section—

3 “(A) shall be retained in each fiscal year in
4 an amount not to exceed the amount specified
5 in appropriation Acts, or otherwise made avail-
6 able for obligation for such fiscal year; and

7 “(B) shall be available for obligation only
8 if appropriated budget authority continues to
9 support at least the total combined number of
10 full-time equivalent employees in the Food and
11 Drug Administration, Center for Drug Evalua-
12 tion and Research, Division of Drug Marketing,
13 Advertising, and Communications, and the Cen-
14 ter for Biologics Evaluation and Research, Ad-
15 vertising and Promotional Labeling Branch
16 supported in fiscal year 2007.

17 “(3) AUTHORIZATION OF APPROPRIATIONS.—

18 There are authorized to be appropriated for fees
19 under this section not less than \$6,250,000 for each
20 of fiscal years 2008, 2009, 2010, 2011, and 2012,
21 as adjusted to reflect adjustments in the total fee
22 revenues made under this section, plus amounts col-
23 lected for the reserve fund under subsection (d).

24 “(4) OFFSET.—Any amount of fees collected
25 for a fiscal year under this section that exceeds the

1 amount of fees specified in appropriation Acts for
2 such fiscal year shall be credited to the appropria-
3 tion account of the Food and Drug Administration
4 as provided in paragraph (1), and shall be sub-
5 tracted from the amount of fees that would other-
6 wise be collected under this section pursuant to ap-
7 propriation Acts for a subsequent fiscal year.

8 “(h) DEFINITIONS.—For purposes of this section:

9 “(1) The term ‘advisory review’ means review-
10 ing and providing advisory comments regarding com-
11 pliance of a proposed advertisement with the re-
12 quirements of this Act prior to its initial public dis-
13 semination.

14 “(2) The term ‘carry over submission’ means a
15 submission for an advisory review for which a fee
16 was paid in a fiscal year that is submitted for review
17 in the following fiscal year.

18 “(3) The term ‘direct-to-consumer television ad-
19 vertisement’ means an advertisement for a prescrip-
20 tion drug product as defined in section 735(3) in-
21 tended to be displayed on any television channel for
22 less than 2 minutes.

23 “(4) The term ‘person’ includes an individual,
24 a partnership, a corporation, and an association, and
25 any affiliate thereof or successor in interest.

1 “(5) The term ‘Program’ means the Program
2 to assess, collect, and use fees for the advisory re-
3 view of prescription drug advertising established by
4 this section.

5 “(6) The term ‘process for the advisory review
6 of prescription drug advertising’ means the activities
7 necessary to review and provide advisory comments
8 on proposed direct-to-consumer television advertise-
9 ments prior to public dissemination and, to the ex-
10 tent the Secretary has additional staff resources
11 available under the Program that are not necessary
12 for the advisory review of direct-to-consumer tele-
13 vision advertisements, the activities necessary to re-
14 view and provide advisory comments on other pro-
15 posed advertisements and promotional material prior
16 to public dissemination.

17 “(7) The term ‘resources allocated for the proe-
18 cess for the advisory review of prescription drug ad-
19 vertising’ means the expenses incurred in connection
20 with the process for the advisory review of prescrip-
21 tion drug advertising for—

22 “(A) officers and employees of the Food
23 and Drug Administration, contractors of the
24 Food and Drug Administration, advisory com-
25 mittees, and costs related to such officers, em-

1 employees, and committees, and to contracts with
2 such contractors;

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

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

11 “(D) collection of fees under this section
12 and accounting for resources allocated for the
13 advisory review of prescription drug advertising;
14 and

15 “(E) terminating the Program under sub-
16 section (f)(2), if necessary.

17 “(8) The term ‘resubmission’ means a subse-
18 quent submission for advisory review of a direct-to-
19 consumer television advertisement that has been re-
20 vised in response to the Secretary’s comments on an
21 original submission. A resubmission may not intro-
22 duce significant new concepts or creative themes into
23 the television advertisement.

24 “(9) The term ‘submission for advisory review’
25 means an original submission of a direct-to-con-

1 sumer television advertisement for which the sponsor
2 voluntarily requests advisory comments before the
3 advertisement is publicly disseminated.”.

4 **SEC. 5. SAVINGS CLAUSE.**

5 Notwithstanding section 509 of the Prescription
6 Drug User Fee Amendments of 2002 (21 U.S.C. 379g
7 note), and notwithstanding the amendments made by this
8 Act, part 2 of subchapter C of chapter VII of the Federal
9 Food, Drug, and Cosmetic Act, as in effect on the day
10 before the date of enactment of this Act, shall continue
11 to be in effect with respect to human drug applications
12 and supplements (as defined in such part as of such day)
13 that on or after October 1, 2002, but before October 1,
14 2007, were accepted by the Food and Drug Administra-
15 tion for filing with respect to assessing and collecting any
16 fee required by such part for a fiscal year prior to fiscal
17 year 2008.

18 **SEC. 6. TECHNICAL AMENDMENTS.**

19 (a) Section 737 (21 U.S.C. 379i) is amended in the
20 matter preceding paragraph (1), by striking “subchapter”
21 and inserting “part”.

22 (b) Section 739 (21 U.S.C. 379j–11) is amended in
23 the matter preceding paragraph (1), by striking “sub-
24 chapter” and inserting “part”.

1 **SEC. 7. EFFECTIVE DATES.**

2 (a) ~~IN GENERAL.~~—Except as provided in subsection
3 (b), the amendments made by this Act shall take effect
4 October 1, 2007.

5 (b) ~~EXCEPTION.~~—The amendment made by section
6 4 of this Act shall take effect on the date of enactment
7 of this Act.

8 **SEC. 8. SUNSET DATE.**

9 Sections 735, 736, and 736A of the Federal Food,
10 Drug, and Cosmetic Act shall cease to be effective on Oc-
11 tober 1, 2012.

12 **SECTION 1. SHORT TITLE.**

13 *This Act may be cited as the “Food and Drug Admin-
14 istration Revitalization Act”.*

15 **TITLE I—PRESCRIPTION DRUG**
16 **USER FEES**

17 **SEC. 101. SHORT TITLE; REFERENCES IN TITLE.**

18 (a) *SHORT TITLE.*—*This title may be cited as the*
19 *“Prescription Drug User Fee Amendments of 2007”.*

20 (b) *REFERENCES IN TITLE.*—*Except as otherwise spec-*
21 *ified, whenever in this title an amendment is expressed in*
22 *terms of an amendment to a section or other provision, the*
23 *reference shall be considered to be made to a section or other*
24 *provision of the Federal Food, Drug, and Cosmetic Act (21*
25 *U.S.C. 301 et seq.).*

1 **SEC. 102. DRUG FEES.**

2 *Section 735 (21 U.S.C. 379g) is amended—*

3 *(1) by striking the section designation and all*
4 *that follows through “For purposes of this sub-*
5 *chapter:” and inserting the following:*

6 **“SEC. 735. DRUG FEES.**

7 *“(a) PURPOSE.—It is the purpose of this part that the*
8 *fees authorized under this part be dedicated toward expe-*
9 *diting the drug development process, the process for the re-*
10 *view of human drug applications, and postmarket drug*
11 *safety, as set forth in the goals identified for purposes of*
12 *this part in the letters from the Secretary to the Chairman*
13 *of the Committee on Health, Education, Labor, and Pen-*
14 *sions of the Senate and the Chairman of the Committee on*
15 *Energy and Commerce of the House of Representatives, as*
16 *set forth in the Congressional Record.*

17 *“(b) REPORTS.—*

18 *“(1) PERFORMANCE REPORT.—For fiscal years*
19 *2008 through 2012, not later than 120 days after the*
20 *end of each fiscal year during which fees are collected*
21 *under this part, the Secretary shall prepare and sub-*
22 *mit to the Committee on Health, Education, Labor,*
23 *and Pensions of the Senate and the Committee on*
24 *Energy and Commerce of the House of Representa-*
25 *tives, a report concerning the progress of the Food*
26 *and Drug Administration in achieving the goals iden-*

1 *tified in the letters described in subsection (a) during*
2 *such fiscal year and the future plans of the Food and*
3 *Drug Administration for meeting the goals. The re-*
4 *port for a fiscal year shall include information on all*
5 *previous cohorts for which the Secretary has not given*
6 *a complete response on all human drug applications*
7 *and supplements in the cohort.*

8 *“(2) FISCAL REPORT.—For fiscal years 2008*
9 *through 2012, not later than 120 days after the end*
10 *of each fiscal year during which fees are collected*
11 *under this part, the Secretary shall prepare and sub-*
12 *mit to the Committee on Health, Education, Labor,*
13 *and Pensions of the Senate and the Committee on*
14 *Energy and Commerce of the House of Representa-*
15 *tives, a report on the implementation of the authority*
16 *for such fees during such fiscal year and the use, by*
17 *the Food and Drug Administration, of the fees col-*
18 *lected during such fiscal year for which the report is*
19 *made.*

20 *“(3) PUBLIC AVAILABILITY.—The Secretary shall*
21 *make the reports required under paragraphs (1) and*
22 *(2) available to the public on the Internet website of*
23 *the Food and Drug Administration.*

24 *“(c) REAUTHORIZATION.—*

1 “(1) *CONSULTATION.*—*In developing rec-*
2 *ommendations to present to Congress with respect to*
3 *the goals, and plans for meeting the goals, for the*
4 *process for the review of human drug applications for*
5 *the first 5 fiscal years after fiscal year 2012, and for*
6 *the reauthorization of this part for such fiscal years,*
7 *the Secretary shall consult with—*

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

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

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

13 “(D) *health care professionals;*

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

16 “(F) *the regulated industry.*

17 “(2) *PUBLIC REVIEW OF RECOMMENDATIONS.*—
18 *After negotiations with the regulated industry, the*
19 *Secretary shall—*

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

23 “(B) *publish such recommendations in the*
24 *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 “(3) TRANSMITTAL OF RECOMMENDATIONS.—Not
11 later than January 15, 2012, the Secretary shall
12 transmit to Congress the revised recommendations
13 under paragraph (2), 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 “(d) DEFINITIONS.—For purposes of this part:”;

18 (2) in subsection (d)—

19 (A) in paragraph (1)—

20 (i) in subparagraph (A), by striking
21 “505(b)(1),” and inserting “505(b), or”;

22 (ii) by striking subparagraph (B);

23 (iii) by redesignating subparagraph
24 (C) as subparagraph (B); and

1 (iv) in the matter following subpara-
2 graph (B), as so redesignated, by striking
3 “subparagraph (C)” and inserting “sub-
4 paragraph (B)”;

5 (B) in paragraph (3)(C), by—

6 (i) striking “the list” and inserting
7 “the list (not including the discontinued
8 section of such list)”; and

9 (ii) striking “a list” and inserting “a
10 list (not including the discontinued section
11 of such a list)”;

12 (C) in paragraph (4), by inserting before
13 the period at the end the following: “(such as
14 capsules, tablets, and lyophilized products before
15 reconstitution)”;

16 (D) by amending paragraph (6)(F) to read
17 as follows:

18 “(F) In the case of drugs approved under
19 human drug applications or supplements,
20 postmarket safety activities, including—

21 “(i) collecting, developing, and review-
22 ing safety information on approved drugs
23 (including adverse event reports);

24 “(ii) developing and using improved
25 adverse event data collection systems (in-

1 cluding information technology systems);
2 and

3 “(iii) developing and using improved
4 analytical tools to assess potential safety
5 problems (including by accessing external
6 data bases).”;

7 (E) in paragraph (8)—

8 (i) by striking “April of the preceding
9 fiscal year” and inserting “October of the
10 preceding fiscal year”; and

11 (ii) by striking “April 1997” and in-
12 serting “October 1996”;

13 (F) by redesignating paragraph (9) as
14 paragraph (10); and

15 (G) by inserting after paragraph (8) the fol-
16 lowing:

17 “(9) The term ‘person’ includes an affiliate of
18 such person.”.

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

20 (a) *TYPES OF FEES.*—Section 736(a) (21 U.S.C.
21 379h(a)) is amended—

22 (1) in the matter preceding paragraph (1), by
23 striking “2003” and inserting “2008”;

24 (2) in paragraph (1)—

25 (A) in subparagraph (D)—

1 (i) in the heading, by inserting “OR
2 WITHDRAWN BEFORE FILING” after “RE-
3 FUND OF FEE IF APPLICATION REFUSED
4 FOR FILING”; and

5 (ii) by inserting before the period at
6 the end the following: “or withdrawn with-
7 out a waiver before filing”;

8 (B) by redesignating subparagraphs (E)
9 and (F) as subparagraphs (F) and (G), respec-
10 tively; and

11 (C) by inserting after subparagraph (D) the
12 following:

13 “(E) FEE FOR APPLICATION PREVIOUSLY
14 REFUSED FOR FILING OR WITHDRAWN BEFORE
15 FILING.—An application or supplement that has
16 been refused for filing or that was withdrawn be-
17 fore filing, if filed under protest or resubmitted,
18 shall be subject to the fee under subparagraph
19 (A) (unless an exception under subparagraph (C)
20 or (F) applies or the fee is waived or reduced
21 under subsection (d)), without regard to previous
22 payment of such a fee and the refund of 75 per-
23 cent of that fee under subparagraph (D).”; and
24 (3) in paragraph (2)—

1 (A) in subparagraph (A), by striking “sub-
2 paragraph (B)” and inserting “subparagraphs
3 (B) and (C)”; and

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

5 “(C) *SPECIAL RULES FOR COMPOUNDED*
6 *POSITRON EMISSION TOMOGRAPHY DRUGS.—*

7 “(i) *IN GENERAL.—Except as provided*
8 *in clause (ii), each person who is named as*
9 *the applicant in an approved human drug*
10 *application for a compounded positron*
11 *emission tomography drug shall be subject*
12 *under subparagraph (A) to one-quarter of*
13 *an annual establishment fee with respect to*
14 *each such establishment identified in the*
15 *application as producing compounded*
16 *positron emission tomography drugs under*
17 *the approved application.*

18 “(ii) *EXCEPTION FROM ANNUAL ESTAB-*
19 *LISHMENT FEE.—Each person who is*
20 *named as the applicant in an application*
21 *described in clause (i) shall not be assessed*
22 *an annual establishment fee for a fiscal*
23 *year if the person certifies to the Secretary,*
24 *at a time specified by the Secretary and*

1 *using procedures specified by the Secretary,*
2 *that—*

3 *“(I) the person is a not-for-profit*
4 *medical center that has only 1 estab-*
5 *lishment for the production of com-*
6 *pounded positron emission tomography*
7 *drugs; and*

8 *“(II) at least 95 percent of the*
9 *total number of doses of each com-*
10 *pounded positron emission tomography*
11 *drug produced by such establishment*
12 *during such fiscal year will be used*
13 *within the medical center.”.*

14 **(b) FEE REVENUE AMOUNTS.**—*Section 736(b) (21*
15 *U.S.C. 379h(b)) is amended to read as follows:*

16 **“(b) FEE REVENUE AMOUNTS.**—*Except as provided in*
17 *subsections (c), (d), (f), and (g), fees under subsection (a)*
18 *shall be established to generate the following revenue*
19 *amounts, in each fiscal year beginning with fiscal year*
20 *2008 and continuing through fiscal year 2012:*
21 *\$392,783,000, plus an adjustment for workload on*
22 *\$354,893,000 of this amount. Such adjustment shall be*
23 *made in accordance with the workload adjustment provi-*
24 *sions in effect for fiscal year 2007, except that instead of*
25 *commercial investigational new drug applications sub-*

1 *mited to the Secretary, all commercial investigational new*
2 *drug applications with a submission during the previous*
3 *12-month period shall be used in the determination. One-*
4 *third of the revenue amount shall be derived from applica-*
5 *tion fees, one-third from establishment fees, and one-third*
6 *from product fees.”.*

7 *(c) ADJUSTMENTS TO FEES.—*

8 *(1) INFLATION ADJUSTMENT.—Section 736(c)(1)*
9 *(21 U.S.C. 379h(c)(1)) is amended—*

10 *(A) in the matter preceding subparagraph*
11 *(A) by striking “The revenues established in sub-*
12 *section (b)” and inserting “Beginning with fiscal*
13 *year 2009, the revenues established in subsection*
14 *(b)”;*

15 *(B) in subparagraph (A) by striking “or”*
16 *at the end;*

17 *(C) in subparagraph (B) by striking the pe-*
18 *riod at the end and inserting “, or,”;*

19 *(D) by inserting after subparagraph (B) the*
20 *following:*

21 *“(C) the average annual change in the cost,*
22 *per full-time equivalent position of the Food and*
23 *Drug Administration, of all personnel compensa-*
24 *tion and benefits paid with respect to such posi-*

1 *tions, for the first 5 fiscal years of the previous*
2 *6 fiscal years.”; and*

3 *(E) in the matter following subparagraph*
4 *(C) (as added by this paragraph), by striking*
5 *“fiscal year 2003” and inserting “fiscal year*
6 *2008”.*

7 (2) *WORKLOAD ADJUSTMENT.—Section 736(c)(2)*
8 *(21 U.S.C. 379h(c)(2)) is amended—*

9 *(A) in the matter preceding subparagraph*
10 *(A,) by striking “2004” and inserting “2009”;*

11 *(B) in the first sentence of subparagraph*
12 *(A)—*

13 *(i) by striking “, commercial investiga-*
14 *tional new drug applications” and insert-*
15 *ing “(adjusted for changes in review activi-*
16 *ties)”;* and

17 *(ii) by inserting before the period at*
18 *the end “, and the change in the number of*
19 *commercial investigational new drug appli-*
20 *cations with a submission during the pre-*
21 *vious 12-month period (adjusted for changes*
22 *in review activities)”;*

23 *(C) in subparagraph (B), by adding at the*
24 *end the following new sentence: “Further, any*
25 *adjustment for changes in review activities made*

1 *in setting fees and fee revenue amounts for fiscal*
2 *year 2009 may not result in the total workload*
3 *adjustment being more than 2 percentage points*
4 *higher than it would be absent the adjustment*
5 *for changes in review activities.”; and*

6 *(D) by adding at the end the following:*

7 *“(C) The Secretary shall contract with an*
8 *independent accounting firm to study the adjust-*
9 *ment for changes in review activities applied in*
10 *setting fees for fiscal year 2009 and to make rec-*
11 *ommendations, if warranted, on future changes*
12 *in the methodology for calculating the adjust-*
13 *ment for changes in review activity. After review*
14 *of the recommendations by the independent ac-*
15 *counting firm, the Secretary shall make appro-*
16 *priate changes to the workload adjustment meth-*
17 *odology in setting fees for fiscal years 2010*
18 *through 2012. If the study is not conducted, no*
19 *adjustment for changes in review activities shall*
20 *be made after fiscal year 2009.”.*

21 (3) *RENT AND RENT-RELATED COST ADJUST-*
22 *MENT.—Section 736(c) (21 U.S.C. 379h(c)) is amend-*
23 *ed—*

1 (A) by redesignating paragraphs (3), (4),
2 and (5) as paragraphs (4), (5), and (6), respec-
3 tively; and

4 (B) by inserting after paragraph (2) the fol-
5 lowing:

6 “(3) *RENT AND RENT-RELATED COST ADJUST-*
7 *MENT.—Beginning with fiscal year 2010, the Sec-*
8 *retary shall, before making the adjustments under*
9 *paragraphs (1) and (2), reduce the fee amounts estab-*
10 *lished in subsection (b), if actual costs paid for rent*
11 *and rent-related expenses are less than \$11,721,000.*
12 *The reductions made under this paragraph, if any,*
13 *shall not exceed the amounts by which costs fell below*
14 *\$11,721,000, and shall not exceed \$11,721,000 in any*
15 *fiscal year.”.*

16 (4) *FINAL YEAR ADJUSTMENT.—Section 736(c)*
17 *(21 U.S.C. 379h(c)) is amended—*

18 (A) in paragraph (4), as redesignated by
19 this subsection—

20 (i) by striking “2007” each place it
21 appears and inserting “2012”; and

22 (ii) by striking “2008” and inserting
23 “2013”; and

1 (B) in paragraph (5), as redesignated by
2 this subsection, by striking “2002” and inserting
3 “2007”.

4 (d) *FEE WAIVER OR REDUCTION*.—Section 736(d) (21
5 *U.S.C. 379h(d)*) is amended—

6 (1) in paragraph (1), in the matter preceding
7 subparagraph (A), by—

8 (A) inserting “to a person who is named as
9 the applicant” after “The Secretary shall grant”;

10 (B) inserting “to that person” after “a
11 waiver from or a reduction of one or more fees
12 assessed”; and

13 (C) striking “finds” and inserting “deter-
14 mines”;

15 (2) by redesignating paragraphs (2) and (3) as
16 paragraphs (3) and (4), respectively;

17 (3) by inserting after paragraph (1) the fol-
18 lowing:

19 “(2) *EVALUATION*.—For the purpose of deter-
20 mining whether to grant a waiver or reduction of a
21 fee under paragraph (1), the Secretary shall consider
22 only the circumstances and assets of the applicant
23 and any affiliate of the applicant.”; and

24 (4) in paragraph (4), as redesignated by this
25 subsection, in subparagraph (A), by inserting before

1 *the period at the end “, and that does not have a drug*
2 *product that has been approved under a human drug*
3 *application and introduced or delivered for introduc-*
4 *tion into interstate commerce”.*

5 *(e) CREDITING AND AVAILABILITY OF FEES.—*

6 *(1) AUTHORIZATION OF APPROPRIATIONS.—Sec-*
7 *tion 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to*
8 *read as follows:*

9 *“(3) AUTHORIZATION OF APPROPRIATIONS.—*
10 *There are authorized to be appropriated for fees under*
11 *this section such sums as are authorized to be assessed*
12 *and collected under this section in each of fiscal years*
13 *2008 through 2012.”.*

14 *(2) OFFSET.—Section 736(g)(4) (21 U.S.C.*
15 *379h(g)(4)) is amended to read as follows:*

16 *“(4) OFFSET.—If the cumulative amount of fees*
17 *collected during fiscal years 2008, 2009, and 2010,*
18 *plus the amount estimated to be collected for fiscal*
19 *year 2011, exceeds the amount of fees specified in ag-*
20 *gregate in appropriation Acts for such fiscal years,*
21 *the aggregate amount in excess shall be credited to the*
22 *appropriation account of the Food and Drug Admin-*
23 *istration as provided in paragraph (1), and shall be*
24 *subtracted from the amount of fees that would other-*

1 *wise be authorized to be collected under this section*
 2 *pursuant to appropriation Acts for fiscal year 2012.”.*

3 *(f) CONFORMING AMENDMENTS.—*

4 *(1) Section 736(a) (21 U.S.C. 379h(a)), as*
 5 *amended by this section, is amended—*

6 *(A) in paragraph (1)(A), by striking “sub-*
 7 *section (c)(4)” each place it appears and insert-*
 8 *ing “subsection (c)(5)”;*

9 *(B) in paragraph (2), by striking “sub-*
 10 *section (c)(4)” and inserting “subsection (c)(5)”;*
 11 *and*

12 *(C) in paragraph (3), by striking “sub-*
 13 *section (c)(4)” and inserting “subsection (c)(5)”.*

14 *(2) Section 736A(h)(3), as added by section 104*
 15 *of this title, is amended by striking “735(3)” and in-*
 16 *serting “735(d)(3)”.*

17 **SEC. 104. AUTHORITY TO ASSESS AND USE PRESCRIPTION**

18 **DRUG ADVERTISING FEES.**

19 *Chapter VII, subchapter C, part 2 (21 U.S.C. 379g et*
 20 *seq.) is amended by adding after section 736 the following*
 21 *new section:*

1 **“SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE**
2 **ADVISORY REVIEW OF PRESCRIPTION DRUG**
3 **ADVERTISING.**

4 *“(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION*
5 *ADVERTISEMENT REVIEW FEES.—Beginning with fiscal*
6 *year 2008, the Secretary shall assess and collect fees in ac-*
7 *cordance with this section as follows:*

8 *“(1) ADVISORY REVIEW FEE.—*

9 *“(A) IN GENERAL.—Except as provided in*
10 *subparagraph (B), each person that on or after*
11 *October 1, 2007, submits a proposed direct-to-*
12 *consumer television advertisement for advisory*
13 *review by the Secretary prior to its initial public*
14 *dissemination shall be subject to a fee established*
15 *under subsection (c)(3).*

16 *“(B) EXCEPTION FOR REQUIRED SUBMIS-*
17 *SIONS.—A direct-to-consumer television adver-*
18 *tisement that is required to be submitted to the*
19 *Secretary prior to initial public dissemination*
20 *shall not be assessed a fee unless the sponsor des-*
21 *ignates it as a submission for advisory review.*

22 *“(C) PAYMENT.—The fee required by sub-*
23 *paragraph (A) shall be due not later than Octo-*
24 *ber 1 of the fiscal year in which the direct-to-*
25 *consumer television advertisement shall be sub-*
26 *mitted to the Secretary for advisory review.*

1 “(D) *MODIFICATION OF ADVISORY REVIEW*
2 *FEE.*—

3 “(i) *LATE PAYMENT.*—*If, on or before*
4 *November 1 of the fiscal year in which the*
5 *fees are due, a person has not paid all fees*
6 *that were due and payable for advisory re-*
7 *views identified in response to the Federal*
8 *Register notice described in subsection*
9 *(c)(3)(A), the fees shall be regarded as late.*
10 *Such fees shall be due and payable 20 days*
11 *before any direct-to-consumer television ad-*
12 *vertisement is submitted by such person to*
13 *the Secretary for advisory review. Notwith-*
14 *standing any other provision of this section,*
15 *such fees shall be due and payable for each*
16 *of those advisory reviews in the amount of*
17 *150 percent of the advisory review fee estab-*
18 *lished for that fiscal year pursuant to sub-*
19 *section (c)(3).*

20 “(ii) *LATE NOTICE OF SUBMISSION.*—
21 *If any person submits any direct-to-con-*
22 *sumer television advertisements for advisory*
23 *review that are in excess of the number*
24 *identified by that person in response to the*
25 *Federal Register notice described in sub-*

1 *section (c)(3)(A), that person must pay a*
2 *fee for each of those advisory reviews in the*
3 *amount of 150 percent of the advisory re-*
4 *view fee established for that fiscal year pur-*
5 *suant to subsection (c)(3). Fees under this*
6 *subparagraph shall be due 20 days before*
7 *the direct-to-consumer television advertise-*
8 *ment is submitted by such person to the*
9 *Secretary for advisory review.*

10 *“(E) LIMITS.—*

11 *“(i) IN GENERAL.—The payment of a*
12 *fee under this paragraph for a fiscal year*
13 *entitles the person that pays the fee to ac-*
14 *ceptance for advisory review by the Sec-*
15 *retary of 1 direct-to-consumer television ad-*
16 *vertisement and acceptance of 1 resubmis-*
17 *sion for advisory review of the same adver-*
18 *tisement. The advertisement shall be sub-*
19 *mitted for review in the fiscal year for*
20 *which the fee was assessed, except that a*
21 *person may carry over no more than 1 paid*
22 *advisory review submission to the next fis-*
23 *cal year. Resubmissions may be submitted*
24 *without regard to the fiscal year of the ini-*
25 *tial advisory review submission.*

1 “(ii) *NO REFUND.*—*Except as provided*
2 *by subsection (f), fees paid under this para-*
3 *graph shall not be refunded.*

4 “(iii) *NO WAIVER, EXEMPTION, OR RE-*
5 *DUCTION.*—*The Secretary shall not grant a*
6 *waiver, exemption, or reduction of any fees*
7 *due or payable under this section.*

8 “(iv) *NON-TRANSFERABILITY.*—*The*
9 *right to an advisory review is not transfer-*
10 *able, except to a successor in interest.*

11 “(2) *OPERATING RESERVE FEE.*—

12 “(A) *IN GENERAL.*—*Each person that, on or*
13 *after October 1, 2007, is assessed an advisory re-*
14 *view fee under paragraph (1) shall be subject to*
15 *an operating reserve fee established under sub-*
16 *section (d)(2) only in the first fiscal year in*
17 *which an advisory review fee is assessed.*

18 “(B) *PAYMENT.*—*Except as provided in*
19 *subparagraph (C), the fee required by subpara-*
20 *graph (A) shall be due not later than October 1*
21 *of the first fiscal year in which the person is re-*
22 *quired to pay an advisory review fee under*
23 *paragraph (1).*

24 “(C) *LATE NOTICE OF SUBMISSION.*—*If, in*
25 *the first fiscal year of a person’s participation in*

1 *the Program, that person submits any direct-to-*
2 *consumer television advertisements for advisory*
3 *review that are in excess of the number identified*
4 *by that person in response to the Federal Reg-*
5 *ister notice described in subsection (c)(3)(A),*
6 *that person must pay an operating reserve fee for*
7 *each of those advisory reviews equal to the advi-*
8 *sory review fee for each submission established*
9 *under paragraph (1)(D)(ii). Fees required by*
10 *this subparagraph shall be in addition to the fees*
11 *required under subparagraph (B), if any. Fees*
12 *under this subparagraph shall be due 20 days be-*
13 *fore any direct-to-consumer television advertise-*
14 *ment is submitted by such person to the Sec-*
15 *retary for advisory review.*

16 “(b) *ADVISORY REVIEW FEE REVENUE AMOUNTS.—*
17 *Fees under subsection (a)(1) shall be established to generate*
18 *revenue amounts of \$6,250,000 for each of fiscal years 2008*
19 *through 2012, as adjusted pursuant to subsection (c).*

20 “(c) *ADJUSTMENTS.—*

21 “(1) *INFLATION ADJUSTMENT.—Beginning with*
22 *fiscal year 2009, the revenues established in subsection*
23 *(b) shall be adjusted by the Secretary by notice, pub-*
24 *lished in the Federal Register, for a fiscal year to re-*
25 *flect the greater of—*

1 “(A) the total percentage change that oc-
2 curred in the Consumer Price Index for all
3 urban consumers (all items; United States city
4 average), for the 12-month period ending June
5 30 preceding the fiscal year for which fees are
6 being established;

7 “(B) the total percentage change for the pre-
8 vious fiscal year in basic pay under the General
9 Schedule in accordance with section 5332 of title
10 5, as adjusted by any locality-based com-
11 parability payment pursuant to section 5304 of
12 such title for Federal employees stationed in the
13 District of Columbia; or

14 “(C) the average annual change in the cost,
15 per full-time equivalent position of the Food and
16 Drug Administration, of all personnel compensa-
17 tion and benefits paid with respect to such posi-
18 tions, for the first 5 fiscal years of the previous
19 6 fiscal years.

20 *The adjustment made each fiscal year by this para-*
21 *graph shall be added on a compounded basis to the*
22 *sum of all adjustments made each fiscal year after fis-*
23 *cal year 2008 under this subsection.*

24 “(2) *WORKLOAD ADJUSTMENT.*—

1 “(A) *IN GENERAL.*—*Beginning with fiscal*
2 *year 2009, after the fee revenues established in*
3 *subsection (b) of this section are adjusted for a*
4 *fiscal year for inflation in accordance with para-*
5 *graph (1), the fee revenues shall be adjusted fur-*
6 *ther for such fiscal year to reflect changes in the*
7 *workload of the Secretary with respect to the sub-*
8 *mission of proposed direct-to-consumer television*
9 *advertisements for advisory review prior to ini-*
10 *tial broadcast.*

11 “(B) *DETERMINATION OF WORKLOAD AD-*
12 *JUSTMENT.*—

13 “(i) *IN GENERAL.*—*The workload ad-*
14 *justment under this paragraph for a fiscal*
15 *year shall be determined by the Secretary—*

16 “(I) *based upon the number of di-*
17 *rect-to-consumer television advertise-*
18 *ments identified pursuant to para-*
19 *graph (3)(A) for that fiscal year, ex-*
20 *cluding allowable previously paid*
21 *carry over submissions; and*

22 “(II) *by multiplying the number*
23 *of such advertisements projected for*
24 *that fiscal year that exceeds 150 by*
25 *\$27,600 (adjusted each year beginning*

1 *with fiscal year 2009 for inflation in*
2 *accordance with paragraph (1)).*

3 “(ii) *PUBLICATION IN FEDERAL REG-*
4 *ISTER.—The Secretary shall publish in the*
5 *Federal Register, as part of the notice de-*
6 *scribed in paragraph (1), the fee revenues*
7 *and fees resulting from the adjustment made*
8 *under this paragraph and the supporting*
9 *methodologies.*

10 “(C) *LIMITATION.—Under no circumstances*
11 *shall the adjustment made under this paragraph*
12 *result in fee revenues for a fiscal year that are*
13 *less than the fee revenues established for the prior*
14 *fiscal year.*

15 “(3) *ANNUAL FEE SETTING.—*

16 “(A) *NUMBER OF ADVERTISEMENTS.—The*
17 *Secretary shall, 120 days before the start of each*
18 *fiscal year, publish a notice in the Federal Reg-*
19 *ister requesting any person to notify the Sec-*
20 *retary within 30 days of the number of direct-*
21 *to-consumer television advertisements the person*
22 *intends to submit for advisory review by the Sec-*
23 *retary in the next fiscal year. Notification to the*
24 *Secretary of the number of advertisements a per-*
25 *son intends to submit for advisory review prior*

1 to initial broadcast shall be a legally binding
2 commitment by that person to pay the annual
3 advisory review fee for that number of submis-
4 sions on or before October 1 of the fiscal year in
5 which the advertisement is intended to be sub-
6 mitted. A person shall at the same time also no-
7 tify the Secretary if such person intends to use
8 a paid submission from the previous fiscal year
9 under subsection (a)(1)(E)(i). If such person does
10 not so notify the Secretary, all submissions for
11 advisory review shall be subject to advisory re-
12 view fees.

13 “(B) ANNUAL FEE.—The Secretary shall, 60
14 days before the start of each fiscal year, establish,
15 for the next fiscal year, the direct-to-consumer
16 television advertisement advisory review fee
17 under subsection (a)(1), based on the revenue
18 amounts established under subsection (b), the ad-
19 justments provided under this subsection and the
20 number of direct-to-consumer television adver-
21 tisements identified pursuant to subparagraph
22 (A), excluding allowable previously paid carry
23 over submissions. The annual advisory review fee
24 shall be established by dividing the fee revenue
25 for a fiscal year (as adjusted pursuant to this

1 *subsection) by the number of direct-to-consumer*
2 *television advertisements identified pursuant to*
3 *subparagraph (A), excluding allowable pre-*
4 *viously paid carry over submissions.*

5 *“(C) FISCAL YEAR 2008 FEE LIMIT.—Not-*
6 *withstanding subsection (b), the fee established*
7 *under subparagraph (B) for fiscal year 2008*
8 *may not be more than \$83,000 per submission*
9 *for advisory review.*

10 *“(D) ANNUAL FEE LIMIT.—Notwithstanding*
11 *subsection (b), the fee established under subpara-*
12 *graph (B) for a fiscal year after fiscal year 2008*
13 *may not be more than 50 percent more than the*
14 *fee established for the prior fiscal year.*

15 *“(E) LIMIT.—The total amount of fees obli-*
16 *gated for a fiscal year may not exceed the total*
17 *costs for such fiscal year for the resources allo-*
18 *cated for the process for the advisory review of*
19 *prescription drug advertising.*

20 *“(d) OPERATING RESERVES.—*

21 *“(1) IN GENERAL.—The Secretary shall establish*
22 *in the Food and Drug Administration salaries and*
23 *expenses appropriation account without fiscal year*
24 *limitation a Direct-to-Consumer Advisory Review*
25 *Operating Reserve, of at least \$6,250,000 in fiscal*

1 *year 2008, to continue the Program in the event the*
2 *fees collected in any subsequent fiscal year pursuant*
3 *to subsection (c)(3) do not generate the fee revenue*
4 *amount established for that fiscal year.*

5 *“(2) FEE SETTING.—The Secretary shall estab-*
6 *lish the operating reserve fee under subsection*
7 *(a)(2)(A) for each person required to pay the fee by*
8 *multiplying the number of direct-to-consumer tele-*
9 *vision advertisements identified by that person pursu-*
10 *ant to subsection (c)(3)(A) by the advisory review fee*
11 *established pursuant to subsection (c)(3) for that fis-*
12 *cal year. In no case shall the operating reserve fee as-*
13 *essed be less than the operating reserve fee assessed*
14 *if the person had first participated in the Program in*
15 *fiscal year 2008.*

16 *“(3) USE OF OPERATING RESERVE.—The Sec-*
17 *retary may use funds from the reserves under this*
18 *subsection only to the extent necessary in any fiscal*
19 *year to make up the difference between the fee revenue*
20 *amount established for that fiscal year under sub-*
21 *section (b) and the amount of fees collected for that*
22 *fiscal year pursuant to subsection (a), or to pay costs*
23 *of ending the Program if it is terminated pursuant*
24 *to subsection (f) or if it is not reauthorized after fiscal*
25 *year 2012.*

1 “(4) *REFUND OF OPERATING RESERVES.*—With-
2 in 120 days of the end of fiscal year 2012, or if the
3 Program is terminated pursuant to subsection (f), the
4 Secretary, after setting aside sufficient operating re-
5 serve amounts to terminate the Program, shall refund
6 all amounts remaining in the operating reserve on a
7 pro rata basis to each person that paid an operating
8 reserve fee assessment. In no event shall the refund to
9 any person exceed the total amount of operating re-
10 serve fees paid by such person pursuant to subsection
11 (a)(2).

12 “(e) *EFFECT OF FAILURE TO PAY FEES.*—Notwith-
13 standing any other law or regulation of the Secretary, a
14 submission for advisory review of a direct-to-consumer tele-
15 vision advertisement submitted by a person subject to fees
16 under subsection (a) shall be considered incomplete and
17 shall not be accepted for review by the Secretary until all
18 fees owed by such person under this section have been paid.

19 “(f) *EFFECT OF INADEQUATE FUNDING OF PRO-*
20 GRAM.—

21 “(1) *FIRST FISCAL YEAR.*—If on November 1,
22 2007, or 120 days after enactment of the Prescription
23 Drug User Fee Amendments of 2007, whichever is
24 later, the Secretary has received less than \$11,250,000
25 in advisory review fees and operating reserve fees

1 *combined, the Program shall be terminated and all*
2 *collected fees shall be refunded.*

3 “(2) *SUBSEQUENT FISCAL YEARS.*—*Beginning in*
4 *fiscal year 2009, if, on November 1 of a fiscal year,*
5 *the combination of the operating reserves, annual fee*
6 *revenues from that fiscal year, and unobligated fee*
7 *revenues from prior fiscal years is less than*
8 *\$9,000,000, adjusted for inflation (in accordance with*
9 *subsection (c)(1)), the Program shall be terminated,*
10 *and the Secretary shall notify all participants, retain*
11 *any money from the unused advisory review fees and*
12 *the operating reserves needed to terminate the Pro-*
13 *gram, and refund the remainder of the unused fees*
14 *and operating reserves. To the extent required to ter-*
15 *minate the Program, the Secretary shall first use un-*
16 *obligated advisory review fee revenues from prior fis-*
17 *cal years, then the operating reserves, and then un-*
18 *used advisory review fees from the relevant fiscal*
19 *year.*

20 “(g) *CREDITING AND AVAILABILITY OF FEES.*—

21 “(1) *IN GENERAL.*—*Fees authorized under sub-*
22 *section (a) shall be collected and available for obliga-*
23 *tion only to the extent and in the amount provided*
24 *in advance in appropriations Acts. Such fees are au-*
25 *thorized to remain available until expended. Such*

1 *sums as may be necessary may be transferred from*
2 *the Food and Drug Administration salaries and ex-*
3 *penses appropriation account without fiscal year lim-*
4 *itation to such appropriation account for salaries and*
5 *expenses with such fiscal year limitation. The sums*
6 *transferred shall be available solely for the process for*
7 *the advisory review of prescription drug advertising.*

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

9 *The fees authorized by this section—*

10 *“(A) shall be retained in each fiscal year in*
11 *an amount not to exceed the amount specified in*
12 *appropriation Acts, or otherwise made available*
13 *for obligation for such fiscal year; and*

14 *“(B) shall be available for obligation only if*
15 *appropriated budget authority continues to sup-*
16 *port at least the total combined number of full-*
17 *time equivalent employees in the Food and Drug*
18 *Administration, Center for Drug Evaluation and*
19 *Research, Division of Drug Marketing, Adver-*
20 *tising, and Communications, and the Center for*
21 *Biologics Evaluation and Research, Advertising*
22 *and Promotional Labeling Branch supported in*
23 *fiscal year 2007.*

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

25 *There are authorized to be appropriated for fees under*

1 *this section not less than \$6,250,000 for each of fiscal*
2 *years 2008, 2009, 2010, 2011, and 2012, as adjusted*
3 *to reflect adjustments in the total fee revenues made*
4 *under this section, plus amounts collected for the re-*
5 *serve fund under subsection (d).*

6 *“(4) OFFSET.—Any amount of fees collected for*
7 *a fiscal year under this section that exceeds the*
8 *amount of fees specified in appropriation Acts for*
9 *such fiscal year shall be credited to the appropriation*
10 *account of the Food and Drug Administration as pro-*
11 *vided in paragraph (1), and shall be subtracted from*
12 *the amount of fees that would otherwise be collected*
13 *under this section pursuant to appropriation Acts for*
14 *a subsequent fiscal year.*

15 *“(h) DEFINITIONS.—For purposes of this section:*

16 *“(1) The term ‘advisory review’ means reviewing*
17 *and providing advisory comments regarding compli-*
18 *ance of a proposed advertisement with the require-*
19 *ments of this Act prior to its initial public dissemina-*
20 *tion.*

21 *“(2) The term ‘carry over submission’ means a*
22 *submission for an advisory review for which a fee was*
23 *paid in a fiscal year that is submitted for review in*
24 *the following fiscal year.*

1 “(3) *The term ‘direct-to-consumer television ad-*
2 *vertisement’ means an advertisement for a prescrip-*
3 *tion drug product as defined in section 735(3) in-*
4 *tended to be displayed on any television channel for*
5 *less than 2 minutes.*

6 “(4) *The term ‘person’ includes an individual, a*
7 *partnership, a corporation, and an association, and*
8 *any affiliate thereof or successor in interest.*

9 “(5) *The term ‘process for the advisory review of*
10 *prescription drug advertising’ means the activities*
11 *necessary to review and provide advisory comments*
12 *on proposed direct-to-consumer television advertise-*
13 *ments prior to public dissemination and, to the extent*
14 *the Secretary has additional staff resources available*
15 *under the Program that are not necessary for the ad-*
16 *visory review of direct-to-consumer television adver-*
17 *tisements, the activities necessary to review and pro-*
18 *vide advisory comments on other proposed advertise-*
19 *ments and promotional material prior to public dis-*
20 *semination.*

21 “(6) *The term ‘Program’ means the Program to*
22 *assess, collect, and use fees for the advisory review of*
23 *prescription drug advertising established by this sec-*
24 *tion.*

1 “(7) The term ‘resources allocated for the process
2 for the advisory review of prescription drug adver-
3 tising’ means the expenses incurred in connection
4 with the process for the advisory review of prescrip-
5 tion drug advertising for—

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

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

15 “(C) leasing, maintenance, renovation, and
16 repair of facilities and acquisition, maintenance,
17 and repair of fixtures, furniture, scientific equip-
18 ment, and other necessary materials and sup-
19 plies;

20 “(D) collection of fees under this section and
21 accounting for resources allocated for the advi-
22 sory review of prescription drug advertising; and

23 “(E) terminating the Program under sub-
24 section (f)(2), if necessary.

1 “(8) *The term ‘resubmission’ means a subsequent*
2 *submission for advisory review of a direct-to-con-*
3 *sumer television advertisement that has been revised*
4 *in response to the Secretary’s comments on an origi-*
5 *nal submission. A resubmission may not introduce*
6 *significant new concepts or creative themes into the*
7 *television advertisement.*

8 “(9) *The term ‘submission for advisory review’*
9 *means an original submission of a direct-to-consumer*
10 *television advertisement for which the sponsor volun-*
11 *tarily requests advisory comments before the adver-*
12 *tisement is publicly disseminated.*

13 **“SEC. 736B. SUNSET.**

14 *“This part shall cease to be effective on October 1,*
15 *2012, except that subsection (b) of section 736 with respect*
16 *to reports shall cease to be effective on January 31, 2013.”.*

17 **SEC. 105. SAVINGS CLAUSE.**

18 *Notwithstanding section 509 of the Prescription Drug*
19 *User Fee Amendments of 2002 (21 U.S.C. 379g note), and*
20 *notwithstanding the amendments made by this title, part*
21 *2 of subchapter C of chapter VII of the Federal Food, Drug,*
22 *and Cosmetic Act, as in effect on the day before the date*
23 *of enactment of this title, shall continue to be in effect with*
24 *respect to human drug applications and supplements (as*
25 *defined in such part as of such day) that on or after October*

1 1, 2002, but before October 1, 2007, were accepted by the
 2 Food and Drug Administration for filing with respect to
 3 assessing and collecting any fee required by such part for
 4 a fiscal year prior to fiscal year 2008.

5 **SEC. 106. TECHNICAL AMENDMENT.**

6 Section 739 (21 U.S.C. 379j–11) is amended in the
 7 matter preceding paragraph (1), by striking “subchapter”
 8 and inserting “part”.

9 **SEC. 107. EFFECTIVE DATES.**

10 (a) *IN GENERAL.*—Except as provided in subsection
 11 (b), the amendments made by this title shall take effect Oc-
 12 tober 1, 2007.

13 (b) *EXCEPTION.*—The amendment made by section 104
 14 of this title shall take effect on the date of enactment of this
 15 title.

16 **TITLE II—DRUG SAFETY**

17 **SEC. 200. SHORT TITLE.**

18 This title may be cited as the “Enhancing Drug Safety
 19 and Innovation Act of 2007”.

20 **Subtitle A—Risk Evaluation and**
 21 **Mitigation Strategies**

22 **SEC. 201. RISK EVALUATION.**

23 (a) *IN GENERAL.*—Subsection (k) of section 505 of the
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is
 25 amended by adding at the end the following:

1 “(3) *RISK IDENTIFICATION AND ASSESSMENT.*—

2 “(A) *ROUTINE ACTIVE SAFETY MONI-*
3 *TORING.*—*The Secretary shall facilitate a public-*
4 *private partnership to—*

5 “(i) *implement a routine active moni-*
6 *toring system for postmarket drug safety;*
7 *and*

8 “(ii) *focus postmarket studies under*
9 *subsection (o)(4)(B) and postapproval clin-*
10 *ical trials under subsection (o)(4)(C) more*
11 *effectively on cases for which reports under*
12 *paragraph (1) and other safety signal detec-*
13 *tion is not sufficient to resolve whether there*
14 *is an elevated risk of a serious adverse event*
15 *associated with use of a drug.*

16 “(B) *PUBLIC-PRIVATE PARTNERSHIP.*—*The*
17 *public-private partnership described in subpara-*
18 *graph (A) shall—*

19 “(i) *develop a mechanism for the pool-*
20 *ing of relevant data from Federal and pri-*
21 *vate electronic health care population data-*
22 *bases that—*

23 “(I) *includes, in aggregate—*

24 “(aa) *at least 25,000,000 pa-*
25 *tients by January 1, 2009; and*

1 “(bb) at least 100,000,000
2 patients by January 1, 2012;

3 “(II) allows access to full-text
4 medical records, where available;

5 “(III) takes into consideration the
6 need for data completeness, coding,
7 cleansing, and transmission;

8 “(IV) may, on a temporary or
9 permanent basis, implement systems or
10 products developed by private entities;
11 and

12 “(V) complies with the require-
13 ments of the Health Insurance Port-
14 ability and Accountability Act of 1996;

15 “(ii) support the routine and system-
16 atic collection and analysis of utilization
17 and safety data from such pooled databases
18 and from the Food and Drug Administra-
19 tion with respect to prescription drugs; and

20 “(iii) allow for prompt investigation of
21 priority drug safety questions, including—

22 “(I) unresolved safety questions
23 for drugs or classes of drugs; and

24 “(II) for a newly-approved
25 drug—

1 “(aa) safety signals from
2 clinical trials used to approve the
3 drug and from other preapproval
4 trials;

5 “(bb) rare, serious drug ad-
6 verse events; and

7 “(cc) the safety of use in do-
8 mestic populations not included
9 in the trials used to approve the
10 drug (such as older people, people
11 with comorbidities, pregnant
12 women, or children).

13 “(C) OTHER APPROACHES.—

14 “(i) IN GENERAL.—The Secretary shall
15 develop, support, and participate in other
16 approaches, including in other public-pri-
17 vate partnerships, to gather and analyze
18 data and information relevant to priority
19 drug safety questions, including—

20 “(I) approaches that are com-
21 plimentary to the routine active safety
22 monitoring described in subparagraphs
23 (A) and (B), especially with respect to
24 assessing the safety of use of a drug in
25 domestic populations not included in

1 *the trials used to approve the drug*
2 *(such as older people, people with*
3 *comorbidities, pregnant women, or*
4 *children); and*

5 *“(II) existing approaches such as*
6 *the Vaccine Adverse Event Reporting*
7 *System and the Vaccine Safety*
8 *Datalink or successor databases.*

9 *“(ii) BEST PRACTICES.—With respect*
10 *to such other approaches, the Secretary shall*
11 *develop and implement best practices in ep-*
12 *idemiology and the use of improved ana-*
13 *lytic tools.*

14 *“(D) PUBLIC PROCESS FOR PRIORITY QUES-*
15 *TIONS.—At least biannually, the Secretary shall*
16 *seek recommendations from the Drug Safety and*
17 *Risk Management Advisory Committee (or suc-*
18 *cessor committee) and from other advisory com-*
19 *mittees, as appropriate, to the Food and Drug*
20 *Administration on—*

21 *“(i) priority drug safety questions; and*

22 *“(ii) mechanisms for answering such*
23 *questions, including through—*

24 *“(I) routine active safety moni-*
25 *toring; and*

1 “(II) when such monitoring is not
2 sufficient, postmarket studies under
3 subsection (o)(4)(B) and postapproval
4 clinical trials under subsection
5 (o)(4)(C).

6 “(E) ANALYSIS OF DRUG SAFETY DATA.—
7 The Secretary shall engage independent private
8 research groups, including through the Centers
9 for Education and Research on Therapeutics
10 provided for under section 905 of the Public
11 Health Service Act, to conduct analyses of data
12 relating to priority drug safety questions.

13 “(F) USE OF ANALYSES.—The Secretary
14 shall provide the analyses described under sub-
15 paragraph (E), including the methods and re-
16 sults of such analyses, about a drug to the spon-
17 sor or sponsors of such drug.

18 “(G) PUBLIC AVAILABILITY OF ANALYSES.—
19 The Secretary shall make the analyses described
20 under subparagraph (E), including the methods
21 and results of such analyses, available to the
22 public for review and comment.

23 “(H) QUALIFIED ENTITIES.—

24 “(i) IN GENERAL.—The Secretary shall
25 enter into contracts with a sufficient num-

1 *ber of qualified entities to develop and pro-*
2 *vide information to the Secretary in a time-*
3 *ly manner.*

4 “(i) *QUALIFICATIONS.—The Secretary*
5 *shall enter into a contract with an entity*
6 *under clause (i) only if the Secretary deter-*
7 *mines that the entity—*

8 “(I) *has the research capability*
9 *and expertise to conduct and complete*
10 *the activities under this paragraph;*

11 “(II) *has in place an information*
12 *technology infrastructure to support*
13 *adverse event surveillance data and*
14 *operational standards to provide secu-*
15 *rity for such data;*

16 “(III) *has experience with, and*
17 *expertise in, the development of drug*
18 *safety and effectiveness research using*
19 *electronic population data;*

20 “(IV) *has an understanding of*
21 *drug development and risk/benefit bal-*
22 *ancing in a clinical setting; and*

23 “(V) *has a significant business*
24 *presence in the United States.*

1 “(I) *CONTRACT REQUIREMENTS.*—*Each con-*
2 *tract with a qualified entity shall contain the*
3 *following requirements:*

4 “(i) *ENSURING PRIVACY.*—*The quali-*
5 *fied entity shall provide assurances that the*
6 *entity will not use the data provided by the*
7 *Secretary in a manner that violates—*

8 “(I) *the Federal regulations pro-*
9 *mulgated under section 264(c) of the*
10 *Health Insurance Portability and Ac-*
11 *countability Act of 1996 (concerning*
12 *the privacy of individually-identifiable*
13 *beneficiary health information); or*

14 “(II) *sections 552 or 552a of title*
15 *5, United States Code, with regard to*
16 *the privacy of individually-identifiable*
17 *beneficiary health information.*

18 “(ii) *COMPONENT OF ANOTHER ORGA-*
19 *NIZATION.*—*If a qualified entity is a com-*
20 *ponent of another organization—*

21 “(I) *the qualified entity shall*
22 *maintain the data related to the activi-*
23 *ties carried out under this paragraph*
24 *separate from the other components of*
25 *the organization and establish appro-*

1 *appropriate security measures to maintain*
2 *the confidentiality and privacy of such*
3 *data; and*

4 *“(II) the entity shall not make an*
5 *unauthorized disclosure of such data to*
6 *the other components of the organiza-*
7 *tion in breach of such confidentiality*
8 *and privacy requirement.*

9 *“(iii) TERMINATION OR NON-*
10 *RENEWAL.—If a contract under this para-*
11 *graph is terminated or not renewed, the fol-*
12 *lowing requirements shall apply:*

13 *“(I) CONFIDENTIALITY AND PRI-*
14 *VACY REGULATIONS.—The entity shall*
15 *continue to comply with the confiden-*
16 *tiality and privacy requirements under*
17 *this paragraph with respect to all data*
18 *disclosed to the entity.*

19 *“(II) DISPOSITION OF DATA.—The*
20 *entity shall return to the Secretary all*
21 *data disclosed to the entity or, if re-*
22 *turning the data is not practicable, de-*
23 *stroy the data.*

24 *“(J) COMPETITIVE PROCEDURES.—The Sec-*
25 *retary shall use competitive procedures (as de-*

1 *fined in section 4(5) of the Federal Procurement*
2 *Policy Act) to enter into contracts under sub-*
3 *paragraph (H).*

4 *“(K) REVIEW OF CONTRACT IN THE EVENT*
5 *OF A MERGER OR ACQUISITION.—The Secretary*
6 *shall review the contract with a qualified entity*
7 *under this paragraph in the event of a merger or*
8 *acquisition of the entity in order to ensure that*
9 *the requirements under this paragraph will con-*
10 *tinue to be met.”.*

11 *(b) AUTHORIZATION OF APPROPRIATIONS.—There are*
12 *authorized to be appropriated to carry out this section*
13 *\$30,000,000 for each of fiscal years 2008 through 2012.*

14 **SEC. 202. RISK EVALUATION AND MITIGATION STRATEGIES.**

15 *Section 505 of the Federal Food, Drug, and Cosmetic*
16 *Act (21 U.S.C. 355) is amended by adding at the end the*
17 *following:*

18 *“(o) RISK EVALUATION AND MITIGATION STRATEGY.—*

19 *“(1) IN GENERAL.—In the case of any drug sub-*
20 *ject to subsection (b) or to section 351 of the Public*
21 *Health Service Act for which a risk evaluation and*
22 *mitigation strategy is approved as provided for in*
23 *this subsection, the applicant shall comply with the*
24 *requirements of such strategy.*

25 *“(2) DEFINITIONS.—In this subsection:*

1 “(A) *ADVERSE DRUG EXPERIENCE*.—The
2 term ‘adverse drug experience’ means any ad-
3 verse event associated with the use of a drug in
4 humans, whether or not considered drug related,
5 including—

6 “(i) an adverse event occurring in the
7 course of the use of the drug in professional
8 practice;

9 “(ii) an adverse event occurring from
10 an overdose of the drug, whether accidental
11 or intentional;

12 “(iii) an adverse event occurring from
13 abuse of the drug;

14 “(iv) an adverse event occurring from
15 withdrawal of the drug; and

16 “(v) any failure of expected pharma-
17 cological action of the drug.

18 “(B) *NEW SAFETY INFORMATION*.—The
19 term ‘new safety information’ with respect to a
20 drug means information about—

21 “(i) a serious risk or an unexpected se-
22 rious risk with use of the drug that the Sec-
23 retary has become aware of since the later
24 of—

1 “(I) the date of initial approval of
2 the drug under this section or initial
3 licensure of the drug under section 351
4 of the Public Health Service Act; or

5 “(II) if applicable, the last assess-
6 ment of the approved risk evaluation
7 and mitigation strategy for the drug;
8 or

9 “(ii) the effectiveness of the approved
10 risk evaluation and mitigation strategy for
11 the drug obtained since the later of—

12 “(I) the approval of such strategy;

13 or

14 “(II) the last assessment of such
15 strategy.

16 “(C) *SERIOUS ADVERSE DRUG EXPERI-*
17 *ENCE.—The term ‘serious adverse drug experi-*
18 *ence’ is an adverse drug experience that—*

19 “(i) results in—

20 “(I) death;

21 “(II) the placement of the patient
22 at immediate risk of death from the
23 adverse drug experience as it occurred
24 (not including an adverse drug experi-

1 ence that might have caused death had
2 it occurred in a more severe form);

3 “(III) inpatient hospitalization or
4 prolongation of existing hospitaliza-
5 tion;

6 “(IV) a persistent or significant
7 incapacity or substantial disruption of
8 the ability to conduct normal life func-
9 tions; or

10 “(V) a congenital anomaly or
11 birth defect; or

12 “(ii) based on appropriate medical
13 judgment, may jeopardize the patient and
14 may require a medical or surgical interven-
15 tion to prevent an outcome described under
16 clause (i).

17 “(D) *SERIOUS RISK*.—The term ‘serious
18 risk’ means a risk of a serious adverse drug expe-
19 rience.

20 “(E) *SIGNAL OF A SERIOUS RISK*.—The
21 term ‘signal of a serious risk’ means information
22 related to a serious adverse drug experience de-
23 rived from—

24 “(i) a clinical trial;

1 “(ii) adverse event reports under sub-
2 section (k)(1);

3 “(iii) routine active safety monitoring
4 under subsection (k)(3);

5 “(iv) a postapproval study, including
6 a study under paragraph (4)(B); or

7 “(v) peer-reviewed biomedical lit-
8 erature.

9 “(F) UNEXPECTED SERIOUS RISK.—The
10 term ‘unexpected serious risk’ means a serious
11 adverse drug experience that—

12 “(i) is not listed in the labeling of a
13 drug; or

14 “(ii) is symptomatically and
15 pathophysiologically related to an adverse
16 drug experience listed in the labeling of the
17 drug, but differs from such adverse drug ex-
18 perience because of greater severity, speci-
19 ficity, or prevalence.

20 “(3) REQUIRED ELEMENTS OF A RISK EVALUA-
21 TION AND MITIGATION STRATEGY.—If a risk evalua-
22 tion and mitigation strategy for a drug is required,
23 such strategy shall include—

1 “(A) the labeling for the drug for use by
2 health care providers as approved under sub-
3 section (c);

4 “(B) a timetable for submission of assess-
5 ments of the strategy, that—

6 “(i) for a drug no active ingredient
7 (including any ester or salt of the active in-
8 gredient) of which has been approved in
9 any other application under this section or
10 section 351 of the Public Health Service
11 Act—

12 “(I) shall be no less frequently
13 than 18 months and 3 years after the
14 drug is initially approved and at a
15 frequency specified in the strategy for
16 subsequent years; and

17 “(II) may be eliminated after the
18 first 3 years if the Secretary deter-
19 mines that serious risks of the drug
20 have been adequately identified and as-
21 sessed and are being adequately man-
22 aged;

23 “(ii) for a drug other than a drug de-
24 scribed under clause (i), shall occur at a fre-
25 quency determined by the Secretary; and

1 “(iii) may be increased or reduced in
2 frequency as necessary as provided for in
3 paragraph (7)(B)(v)(VI).

4 “(4) *ADDITIONAL POTENTIAL EVALUATION ELE-*
5 *MENTS OF A RISK EVALUATION AND MITIGATION*
6 *STRATEGY.—*

7 “(A) *RISK EVALUATION.—If a risk evalua-*
8 *tion and mitigation strategy for a drug is re-*
9 *quired, such strategy may include 1 or more of*
10 *the additional evaluation elements described in*
11 *this paragraph, so long as the Secretary makes*
12 *the determination required with respect to each*
13 *additional included element.*

14 “(B) *POSTAPPROVAL STUDIES.—If the Sec-*
15 *retary determines that the reports under sub-*
16 *section (k)(1) and routine active safety moni-*
17 *toring as available under subsection (k)(3) (in-*
18 *cluding available other approaches under sub-*
19 *section (k)(3)(C)) are not sufficient to—*

20 “(i) *assess a signal of a serious risk*
21 *with use of a drug; or*

22 “(ii) *identify unexpected serious risks*
23 *in a domestic population who use the drug,*
24 *including a population not included in*
25 *trials used to approve the drug (such as*

1 older people, people with comorbidities,
2 pregnant women, or children),
3 the risk evaluation and mitigation strategy for
4 the drug may require that the applicant conduct
5 an appropriate postapproval study, such as a
6 prospective or retrospective observational study,
7 of the drug (which shall include a timeframe
8 specified by the Secretary for completing the
9 study and reporting the results to the Secretary).

10 “(C) *POSTAPPROVAL CLINICAL TRIALS.*—If
11 the Secretary determines that the reports under
12 subsection (k)(1), routine active safety moni-
13 toring as available under subsection (k)(3) (in-
14 cluding available other approaches under sub-
15 section (k)(3)(C)), and a study or studies under
16 subparagraph (B) will likely be inadequate to
17 assess a signal of a serious risk with use of a
18 drug, and there is no effective approved applica-
19 tion for the drug under subsection (j) as of the
20 date that the requirement is first imposed, the
21 risk evaluation and mitigation strategy for the
22 drug may require that the applicant conduct an
23 appropriate postapproval clinical trial of the
24 drug (which shall include a timeframe specified
25 by the Secretary for completing the clinical trial

1 *and reporting the results to the Secretary) to be*
2 *included in the clinical trial registry data bank*
3 *provided for under subsections (i) and (j) of sec-*
4 *tion 402 of the Public Health Service Act.*

5 “(5) *ADDITIONAL POTENTIAL COMMUNICATION*
6 *ELEMENTS OF A RISK EVALUATION AND MITIGATION*
7 *STRATEGY.—*

8 “(A) *RISK COMMUNICATION.—If a risk eval-*
9 *uation and mitigation strategy for a drug is re-*
10 *quired, such strategy may include 1 or more of*
11 *the additional communication elements described*
12 *in this paragraph, so long as the Secretary*
13 *makes the determination required with respect to*
14 *each additional included element.*

15 “(B) *MEDGUIDE; PATIENT PACKAGE IN-*
16 *SERT.—The risk evaluation and mitigation*
17 *strategy for a drug may require that the appli-*
18 *cant develop for distribution to each patient*
19 *when the drug is dispensed either or both of the*
20 *following:*

21 “(i) *A Medication Guide, as provided*
22 *for under part 208 of title 21, Code of Fed-*
23 *eral Regulations (or any successor regula-*
24 *tions).*

1 “(ii) A patient package insert, if the
2 Secretary determines that such insert may
3 help mitigate a serious risk listed in the la-
4 beling of the drug.

5 “(C) COMMUNICATION PLAN.—If the Sec-
6 retary determines that a communication plan to
7 health care providers may support implementa-
8 tion of an element of the risk evaluation and
9 mitigation strategy for a drug, such as a label-
10 ing change, the strategy may require that the ap-
11 plicant conduct such a plan, which may in-
12 clude—

13 “(i) sending letters to health care pro-
14 viders;

15 “(ii) disseminating information about
16 the elements of the strategy to encourage im-
17 plementation by health care providers of
18 components that apply to such health care
19 providers, or to explain certain safety pro-
20 tocols (such as medical monitoring by peri-
21 odic laboratory tests); or

22 “(iii) disseminating information to
23 health care providers through professional
24 societies about any serious risks of the drug
25 and any protocol to assure safe use.

1 “(D) *PREREVIEW.*—

2 “*(i) IN GENERAL.*—If the Secretary de-
3 termines that prereview of advertisements is
4 necessary to ensure the inclusion of a true
5 statement in such advertisements of infor-
6 mation in brief summary relating to a seri-
7 ous risk listed in the labeling of a drug, the
8 risk evaluation and mitigation strategy for
9 the drug may require that the applicant
10 submit to the Secretary advertisements of
11 the drug for prereview not later than 45
12 days before dissemination of the advertise-
13 ment

14 “*(ii) SPECIFICATION OF ADVERTISE-*
15 *MENTS.*—The Secretary may specify the ad-
16 vertisements required to be submitted under
17 clause (i).

18 “(E) *SPECIFIC DISCLOSURES.*—

19 “*(i) SERIOUS RISK; SAFETY PRO-*
20 *TOCOL.*—If the Secretary determines that
21 advertisements lacking a specific disclosure
22 about a serious risk listed in the labeling of
23 a drug or about a protocol to ensure safe
24 use described in the labeling of the drug
25 would be false or misleading, the risk eval-

1 *uation and mitigation strategy for the drug*
2 *may require that the applicant include in*
3 *advertisements of the drug such disclosure.*

4 “(ii) *DATE OF APPROVAL.*—*If the Sec-*
5 *retary determines that advertisements lack-*
6 *ing a specific disclosure of the date a drug*
7 *was approved and that the existing infor-*
8 *mation may not have identified or allowed*
9 *for full assessment of all serious risks of*
10 *using the drug is necessary to protect public*
11 *health and safety, the risk evaluation and*
12 *mitigation strategy for the drug may re-*
13 *quire that the applicant include in adver-*
14 *tisements of the drug such disclosure.*

15 “(iii) *SPECIFICATION OF ADVERTISE-*
16 *MENTS.*—*The Secretary may specify the ad-*
17 *vertisements required to include a specific*
18 *disclosure under clause (i) or (ii).*

19 “(F) *TEMPORARY MORATORIUM.*—*To the ex-*
20 *tent consistent with the Constitution, if the Sec-*
21 *retary determines that disclosure under subpara-*
22 *graph (E)(ii) is inadequate to protect public*
23 *health and safety, and that a prohibition of di-*
24 *rect-to-consumer advertisements of the drug for a*
25 *fixed period after initial approval of the drug,*

1 *not to exceed 2 years, is necessary to protect pub-*
2 *lic health and safety while additional informa-*
3 *tion about serious risks of the drug is collected*
4 *using the reports under subsection (k)(1) and the*
5 *routine active safety monitoring as available*
6 *under subsection (k)(3) (including available*
7 *other approaches under subsection (k)(3)(C)), the*
8 *risk evaluation and mitigation strategy for the*
9 *drug may require that the applicant not issue or*
10 *cause to be issued direct-to-consumer advertise-*
11 *ments of the drug for such fixed period. In mak-*
12 *ing such determination, the Secretary shall con-*
13 *sider—*

14 *“(i) the number of patients who may*
15 *be treated with the drug;*

16 *“(ii) the seriousness of the condition*
17 *for which the drug will be used;*

18 *“(iii) the serious risks listed in the la-*
19 *beling of the drug;*

20 *“(iv) the extent to which patients have*
21 *access to other approved drugs in the phar-*
22 *macological class of the drug and with the*
23 *same intended use as the drug; and*

24 *“(v) the extent to which clinical trials*
25 *used to approve the drug may not have*

1 *identified serious risks that might occur*
2 *among patients expected to be treated with*
3 *the drug.*

4 “(6) *RESTRICTIONS ON DISTRIBUTION OR USE*
5 *FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS*
6 *RISKS.—*

7 “(A) *IN GENERAL.—When a risk evaluation*
8 *and mitigation strategy for a drug is required,*
9 *and considering the adequacy of the labeling of*
10 *the drug and 1 or more communication elements*
11 *under paragraph (5) to mitigate a specific seri-*
12 *ous risk listed in the labeling of the drug, if the*
13 *Secretary determines that the drug, which has*
14 *been shown to be effective, can be safely used only*
15 *if distribution or use of such drug is restricted,*
16 *the Secretary may require as elements of such*
17 *strategy such restrictions on distribution or use*
18 *as are needed to assure safe use of the drug.*

19 “(B) *LIMITS ON RESTRICTIONS TO ASSURE*
20 *ACCESS AND MINIMIZE BURDEN.—Such restric-*
21 *tions under subparagraph (A) shall—*

22 “(i) *be commensurate with the specific,*
23 *serious risk presented by the drug;*

1 “(ii) not be unduly burdensome on pa-
2 tient access to the drug, considering in par-
3 ticular—

4 “(I) patients with serious or life-
5 threatening diseases or conditions; and

6 “(II) patients (such as patients in
7 rural areas) who have difficulty access-
8 ing health care; and

9 “(iii) to the extent practicable, so as to
10 minimize the burden on the health care de-
11 livery system—

12 “(I) conform with restrictions on
13 distribution or use for other drugs with
14 similar, serious risks; and

15 “(II) be designed to be compatible
16 with established distribution, procure-
17 ment, and dispensing systems for
18 drugs.

19 “(C) *ELEMENTS TO PROTECT PATIENT*
20 *SAFETY.*—The restrictions on distribution or use
21 described under subparagraph (A) shall include
22 1 or more goals to evaluate or mitigate a specific
23 serious risk listed in the labeling of the drug
24 and, to mitigate such risk, may require that—

1 “(i) health care providers that pre-
2 scribe the drug have particular training or
3 experience, or are specially certified;

4 “(ii) pharmacies, practitioners, or
5 health care settings that dispense the drug
6 are specially certified;

7 “(iii) the drug be dispensed to patients
8 only in certain health care settings, such as
9 hospitals;

10 “(iv) the drug be dispensed to patients
11 with evidence or other documentation of
12 safe-use conditions, such as laboratory test
13 results;

14 “(v) each patient using the drug be
15 subject to certain monitoring; or

16 “(vi) each patient using the drug be
17 enrolled in a registry.

18 “(D) IMPLEMENTATION SYSTEM.—The re-
19 strictions on distribution or use described under
20 subparagraph (A) that employ elements described
21 in clauses (ii), (iii), or (iv) of subparagraph (C)
22 may include a system through which the appli-
23 cant is able to take reasonable steps to—

24 “(i) monitor and evaluate implementa-
25 tion of such elements by health care pro-

1 *viders, pharmacists, and other parties in*
2 *the health care system who are responsible*
3 *for implementing such elements; and*

4 *“(i) work to improve implementation*
5 *of such elements by such persons.*

6 *“(E) EVALUATION OF RESTRICTIONS.—The*
7 *Secretary, through the Drug Safety and Risk*
8 *Management Advisory Committee (or successor*
9 *committee) of the Food and Drug Administra-*
10 *tion, shall—*

11 *“(i) seek input from patients, physi-*
12 *cians, pharmacists, and other health care*
13 *providers about how restrictions on dis-*
14 *tribution or use under this paragraph for 1*
15 *or more drugs may be standardized so as*
16 *not to be—*

17 *“(I) unduly burdensome on pa-*
18 *tient access to the drug; and*

19 *“(II) to the extent practicable,*
20 *minimize the burden on the health care*
21 *delivery system;*

22 *“(ii) at least annually, evaluate, for 1*
23 *or more drugs, the restrictions on distribu-*
24 *tion or use of such drug to assess whether*
25 *the restrictions—*

1 “(I) assure safe use of the drug;

2 “(II) are not unduly burdensome
3 on patient access to the drug; and

4 “(III) to the extent practicable,
5 minimize the burden on the health care
6 delivery system; and

7 “(iii) considering such input and eval-
8 uations—

9 “(I) issue or modify agency guid-
10 ance about how to implement the re-
11 quirements of this paragraph; and

12 “(II) modify restrictions under
13 this paragraph for 1 or more drugs as
14 appropriate.

15 “(7) SUBMISSION AND REVIEW OF RISK EVALUA-
16 TION AND MITIGATION STRATEGY.—

17 “(A) PROPOSED RISK EVALUATION AND
18 MITIGATION STRATEGY.—

19 “(i) VOLUNTARY PROPOSAL.—An ap-
20 plicant may include a proposed risk evalua-
21 tion and mitigation strategy for a drug in
22 an application, including in a supple-
23 mental application, under subsection (b) or
24 section 351 of the Public Health Service Act
25 for the drug.

1 “(i) *REQUIRED PROPOSAL.*—*The ap-*
2 *plicant shall submit a proposed risk evalua-*
3 *tion and mitigation strategy for a drug—*

4 “(I) *within a timeframe specified*
5 *by the Secretary, not to be less than 45*
6 *days, when ordered by the Secretary*
7 *(acting through the office responsible*
8 *for reviewing the drug and the office*
9 *responsible for postapproval safety*
10 *with respect to the drug), if the Sec-*
11 *retary determines that new safety in-*
12 *formation indicates that—*

13 “(aa) *the labeling of the drug*
14 *should be changed; or*

15 “(bb) *an element under para-*
16 *graph (4) or (5) should be in-*
17 *cluded in a strategy for the drug;*
18 *or*

19 “(II) *within 90 days when or-*
20 *dered by the Secretary (acting through*
21 *such offices), if the Secretary deter-*
22 *mines that new safety information in-*
23 *dicates that an element under para-*
24 *graph (6) should be included in a*
25 *strategy for the drug.*

1 “(iii) *CONTENT OF ORDER.*—An order
2 under subclauses (I) or (II) of clause (ii)
3 shall describe—

4 “(I) *the new safety information*
5 *with respect to the drug that warrants*
6 *the proposal of a risk evaluation and*
7 *mitigation strategy for the drug; and*

8 “(II) *whether and how the label-*
9 *ing of the drug should be changed and*
10 *what elements under paragraphs (4),*
11 *(5), or (6) should be included in a*
12 *strategy for the drug.*

13 “(iv) *CONTENT OF PROPOSAL.*—A pro-
14 posed risk evaluation and mitigation strat-
15 egy—

16 “(I) *shall include a timetable as*
17 *described under paragraph (3)(B); and*

18 “(II) *may also include additional*
19 *elements as provided for under para-*
20 *graphs (4), (5), and (6).*

21 “(B) *ASSESSMENT AND MODIFICATION OF A*
22 *RISK EVALUATION AND MITIGATION STRATEGY.*—

23 “(i) *VOLUNTARY ASSESSMENTS.*—If a
24 risk evaluation and mitigation strategy for
25 a drug is required, the applicant may sub-

1 *mit to the Secretary an assessment of, and*
2 *propose a modification to, such approved*
3 *strategy for the drug at any time.*

4 “(ii) *REQUIRED ASSESSMENTS.—If a*
5 *risk evaluation and mitigation strategy for*
6 *a drug is required, the applicant shall sub-*
7 *mit an assessment of, and may propose a*
8 *modification to, such approved strategy for*
9 *the drug—*

10 “(I) *when submitting an applica-*
11 *tion, including a supplemental appli-*
12 *cation, for a new indication under sub-*
13 *section (b) or section 351 of the Public*
14 *Health Service Act;*

15 “(II) *when required by the strat-*
16 *egy, as provided for in the timetable*
17 *under paragraph (3)(B);*

18 “(III) *within a timeframe speci-*
19 *fied by the Secretary, not to be less*
20 *than 45 days, when ordered by the Sec-*
21 *retary (acting through the offices de-*
22 *scribed in subparagraph (A)(ii)(I)), if*
23 *the Secretary determines that new safe-*
24 *ty information indicates that an ele-*
25 *ment under paragraph (3) or (4)*

1 *should be modified or added to the*
2 *strategy;*

3 “(IV) *within 90 days when or-*
4 *dered by the Secretary (acting through*
5 *such offices), if the Secretary deter-*
6 *mines that new safety information in-*
7 *dicates that an element under para-*
8 *graph (6) should be modified or added*
9 *to the strategy; or*

10 “(V) *within 15 days when ordered*
11 *by the Secretary (acting through such*
12 *offices), if the Secretary determines*
13 *that there may be a cause for action by*
14 *the Secretary under subsection (e).*

15 “(iii) *CONTENT OF ORDER.—An order*
16 *under subclauses (III), (IV), or (V) of clause*
17 *(ii) shall describe—*

18 “(I) *the new safety information*
19 *with respect to the drug that warrants*
20 *an assessment of the approved risk*
21 *evaluation and mitigation strategy for*
22 *the drug; and*

23 “(II) *whether and how such strat-*
24 *egy should be modified because of such*
25 *information.*

1 “(iv) *ASSESSMENT.*—*An assessment of*
2 *the approved risk evaluation and mitiga-*
3 *tion strategy for a drug shall include—*

4 “(I) *a description of new safety*
5 *information, if any, with respect to the*
6 *drug;*

7 “(II) *whether and how to modify*
8 *such strategy because of such informa-*
9 *tion;*

10 “(III) *with respect to any post-*
11 *approval study required under para-*
12 *graph (4)(B) or otherwise undertaken*
13 *by the applicant to investigate a safety*
14 *issue, the status of such study, includ-*
15 *ing whether any difficulties completing*
16 *the study have been encountered;*

17 “(IV) *with respect to any post-*
18 *approval clinical trial required under*
19 *paragraph (4)(C) or otherwise under-*
20 *taken by the applicant to investigate a*
21 *safety issue, the status of such clinical*
22 *trial, including whether enrollment has*
23 *begun, the number of participants en-*
24 *rolled, the expected completion date,*
25 *whether any difficulties completing the*

1 *clinical trial have been encountered,*
2 *and registration information with re-*
3 *spect to requirements under subsections*
4 *(i) and (j) of section 402 of the Public*
5 *Health Service Act; and*

6 “(V) *with respect to any goal*
7 *under paragraph (6) and considering*
8 *input and evaluations, if applicable,*
9 *under paragraph (6)(E), an assessment*
10 *of how well the restrictions on distribu-*
11 *tion or use are meeting the goal or*
12 *whether the goal or such restrictions*
13 *should be modified.*

14 “(v) *MODIFICATION.—A modification*
15 *(whether an enhancement or a reduction) to*
16 *the approved risk evaluation and mitiga-*
17 *tion strategy for a drug may include the*
18 *addition or modification of any element*
19 *under subparagraph (A) or (B) of para-*
20 *graph (3) or the addition, modification, or*
21 *removal of any element under paragraph*
22 *(4), (5), or (6), such as—*

23 “(I) *a labeling change, including*
24 *the addition of a boxed warning;*

1 “(II) adding a postapproval study
2 or clinical trial requirement;

3 “(III) modifying a postapproval
4 study or clinical trial requirement
5 (such as a change in trial design due
6 to legitimate difficulties recruiting
7 participants);

8 “(IV) adding, modifying, or re-
9 moving a restriction on advertising
10 under subparagraph (D), (E), or (F) of
11 paragraph (5);

12 “(V) adding, modifying, or remov-
13 ing a restriction on distribution or use
14 under paragraph (6); or

15 “(VI) modifying the timetable for
16 assessments of the strategy under para-
17 graph (3)(B), including to eliminate
18 assessments.

19 “(C) REVIEW.—The Secretary (acting
20 through the offices described in subparagraph
21 (A)(ii)(I)) shall promptly review the proposed
22 risk evaluation and mitigation strategy for a
23 drug submitted under subparagraph (A), or an
24 assessment of the approved risk evaluation and

1 *mitigation strategy for a drug submitted under*
2 *subparagraph (B).*

3 “(D) *DISCUSSION.—The Secretary (acting*
4 *through the offices described in subparagraph*
5 *(A)(ii)(I)) shall initiate discussions of the pro-*
6 *posed risk evaluation and mitigation strategy for*
7 *a drug submitted under subparagraph (A)(i), or*
8 *of an assessment of the approved risk evaluation*
9 *and mitigation strategy for a drug submitted*
10 *under subparagraph (B), with the applicant to*
11 *determine a strategy—*

12 “(i) *if the proposed strategy or assess-*
13 *ment is submitted as part of an application*
14 *(including a supplemental application)*
15 *under subparagraph (A)(i) or (B)(ii)(I), by*
16 *the target date for communication of feed-*
17 *back from the review team to the applicant*
18 *regarding proposed labeling and post-*
19 *marketing study commitments, as set forth*
20 *in the letters described in section 735(a);*

21 “(ii) *if the proposed strategy is sub-*
22 *mitted under subparagraph (A)(ii)(I) or the*
23 *assessment is submitted under subclause (II)*
24 *or (III) of subparagraph (B)(ii), not later*
25 *than 20 days after such submission;*

1 “(iii) if the proposed strategy is sub-
2 mitted under subparagraph (A)(ii)(II) or
3 the assessment is submitted under subpara-
4 graph (B)(i) or under subparagraph
5 (B)(ii)(IV), not later than 30 days after
6 such submission; or

7 “(iv) if the assessment is submitted
8 under subparagraph (B)(ii)(V), not later
9 than 10 days after such submission.

10 “(E) ACTION.—

11 “(i) IN GENERAL.—Unless the appli-
12 cant requests the dispute resolution process
13 as described under subparagraph (F) or
14 (G), the Secretary (acting through the of-
15 fices described in subparagraph (A)(ii)(I))
16 shall approve and include the risk evalua-
17 tion and mitigation strategy for a drug, or
18 any modification to the strategy (including
19 a timeframe for implementing such modi-
20 fication), with—

21 “(I) the action letter on the appli-
22 cation, if a proposed strategy is sub-
23 mitted under subparagraph (A)(i) or
24 an assessment of the strategy is sub-

1 mitted under subparagraph (B)(ii)(I);

2 or

3 “(II) an order, which shall be
4 made public, issued not later than 50
5 days after the date discussions of such
6 proposed strategy or modification
7 begin under subparagraph (D), if a
8 proposed strategy is submitted under
9 subparagraph (A)(ii) or an assessment
10 of the strategy is submitted under sub-
11 paragraph (B)(i) or under subclause
12 (II), (III), (IV), or (V) of subpara-
13 graph (B)(ii).

14 “(ii) *INACTION*.—An approved risk
15 evaluation and mitigation strategy shall re-
16 main in effect until the Secretary acts, if
17 the Secretary fails to act as provided under
18 clause (i).

19 “(F) *DISPUTE RESOLUTION AT INITIAL AP-*
20 *PROVAL*.—If a proposed risk evaluation and
21 mitigation strategy is submitted under subpara-
22 graph (A)(i) in an application for initial ap-
23 proval of a drug and there is a dispute about the
24 strategy, the applicant shall use the major dis-

1 *pute resolution procedures as set forth in the let-*
2 *ters described in section 735(a).*

3 “(G) *DISPUTE RESOLUTION IN ALL OTHER*
4 *CASES.—*

5 “(i) *REQUEST FOR REVIEW.—In any*
6 *case other than a submission under sub-*
7 *paragraph (A)(i) in an application for ini-*
8 *tial approval of a drug if there is a dispute*
9 *about the strategy, not earlier than 15 days,*
10 *and not later than 35 days, after discus-*
11 *sions under subparagraph (D) have begun,*
12 *the applicant shall request in writing that*
13 *the dispute be reviewed by the Drug Safety*
14 *Oversight Board.*

15 “(ii) *SCHEDULING REVIEW.—If the ap-*
16 *plicant requests review under clause (i), the*
17 *Secretary—*

18 “(I)(aa) *shall schedule the dispute*
19 *for review at 1 of the next 2 regular*
20 *meetings of the Drug Safety Oversight*
21 *Board, whichever meeting date is more*
22 *practicable; or*

23 “(bb) *may convene a special meet-*
24 *ing of the Drug Safety Oversight*
25 *Board to review the matter more*

1 *promptly, including to meet an action*
2 *deadline on an application (including*
3 *a supplemental application);*

4 “(II) *shall give advance notice to*
5 *the public through the Federal Register*
6 *and on the Internet website of the Food*
7 *and Drug Administration—*

8 “(aa) *that the drug is to be*
9 *discussed by the Drug Safety*
10 *Oversight Board; and*

11 “(bb) *the date on which the*
12 *Drug Safety Oversight Board*
13 *shall discuss such drug; and*

14 “(III) *shall apply section 301(j),*
15 *section 552 of title 5, and section 1905*
16 *of title 18, United States Code, to any*
17 *request for information about such re-*
18 *view.*

19 “(iii) *AGREEMENT AFTER DISCUSSION*
20 *OR ADMINISTRATIVE APPEALS.—*

21 “(I) *FURTHER DISCUSSION OR*
22 *ADMINISTRATIVE APPEALS.—A request*
23 *for review under clause (i) shall not*
24 *preclude—*

1 “(aa) further discussions to
2 reach agreement on the risk eval-
3 uation and mitigation strategy; or

4 “(bb) the use of administra-
5 tive appeals within the Food and
6 Drug Administration to reach
7 agreement on the strategy, includ-
8 ing the major dispute resolution
9 procedures as set forth in the let-
10 ters described in section 735(a).

11 “(II) *AGREEMENT TERMINATES*
12 *DISPUTE RESOLUTION.*—At any time
13 before a decision and order is issued
14 under clause (vi), the Secretary (acting
15 through the offices described in sub-
16 paragraph (A)(ii)(I)) and the appli-
17 cant may reach an agreement on the
18 risk evaluation and mitigation strat-
19 egy through further discussion or ad-
20 ministrative appeals, terminating the
21 dispute resolution process, and the Sec-
22 retary shall issue an action letter or
23 order, as appropriate, that describes
24 the strategy.

1 “(iv) *MEETING OF THE BOARD.—At*
2 *the meeting of the Drug Safety Oversight*
3 *Board described in clause (ii), the Board*
4 *shall—*

5 “(I) *hear from both parties; and*

6 “(II) *review the dispute.*

7 “(v) *RECOMMENDATION OF THE*
8 *BOARD.—Not later than 5 days after such*
9 *meeting of the Drug Safety Oversight*
10 *Board, the Board shall provide a written*
11 *recommendation on resolving the dispute to*
12 *the Secretary.*

13 “(vi) *ACTION BY THE SECRETARY.—*

14 “(I) *ACTION LETTER.—With re-*
15 *spect to a proposed risk evaluation and*
16 *mitigation strategy submitted under*
17 *subparagraph (A)(i) or to an assess-*
18 *ment of the strategy submitted under*
19 *subparagraph (B)(ii)(I), the Secretary*
20 *shall issue an action letter that resolves*
21 *the dispute not later than the later*
22 *of—*

23 “(aa) *the action deadline for*
24 *the action letter on the applica-*
25 *tion; or*

1 “(bb) 7 days after receiving
2 the recommendation of the Drug
3 Safety Oversight Board.

4 “(II) ORDER.—With respect to a
5 proposed risk evaluation and mitiga-
6 tion strategy submitted under subpara-
7 graph (A)(ii) or an assessment of the
8 risk evaluation and mitigation strat-
9 egy under subparagraph (B)(i) or
10 under subclause (II), (III), (IV), or (V)
11 of subparagraph (B)(ii), the Secretary
12 shall issue an order, which (with the
13 recommendation of the Drug Safety
14 Oversight Board) shall be made public,
15 that resolves the dispute not later than
16 7 days after receiving the recommenda-
17 tion of the Drug Safety Oversight
18 Board.

19 “(vii) INACTION.—An approved risk
20 evaluation and mitigation strategy shall re-
21 main in effect until the Secretary acts, if
22 the Secretary fails to act as provided for
23 under clause (vi).

24 “(viii) EFFECT ON ACTION DEAD-
25 LINE.—With respect to the application or

1 *supplemental application in which a pro-*
2 *posed risk evaluation and mitigation strat-*
3 *egy is submitted under subparagraph (A)(i)*
4 *or in which an assessment of the strategy is*
5 *submitted under subparagraph (B)(ii)(I),*
6 *the Secretary shall be considered to have*
7 *met the action deadline for the action letter*
8 *on such application if the applicant re-*
9 *quests the dispute resolution process de-*
10 *scribed in this subparagraph and if the Sec-*
11 *retary—*

12 *“(I) has initiated the discussions*
13 *described under subparagraph (D) by*
14 *the target date referred to in subpara-*
15 *graph (D)(i); and*

16 *“(II) has complied with the tim-*
17 *ing requirements of scheduling review*
18 *by the Drug Safety Oversight Board,*
19 *providing a written recommendation,*
20 *and issuing an action letter under*
21 *clauses (ii), (v), and (vi), respectively.*

22 *“(ix) DISQUALIFICATION.—No indi-*
23 *vidual who is an employee of the Food and*
24 *Drug Administration and who reviews a*
25 *drug or who participated in an administra-*

1 *tive appeal under clause (iii)(I) with re-*
2 *spect to such drug may serve on the Drug*
3 *Safety Oversight Board at a meeting under*
4 *clause (iv) to review a dispute about the*
5 *risk evaluation and mitigation strategy for*
6 *such drug.*

7 “(x) *ADDITIONAL EXPERTISE.—The*
8 *Drug Safety Oversight Board may add*
9 *members with relevant expertise from the*
10 *Food and Drug Administration, including*
11 *the Office of Pediatrics, the Office of Wom-*
12 *en’s Health, or the Office of Rare Diseases,*
13 *or from other Federal public health or*
14 *health care agencies, for a meeting under*
15 *clause (iv) of the Drug Safety Oversight*
16 *Board.*

17 “(H) *USE OF ADVISORY COMMITTEES.—The*
18 *Secretary (acting through the offices described in*
19 *subparagraph (A)(ii)(I)) may convene a meeting*
20 *of 1 or more advisory committees of the Food*
21 *and Drug Administration to—*

22 “(i) *review a concern about the safety*
23 *of a drug or class of drugs, including before*
24 *an assessment of the risk evaluation and*
25 *mitigation strategy or strategies of such*

1 *drug or drugs is required to be submitted*
2 *under subclause (II), (III), (IV), or (V) of*
3 *subparagraph (B)(ii);*

4 *“(ii) review the risk evaluation and*
5 *mitigation strategy or strategies of a drug*
6 *or group of drugs; or*

7 *“(iii) with the consent of the applicant,*
8 *review a dispute under subparagraph (G).*

9 *“(I) PROCESS FOR ADDRESSING DRUG*
10 *CLASS EFFECTS.—*

11 *“(i) IN GENERAL.—When a concern*
12 *about a serious risk of a drug may be re-*
13 *lated to the pharmacological class of the*
14 *drug, the Secretary (acting through the of-*
15 *fices described in subparagraph (A)(ii)(I))*
16 *may defer assessments of the approved risk*
17 *evaluation and mitigation strategies for*
18 *such drugs until the Secretary has—*

19 *“(I) convened, after appropriate*
20 *public notice, 1 or more public meet-*
21 *ings to consider possible responses to*
22 *such concern; or*

23 *“(II) gathered additional infor-*
24 *mation or data about such concern.*

1 “(ii) *PUBLIC MEETINGS.*—Such public
2 *meetings may include—*

3 “(I) *1 or more meetings of the ap-*
4 *plicants for such drugs;*

5 “(II) *1 or more meetings of 1 or*
6 *more advisory committees of the Food*
7 *and Drug Administration, as provided*
8 *for under subparagraph (H); or*

9 “(III) *1 or more workshops of sci-*
10 *entific experts and other stakeholders.*

11 “(iii) *ACTION.*—After considering the
12 *discussions from any meetings under clause*
13 *(ii), the Secretary may—*

14 “(I) *announce in the Federal Reg-*
15 *ister a planned regulatory action, in-*
16 *cluding a modification to each risk*
17 *evaluation and mitigation strategy, for*
18 *drugs in the pharmacological class;*

19 “(II) *seek public comment about*
20 *such action; and*

21 “(III) *after seeking such comment,*
22 *issue an order addressing such regu-*
23 *latory action.*

24 “(J) *INTERNATIONAL COORDINATION.*—The
25 *Secretary (acting through the offices described in*

1 subparagraph (A)(ii)(I) may coordinate the
2 timetable for submission of assessments under
3 paragraph (3)(B), a study under paragraph
4 (4)(B), or a clinical trial under paragraph
5 (4)(C), with efforts to identify and assess the se-
6 rious risks of such drug by the marketing au-
7 thorities of other countries whose drug approval
8 and risk management processes the Secretary
9 deems comparable to the drug approval and risk
10 management processes of the United States.

11 “(K) *EFFECT.*—Use of the processes de-
12 scribed in subparagraphs (I) and (J) shall not
13 delay action on an application or a supplement
14 to an application for a drug.

15 “(L) *NO EFFECT ON LABELING CHANGES*
16 *THAT DO NOT REQUIRE PREAPPROVAL.*—In the
17 case of a labeling change to which section 314.70
18 of title 21, Code of Federal Regulations (or any
19 successor regulation), applies for which the sub-
20 mission of a supplemental application is not re-
21 quired or for which distribution of the drug in-
22 volved may commence upon the receipt by the
23 Secretary of a supplemental application for the
24 change, the submission of an assessment of the
25 approved risk evaluation and mitigation strat-

1 *egy for the drug under this subsection is not re-*
2 *quired.*

3 “(8) *DRUG SAFETY OVERSIGHT BOARD.*—

4 “(A) *IN GENERAL.*—*There is established a*
5 *Drug Safety Oversight Board.*

6 “(B) *COMPOSITION; MEETINGS.*—*The Drug*
7 *Safety Oversight Board shall—*

8 “(i) *be composed of scientists and*
9 *health care practitioners appointed by the*
10 *Secretary, each of whom is an employee of*
11 *the Federal Government;*

12 “(ii) *include representatives from of-*
13 *fices throughout the Food and Drug Admin-*
14 *istration (including the offices responsible*
15 *for postapproval safety of drugs);*

16 “(iii) *include at least 1 representative*
17 *each from the National Institutes of Health,*
18 *the Department of Health and Human*
19 *Services (other than the Food and Drug Ad-*
20 *ministration), and the Veterans Health Ad-*
21 *ministration; and*

22 “(iv) *meet at least monthly to provide*
23 *oversight and advice to the Secretary on the*
24 *management of important drug safety*
25 *issues.”.*

1 **SEC. 203. ENFORCEMENT.**

2 (a) *MISBRANDING.*—Section 502 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 352) is amended by
4 adding at the end the following:

5 “(x) If it is a drug subject to an approved risk evalua-
6 tion and mitigation strategy under section 505(o) and the
7 applicant for such drug fails to—

8 “(1) make a labeling change required by such
9 strategy after the Secretary has approved such strat-
10 egy or completed review of, and acted on, an assess-
11 ment of such strategy under paragraph (7) of such
12 section; or

13 “(2) comply with a requirement of such strategy
14 with respect to advertising as provided for under sub-
15 paragraph (D), (E), or (F) of paragraph (5) of such
16 section.”.

17 (b) *CIVIL PENALTIES.*—Section 303(f) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amend-
19 ed—

20 (1) by redesignating paragraphs (3), (4), and (5)
21 as paragraphs (4), (5), and (6), respectively;

22 (2) by inserting after paragraph (2) the fol-
23 lowing:

24 “(3) An applicant (as such term is used in sec-
25 tion 505(o)) who knowingly fails to comply with a re-
26 quirement of an approved risk evaluation and mitiga-

1 *tion strategy under such section 505(o) shall be sub-*
 2 *ject to a civil money penalty of not less than \$15,000*
 3 *and not more than \$250,000 per violation, and not*
 4 *to exceed \$1,000,000 for all such violations adju-*
 5 *dicated in a single proceeding.”;*

6 *(3) in paragraph (2)(C), by striking “paragraph*
 7 *(3)(A)” and inserting “paragraph (4)(A)”;*

8 *(4) in paragraph (4), as so redesignated, by*
 9 *striking “paragraph (1) or (2)” each place it appears*
 10 *and inserting “paragraph (1), (2), or (3)”;* and

11 *(5) in paragraph (6), as so redesignated, by*
 12 *striking “paragraph (4)” each place it appears and*
 13 *inserting “paragraph (5)”.*

14 **SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL**
 15 **PRODUCTS.**

16 *Section 351 of the Public Health Service Act (42*
 17 *U.S.C. 262) is amended—*

18 *(1) in subsection (a)(2), by adding at the end the*
 19 *following:*

20 *“(D) RISK EVALUATION AND MITIGATION STRAT-*
 21 *EGY.—A person that submits an application for a license*
 22 *for a drug under this paragraph may submit to the Sec-*
 23 *retary as part of the application a proposed risk evaluation*
 24 *and mitigation strategy as described under section 505(o)*
 25 *of the Federal Food, Drug, and Cosmetic Act.”; and*

1 (2) in subsection (j), by inserting “, including
2 the requirements under section 505(o) of such Act,”
3 after “, and Cosmetic Act”.

4 **SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**
5 **APPROVAL.**

6 Section 505(e) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 355(e)) is amended by adding at the
8 end the following: “The Secretary may withdraw the ap-
9 proval of an application submitted under this section, or
10 suspend the approval of such an application, as provided
11 under this subsection, without first ordering the applicant
12 to submit an assessment of the approved risk evaluation
13 and mitigation strategy for the drug under subsection
14 (o)(7)(B)(ii)(V).”.

15 **SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG**
16 **APPLICATION.**

17 Section 505(j)(2) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(j)(2)) is amended by adding at
19 the end the following:

20 “(E) *RISK EVALUATION AND MITIGATION STRATEGY*
21 *REQUIREMENT.*—

22 “(i) *IN GENERAL.*—A drug that is the subject of
23 an abbreviated new drug application under this sub-
24 section shall be subject to only the following elements
25 of the approved risk evaluation and mitigation strat-

1 *egy if required under subsection (o) for the applicable*
2 *listed drug:*

3 *“(I) Labeling, as required under subsection*
4 *(o)(3)(A) for the applicable listed drug.*

5 *“(II) A Medication Guide or patient pack-*
6 *age insert, if required under subsection (o)(5)(B)*
7 *for the applicable listed drug.*

8 *“(III) Prereview of advertising, if required*
9 *under subsection (o)(5)(D) for the applicable list-*
10 *ed drug.*

11 *“(IV) Specific disclosures in advertising, if*
12 *required under subsection (o)(5)(E) for the ap-*
13 *plicable listed drug.*

14 *“(V) A temporary moratorium on direct-to-*
15 *consumer advertising, if required under sub-*
16 *section (o)(5)(F) for the applicable listed drug.*

17 *“(VI) Restrictions on distribution or use, if*
18 *required under subsection (o)(6) for the applica-*
19 *ble listed drug, except that such drug may use a*
20 *different, comparable aspect of such restrictions*
21 *on distribution or use as are needed to assure*
22 *safe use of such drug if —*

23 *“(aa) the corresponding aspect of the*
24 *restrictions on distribution or use for the*
25 *applicable listed drug is claimed by a pat-*

1 *ent that has not expired or is a method or*
2 *process that as a trade secret is entitled to*
3 *protection; and*

4 *“(bb) the applicant certifies that it has*
5 *sought a license for use of such aspect of the*
6 *restrictions on distribution or use for the*
7 *applicable listed drug.*

8 *“(ii) ACTION BY SECRETARY.—For an applicable*
9 *listed drug for which a drug is approved under this*
10 *subsection, the Secretary—*

11 *“(I) shall undertake any communication*
12 *plan to health care providers required under sec-*
13 *tion (o)(5)(C) for the applicable listed drug;*

14 *“(II) shall conduct, or contract for, any*
15 *postapproval study required under subsection*
16 *(o)(4)(B) for the applicable listed drug;*

17 *“(III) shall inform the applicant for a drug*
18 *approved under this subsection if the approved*
19 *risk evaluation and mitigation strategy for the*
20 *applicable listed drug is modified; and*

21 *“(IV) in order to minimize the burden on*
22 *the health care delivery system of different re-*
23 *strictions on distribution or use for the drug ap-*
24 *proved under this subsection and the applicable*
25 *listed drug, may seek to negotiate a voluntary*

1 *agreement with the owner of the patent, method,*
2 *or process for a license under which the appli-*
3 *cant for such drug may use an aspect of the re-*
4 *strictions on distribution or use, if required*
5 *under subsection (o)(6) for the applicable listed*
6 *drug, that is claimed by a patent that has not*
7 *expired or is a method or process that as a trade*
8 *secret is entitled to protection.”.*

9 **SEC. 207. RESOURCES.**

10 (a) *USER FEES.*—Subparagraph (F) of section
11 735(d)(6) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379g(d)(6)), as amended by section 103, is amend-
13 ed—

14 (1) *in clause (ii), by striking “systems); and”*
15 *and inserting “systems);”*

16 (2) *in clause (iii), by striking “bases).” and in-*
17 *serting “bases); and”; and*

18 (3) *by adding at the end the following:*

19 *“(iv) reviewing, implementing, and en-*
20 *suring compliance with risk evaluation and*
21 *mitigation strategies.”.*

22 (b) *WORKLOAD ADJUSTMENT.*—Subparagraph (A) of
23 section 736(c)(2) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 379h(c)(2)), as amended by section 103, is
25 amended in the first sentence by striking “and manufac-

1 turing changes submitted to the Secretary, and” and insert-
 2 ing “manufacturing changes, and assessments of risk eval-
 3 uation and mitigation strategies submitted to the Secretary,
 4 uses of dispute resolution under the process for reviewing
 5 and assessing risk evaluation and mitigation strategies,
 6 and”.

7 (c) *ADDITIONAL FEE REVENUES FOR DRUG SAFE-*
 8 *TY.*—Section 736 of the Federal Food, Drug, and Cosmetic
 9 Act (21 U.S.C. 379h), as amended by section 103, is amend-
 10 ed by—

11 (1) striking the subsection designation and all
 12 that follows through “.—*Except*” and inserting the
 13 following:

14 “(b) *FEE REVENUE AMOUNTS.*—

15 “(1) *IN GENERAL.*—*Except*”; and

16 (2) adding at the end the following:

17 “(2) *ADDITIONAL FEE REVENUES FOR DRUG*
 18 *SAFETY.*—

19 “(A) *IN GENERAL.*—Subject to subpara-
 20 graph (C), in each of fiscal years 2008 through
 21 2012, paragraph (1) shall be applied by sub-
 22 stituting the amount determined under subpara-
 23 graph (B) for ‘\$392,783,000’.

1 “(B) *AMOUNT DETERMINED.*—*For any fis-*
2 *cal year 2008 through 2012, the amount deter-*
3 *mined under this subparagraph is the sum of—*

4 “(i) \$392,783,000; plus

5 “(ii) *the amount equal to—*

6 “(I) \$50,000,000; minus

7 “(II) *the amount equal to one-*
8 *fifth of the amount by which the ap-*
9 *propriations for salaries and expenses*
10 *of the Food and Drug Administration*
11 *for such fiscal year (excluding the*
12 *amount of fees appropriated for such*
13 *fiscal year) exceed the amount of ap-*
14 *propriations for the salaries and ex-*
15 *penditures of the Food and Drug Adminis-*
16 *tration for the fiscal year 2007 (exclud-*
17 *ing the amount of fees appropriated for*
18 *such fiscal year), adjusted as provided*
19 *under subsection (c)(1).*

20 *In making the adjustment under subclause*
21 *(II) for any fiscal year 2008 through 2012,*
22 *subsection (c)(1) shall be applied by sub-*
23 *stituting ‘2007’ for ‘2008’.*

24 “(C) *LIMITATION.*—*This paragraph shall*
25 *not apply for any fiscal year if the amount de-*

1 scribed under subparagraph (B)(ii) is less than
2 0.”.

3 (d) *STRATEGIC PLAN FOR INFORMATION TECH-*
4 *NOLOGY.*—Not later than 1 year after the date of enactment
5 of this title, the Secretary of Health and Human Services
6 (referred to in this title as the “Secretary”) shall submit
7 to the Committee on Health, Education, Labor, and Pen-
8 sions and the Committee on Appropriations of the Senate
9 and the Committee on Energy and Commerce and the Com-
10 mittee on Appropriations of the House of Representatives,
11 a strategic plan on information technology that includes—

12 (1) an assessment of the information technology
13 infrastructure, including systems for data collection,
14 access to data in external health care databases, data
15 mining capabilities, personnel, and personnel train-
16 ing programs, needed by the Food and Drug Admin-
17 istration to—

18 (A) comply with the requirements of this
19 subtitle (and the amendments made by this sub-
20 title);

21 (B) achieve interoperability within and
22 among the centers of the Food and Drug Admin-
23 istration and between the Food and Drug Ad-
24 ministration and product application sponsors;

25 (C) utilize electronic health records; and

1 (D) implement routine active safety moni-
 2 toring under section 505(k)(3) (including other
 3 approaches under subsection (c) of such section)
 4 of the Federal Food, Drug, and Cosmetic Act, as
 5 added by section 201 of this Act;

6 (2) an assessment of the extent to which the cur-
 7 rent information technology assets of the Food and
 8 Drug Administration are sufficient to meet the needs
 9 assessments under paragraph (1);

10 (3) a plan for enhancing the information tech-
 11 nology assets of the Food and Drug Administration
 12 toward meeting the needs assessments under para-
 13 graph (1); and

14 (4) an assessment of additional resources needed
 15 to so enhance the information technology assets of the
 16 Food and Drug Administration.

17 **SEC. 208. SAFETY LABELING CHANGES.**

18 (a) *IN GENERAL.*—Subchapter A of chapter V of the
 19 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 351 et
 20 *seq.*) is amended by inserting after section 506C the fol-
 21 *lowing:*

22 **“SEC. 506D. SAFETY LABELING CHANGES.**

23 “(a) *NEW SAFETY INFORMATION.*—

24 “(1) *NOTIFICATION.*—The holder of an approved
 25 application under section 505 of this Act or a license

1 *under section 351 of the Public Health Service Act*
2 *(referred to in this section as a ‘holder’) shall prompt-*
3 *ly notify the Secretary if the holder becomes aware of*
4 *new safety information that the holder believes should*
5 *be included in the labeling of the drug. The Secretary*
6 *shall promptly notify the holder if the Secretary be-*
7 *comes aware of new safety information that the Sec-*
8 *retary believes should be included in the labeling of*
9 *the drug.*

10 *“(2) DISCUSSION REGARDING LABELING*
11 *CHANGES.—Following notification pursuant to para-*
12 *graph (1), the Secretary and holder shall initiate dis-*
13 *cussions of the new safety information in order to*
14 *reach agreement on whether the labeling for the drug*
15 *should be modified to reflect the new safety informa-*
16 *tion and, if so, on the contents of such labeling*
17 *changes.*

18 *“(3) SUPPLEMENT.—If the Secretary determines*
19 *that there is reasonable scientific evidence that an ad-*
20 *verse event is associated with use of the drug, the Sec-*
21 *retary may request the holder to submit a supplement*
22 *to an application under section 505 of this Act or to*
23 *a license under section 351 of the Public Health Serv-*
24 *ice Act (referred to in this section as a ‘supplement’)*
25 *proposing changes to the approved labeling to reflect*

1 *the new safety information, including changes to*
2 *boxed warnings, contraindications, warnings, pre-*
3 *cautions, or adverse reactions (referred to in this sec-*
4 *tion as a ‘safety labeling change’). If the Secretary de-*
5 *termines that no safety labeling change is necessary*
6 *or appropriate based upon the new safety informa-*
7 *tion, the Secretary shall notify the holder of this de-*
8 *termination in writing.*

9 “(b) *LABELING SUPPLEMENTS.*—

10 “(1) *IN GENERAL.*—*The holder shall submit a*
11 *supplement whenever the holder seeks, either at the*
12 *holder’s own initiative or at the request of the Sec-*
13 *retary, to make a safety labeling change.*

14 “(2) *NONACCELERATED PROCESS.*—*Unless the*
15 *accelerated labeling review process described in sub-*
16 *section (c) is initiated, any supplement proposing a*
17 *safety labeling change shall be reviewed and acted*
18 *upon by the Secretary not later than 30 days after*
19 *the date the Secretary receives the supplement. Until*
20 *the Secretary acts on such a supplement proposing a*
21 *safety labeling change, the existing approved labeling*
22 *shall remain in effect and be distributed by the holder*
23 *without change.*

24 “(3) *NEW SAFETY INFORMATION.*—*Nothing in*
25 *this section shall prohibit the Secretary from inform-*

1 *ing health care professionals or the public about new*
2 *safety information prior to approval of a supplement*
3 *proposing a safety labeling change.*

4 *“(c) ACCELERATED LABELING REVIEW PROCESS.—An*
5 *accelerated labeling review process shall be available to re-*
6 *solve disagreements in a timely manner between the Sec-*
7 *retary and a holder about the need for, or content of, a safe-*
8 *ty labeling change, as follows:*

9 *“(1) REQUEST TO INITIATE ACCELERATED PROC-*
10 *ESS.—The accelerated labeling review process shall be*
11 *initiated upon the written request of either the Sec-*
12 *retary or the holder. Such request may be made at*
13 *any time after the notification described in subsection*
14 *(a)(1), including during the Secretary’s review of a*
15 *supplement proposing a safety labeling change.*

16 *“(2) SCIENTIFIC DISCUSSION AND MEETINGS.—*

17 *“(A) IN GENERAL.—Following initiation of*
18 *the accelerated labeling review process, the Sec-*
19 *retary and holder shall immediately initiate dis-*
20 *ussions to review and assess the new safety in-*
21 *formation and to reach agreement on whether*
22 *safety labeling changes are necessary and appro-*
23 *priate and, if so, the content of such safety label-*
24 *ing changes.*

1 “(B) *TIME PERIOD.*—*The discussions under*
2 *this paragraph shall not extend for more than 45*
3 *calendar days after the initiation of the acceler-*
4 *ated labeling review process.*

5 “(C) *DISPUTE PROCEEDINGS.*—*If the Sec-*
6 *retary and holder do not reach an agreement re-*
7 *garding the safety labeling changes by not later*
8 *than 25 calendar days after the initiation of the*
9 *accelerated labeling review process, the dispute*
10 *automatically shall be referred to the director of*
11 *the drug evaluation office responsible for the*
12 *drug under consideration, who shall be required*
13 *to take an active role in such discussions.*

14 “(3) *REQUEST FOR SAFETY LABELING CHANGE*
15 *AND FAILURE TO AGREE.*—*If the Secretary and holder*
16 *fail to reach an agreement on appropriate safety la-*
17 *beling changes by not later than 45 calendar days*
18 *after the initiation of the accelerated labeling review*
19 *process—*

20 “(A) *on the next calendar day (other than*
21 *a weekend or Federal holiday) after such period,*
22 *the Secretary shall—*

23 “(i) *request in writing that the holder*
24 *make any safety labeling change that the*
25 *Secretary determines to be necessary and*

1 *appropriate based upon the new safety in-*
2 *formation; or*

3 “(ii) *notify the holder in writing that*
4 *the Secretary has determined that no safety*
5 *labeling change is necessary or appropriate;*
6 *and*

7 “(B) *if the Secretary fails to act within the*
8 *specified time, or if the holder does not agree to*
9 *make a safety labeling change requested by the*
10 *Secretary or does not agree with the Secretary’s*
11 *determination that no labeling change is nec-*
12 *essary or appropriate, the Secretary (on his own*
13 *initiative or upon request by the holder) shall*
14 *refer the matter for expedited review to the Drug*
15 *Safety Oversight Board.*

16 “(4) *ACTION BY THE DRUG SAFETY OVERSIGHT*
17 *BOARD.—Not later than 45 days after receiving a re-*
18 *ferral under paragraph (3)(B), the Drug Safety Over-*
19 *sight Board shall—*

20 “(A) *review the new safety information;*

21 “(B) *review all written material submitted*
22 *by the Secretary and the holder;*

23 “(C) *convene a meeting to hear oral presen-*
24 *tations and arguments from the Secretary and*
25 *holder; and*

1 “(D) make a written recommendation to the
2 Secretary—

3 “(i) concerning appropriate safety la-
4 beling changes, if any; or

5 “(ii) stating that no safety labeling
6 changes are necessary or appropriate based
7 upon the new safety information.

8 “(5) CONSIDERATION OF RECOMMENDATIONS.—

9 “(A) ACTION BY THE SECRETARY.—The
10 Secretary shall consider the recommendation of
11 the Drug Safety Oversight Board made under
12 paragraph (4)(D) and, not later than 20 days
13 after receiving the recommendation—

14 “(i) issue an order requiring the holder
15 to make any safety labeling change that the
16 Secretary determines to be necessary and
17 appropriate; or

18 “(ii) if the Secretary determines that
19 no safety labeling change is necessary or ap-
20 propriate, the Secretary shall notify the
21 holder of this determination in writing.

22 “(B) FAILURE TO ACT.—If the Secretary
23 fails to act by not later than 20 days after re-
24 ceiving the recommendation of the Drug Safety
25 Oversight Board, the written recommendation of

1 *the Drug Safety Oversight Board shall be consid-*
2 *ered the order of the Secretary under this para-*
3 *graph.*

4 “(C) *NONDELEGATION.*—*The Secretary’s*
5 *authority under this paragraph shall not be re-*
6 *delegated to an individual below the level of the*
7 *Director of the Center for Drug Evaluation and*
8 *Research, or the Director of the Center for Bio-*
9 *logics Evaluation and Research, of the Food and*
10 *Drug Administration.*

11 “(6) *MISBRANDING.*—*If the holder, not later*
12 *than 10 days after receiving an order under subpara-*
13 *graph (A) or (B) of paragraph (5), does not agree to*
14 *make a safety labeling change ordered by the Sec-*
15 *retary, the Secretary may deem the drug that is the*
16 *subject of the request to be misbranded.*

17 “(d) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
18 *tion shall be construed to change the standards in existence*
19 *on the date of enactment of this section for determining*
20 *whether safety labeling changes are necessary or appro-*
21 *priate.”.*

22 “(b) *CONFORMING AMENDMENT.*—*Section 502 of the*
23 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 et*
24 *seq.), as amended by section 203, is further amended by*
25 *adding at the end the following:*

1 “(y) *If it is a drug and the holder does not agree to*
2 *make a safety labeling change ordered by the Secretary*
3 *under section 506D(c) within 10 days after issuance of such*
4 *an order.*”.

5 **SEC. 209. DRUG LABELING.**

6 (a) *ACCESSIBLE REPOSITORY OF DRUG LABELING.—*
7 *Not later than the effective date of this subtitle, the Sec-*
8 *retary, through the Commissioner of Food and Drugs, and*
9 *the Director of the National Institutes of Health, shall estab-*
10 *lish a searchable repository of structured, electronic product*
11 *information, including the approved professional labeling*
12 *and any required patient labeling of each drug approved*
13 *under section 505 of the Federal Food, Drug, and Cosmetic*
14 *Act (21 U.S.C. 355) or licensed under section 351 of the*
15 *Public Health Service Act (42 U.S.C. 262) in order to im-*
16 *prove patient safety through accessible product information,*
17 *support initiatives to improve patient care by better man-*
18 *agement of health care information, and provide standards*
19 *for drug information. Such repository shall be made pub-*
20 *licly accessible on the Internet website of the National Li-*
21 *brary of Medicine and through a link on the homepage of*
22 *the Internet website of the Food and Drug Administration.*
23 (b) *POSTING UPON APPROVAL.—The Secretary shall*
24 *post in the repository under subsection (a) the approved*
25 *professional labeling and any required patient labeling of*

1 *a drug approved under such section 505 or licensed under*
2 *such section 351 not later than 21 days after the date the*
3 *drug is approved, including in a supplemental application*
4 *with respect to a labeling change.*

5 *(c) REPORT.—The Secretary shall report annually to*
6 *the Committee on Health, Education, Labor and Pensions*
7 *of the Senate and the Committee on Energy and Commerce*
8 *of the House of Representatives on the status of the reposi-*
9 *tory under subsection (a), and on progress in posting struc-*
10 *tured electronic product information, including posting of*
11 *information regarding drugs approved prior to the effective*
12 *date of this subtitle.*

13 *(d) MEDICATION GUIDES.—Not later than the effective*
14 *date of this subtitle, the Secretary, through the Commis-*
15 *sioner of Food and Drugs, shall establish on the Internet*
16 *website for the repository under subsection (a), a link to*
17 *a list of each drug, whether approved under such section*
18 *505 or licensed under such section 351, for which a Medica-*
19 *tion Guide, as provided for under part 208 of title 21, Code*
20 *of Federal Regulations (or any successor regulations), is re-*
21 *quired.*

22 **SEC. 210. ACTION PACKAGE FOR APPROVAL.**

23 *Section 505(l) of the Federal Food, Drug, and Cos-*
24 *metic Act (21 U.S.C. 355(l)) is amended by—*

1 (1) redesignating paragraphs (1), (2), (3), (4),
2 and (5) as subparagraphs (A), (B), (C), (D), and (E),
3 respectively;

4 (2) striking “(l) Safety and” and inserting
5 “(l)(1) Safety and”; and

6 (3) adding at the end the following:

7 “(2) ACTION PACKAGE FOR APPROVAL.—

8 “(A) ACTION PACKAGE.—The Secretary shall
9 publish the action package for approval of an appli-
10 cation under subsection (b) or section 351 of the Pub-
11 lic Health Service Act on the Internet website of the
12 Food and Drug Administration—

13 “(i) not later than 30 days after the date of
14 approval of such application for a drug no ac-
15 tive ingredient (including any ester or salt of the
16 active ingredient) of which has been approved in
17 any other application under this section or sec-
18 tion 351 of the Public Health Service Act; and

19 “(ii) not later than 30 days after the third
20 request for such action package for approval re-
21 ceived under section 552 of title 5, United States
22 Code, for any other drug.

23 “(B) IMMEDIATE PUBLICATION OF SUMMARY RE-
24 VIEW.—Notwithstanding subparagraph (A), the Sec-
25 retary shall publish, on the Internet website of the

1 *Food and Drug Administration, the materials de-*
2 *scribed in subparagraph (C)(iv) not later than 48*
3 *hours after the date of approval of the drug, except*
4 *where such materials require redaction by the Sec-*
5 *retary.*

6 “(C) CONTENTS.—*An action package for ap-*
7 *proval of an application under subparagraph (A)*
8 *shall be dated and shall include the following:*

9 “(i) *Documents generated by the Food and*
10 *Drug Administration related to review of the ap-*
11 *plication.*

12 “(ii) *Documents pertaining to the format*
13 *and content of the application generated during*
14 *drug development.*

15 “(iii) *Labeling submitted by the applicant.*

16 “(iv) *A summary review that documents*
17 *conclusions from all reviewing disciplines about*
18 *the drug, noting any critical issues and disagree-*
19 *ments with the applicant and how they were re-*
20 *solved, recommendation for action, and an expla-*
21 *nation of any nonconcurrence with review con-*
22 *clusions.*

23 “(v) *If applicable, a separate review from a*
24 *supervisor who does not concur with the sum-*
25 *mary review.*

1 “(vi) Identification by name of each officer
2 or employee of the Food and Drug Administra-
3 tion who—

4 “(I) participated in the decision to ap-
5 prove the application; and

6 “(II) consents to have his or her name
7 included in the package.

8 “(D) DISAGREEMENTS.—A scientific review of
9 an application is considered the work of the reviewer
10 and shall not be altered by management or the re-
11 viewer once final. Disagreements by team leaders, di-
12 vision directors, or office directors with any or all of
13 the major conclusions of a reviewer shall be document
14 in a separate review or in an addendum to the re-
15 view.

16 “(E) CONFIDENTIAL INFORMATION.—This para-
17 graph does not authorize the disclosure of any trade
18 secret or confidential commercial or financial infor-
19 mation described in section 552(b)(4) of title 5,
20 United States Code, unless the Secretary declares an
21 emergency under section 319 of the Public Health
22 Service Act and such disclosure is necessary to miti-
23 gate the effects of such emergency.”.

1 **SEC. 211. RISK COMMUNICATION.**

2 *Subchapter E of chapter V of the Federal Food, Drug,*
 3 *and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended*
 4 *by adding at the end the following:*

5 **“SEC. 566. ADVISORY COMMITTEE ON RISK COMMUNICA-**
 6 **TION.**

7 *“(a) IN GENERAL.—The Secretary shall establish an*
 8 *advisory committee to be known as the ‘Advisory Committee*
 9 *on Risk Communication’ (referred to in this section as the*
 10 *‘Committee’).*

11 *“(b) DUTIES OF COMMITTEE.—The Committee shall*
 12 *advise the Commissioner on methods to effectively commu-*
 13 *nicate risks associated with the products regulated by the*
 14 *Food and Drug Administration.*

15 *“(c) MEMBERS.—The Secretary shall ensure that the*
 16 *Committee is composed of experts on risk communication,*
 17 *experts on the risks described in subsection (b), and rep-*
 18 *resentatives of patient, consumer, and health professional*
 19 *organizations.*

20 *“(d) PERMANENCE OF COMMITTEE.—Section 14 of the*
 21 *Federal Advisory Committee Act shall not apply to the*
 22 *Committee established under this section.”.*

23 **SEC. 212. REFERRAL TO ADVISORY COMMITTEE.**

24 *Section 505 of the Federal Food, Drug, and Cosmetic*
 25 *Act, as amended by this section 202, is further amended*
 26 *by adding at the end the following:*

1 “(p) *REFERRAL TO ADVISORY COMMITTEE.*—

2 “(1) *IN GENERAL.*—Prior to the approval of a
3 *drug no active ingredient (including any ester or salt*
4 *of the active ingredient) of which has been approved*
5 *in any other application under this section or section*
6 *351 of the Public Health Service Act, the Secretary*
7 *shall refer such drug to a Food and Drug Administra-*
8 *tion advisory committee for review at a meeting of*
9 *such advisory committee.*

10 “(2) *EXCEPTION.*—Notwithstanding paragraph
11 *(1), an advisory committee review of a drug described*
12 *under such paragraph may occur within 1 year after*
13 *approval of such a drug if—*

14 “(A) *the clinical trial that formed the pri-*
15 *mary basis of the safety and efficacy determina-*
16 *tion was halted by a drug safety monitoring*
17 *board or an Institutional Review Board before*
18 *its scheduled completion due to early unantici-*
19 *pated therapeutic results; or*

20 “(B) *the Secretary determines that it would*
21 *be beneficial to the public health.”.*

22 **SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE.**

23 “(a) *IN GENERAL.*—Not later than 1 year after the date
24 *of enactment of this title, the Secretary shall issue a report*
25 *responding to the 2006 report of the Institute of Medicine*

1 *entitled “The Future of Drug Safety—Promoting and Pro-*
2 *tecting the Health of the Public”.*

3 (b) *CONTENT OF REPORT.—The report issued by the*
4 *Secretary under subsection (a) shall include—*

5 (1) *an update on the implementation by the*
6 *Food and Drug Administration of its plan to respond*
7 *to the Institute of Medicine report described under*
8 *such subsection; and*

9 (2) *an assessment of how the Food and Drug Ad-*
10 *ministration has implemented—*

11 (A) *the recommendations described in such*
12 *Institute of Medicine report; and*

13 (B) *the requirement under paragraph (7) of*
14 *section 505(o) of the Federal Food, Drug, and*
15 *Cosmetic Act (as added by this title), that the*
16 *appropriate office responsible for reviewing a*
17 *drug and the office responsible for postapproval*
18 *safety with respect to the drug act together to as-*
19 *sess, implement, and ensure compliance with the*
20 *requirements of such section 505(o).*

21 **SEC. 214. EFFECTIVE DATE AND APPLICABILITY.**

22 (a) *EFFECTIVE DATES.—*

23 (1) *IN GENERAL.—Except as provided in para-*
24 *graph (2), this subtitle shall take effect 180 days after*
25 *the date of enactment of this title.*

1 (2) *USER FEES.*—*The amendments made by sub-*
2 *sections (a) through (c) of section 207 shall take effect*
3 *on October 1, 2007.*

4 ***(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND***
5 ***MITIGATION STRATEGIES.***—

6 (1) *IN GENERAL.*—*A drug that was approved be-*
7 *fore the effective date of this subtitle shall be deemed*
8 *to have an approved risk evaluation and mitigation*
9 *strategy under section 505(o) of the Federal Food,*
10 *Drug, and Cosmetic Act (as added by this subtitle) if*
11 *there are in effect on the effective date of this subtitle*
12 *restrictions on distribution or use—*

13 (A) *required under section 314.520 or sec-*
14 *tion 601.42 of title 21, Code of Federal Regula-*
15 *tions; or*

16 (B) *otherwise agreed to by the applicant*
17 *and the Secretary for such drug.*

18 (2) *RISK EVALUATION AND MITIGATION STRAT-*
19 *EGY.*—*The approved risk evaluation and mitigation*
20 *strategy deemed in effect for a drug under paragraph*
21 *(1) shall consist of the elements described in subpara-*
22 *graphs (A) and (B) of paragraph (3) of such section*
23 *505(o) and any other additional elements under para-*
24 *graphs (4), (5), and (6) in effect for such drug on the*
25 *effective date of this subtitle.*

1 (3) *NOTIFICATION.*—*Not later than 30 days after*
2 *the effective date of this subtitle, the Secretary shall*
3 *notify the applicant for each drug described in para-*
4 *graph (1)—*

5 (A) *that such drug is deemed to have an ap-*
6 *proved risk evaluation and mitigation strategy*
7 *pursuant to such paragraph; and*

8 (B) *of the date, which, unless a safety issue*
9 *with the drug arises, shall be no earlier than 6*
10 *months after the applicant is so notified, by*
11 *which the applicant shall submit to the Secretary*
12 *an assessment of such approved strategy under*
13 *paragraph (7)(B) of such section 505(o).*

14 (4) *ENFORCEMENT ONLY AFTER ASSESSMENT*
15 *AND REVIEW.*—*Neither the Secretary nor the Attorney*
16 *General may seek to enforce a requirement of a risk*
17 *evaluation and mitigation strategy deemed in effect*
18 *under paragraph (1) before the Secretary has com-*
19 *pleted review of, and acted on, the first assessment of*
20 *such strategy under such section 505(o).*

1 ***Subtitle B—Reagan-Udall Founda-***
 2 ***tion for the Food and Drug Ad-***
 3 ***ministration***

4 **SEC. 221. THE REAGAN-UDALL FOUNDATION FOR THE FOOD**
 5 **AND DRUG ADMINISTRATION.**

6 (a) *IN GENERAL.*—Chapter VII of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended
 8 by adding at the end the following:

9 ***“Subchapter I—Reagan-Udall Foundation for***
 10 ***the Food and Drug Administration***

11 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUN-**
 12 **DATION.**

13 “(a) *IN GENERAL.*—A nonprofit corporation to be
 14 known as the Reagan-Udall Foundation for the Food and
 15 Drug Administration (referred to in this subchapter as the
 16 ‘Foundation’) shall be established in accordance with this
 17 section. The Foundation shall be headed by an Executive
 18 Director, appointed by the members of the Board of Direc-
 19 tors under subsection (e). The Foundation shall not be an
 20 agency or instrumentality of the United States Government.

21 “(b) *PURPOSE OF FOUNDATION.*—The purpose of the
 22 Foundation is to advance the mission of the Food and Drug
 23 Administration to modernize medical, veterinary, food, food
 24 ingredient, and cosmetic product development, accelerate
 25 innovation, and enhance product safety.

1 “(c) *DUTIES OF THE FOUNDATION.*—*The Foundation*
2 *shall—*

3 “(1) *taking into consideration the Critical Path*
4 *reports and priorities published by the Food and*
5 *Drug Administration, identify unmet needs in the de-*
6 *velopment, manufacture, and evaluation of the safety*
7 *and effectiveness, including postapproval, of devices,*
8 *including diagnostics, biologics, and drugs, and the*
9 *safety of food, food ingredients, and cosmetics;*

10 “(2) *establish goals and priorities in order to*
11 *meet the unmet needs identified in paragraph (1);*

12 “(3) *in consultation with the Secretary, identify*
13 *existing and proposed Federal intramural and extra-*
14 *mural research and development programs relating to*
15 *the goals and priorities established under paragraph*
16 *(2), coordinate Foundation activities with such pro-*
17 *grams, and minimize Foundation duplication of ex-*
18 *isting efforts;*

19 “(4) *award grants to, or enter into contracts,*
20 *memoranda of understanding, or cooperative agree-*
21 *ments with, scientists and entities, which may include*
22 *the Food and Drug Administration, university con-*
23 *sortia, public-private partnerships, institutions of*
24 *higher education, entities described in section*
25 *501(c)(3) of the Internal Revenue Code (and exempt*

1 *from tax under section 501(a) of such Code), and in-*
2 *dustry, to efficiently and effectively advance the goals*
3 *and priorities established under paragraph (2);*

4 *“(5) recruit meeting participants and hold or*
5 *sponsor (in whole or in part) meetings as appropriate*
6 *to further the goals and priorities established under*
7 *paragraph (2);*

8 *“(6) release and publish information and data*
9 *and, to the extent practicable, license, distribute, and*
10 *release material, reagents, and techniques to maxi-*
11 *mize, promote, and coordinate the availability of such*
12 *material, reagents, and techniques for use by the Food*
13 *and Drug Administration, nonprofit organizations,*
14 *and academic and industrial researchers to further*
15 *the goals and priorities established under paragraph*
16 *(2);*

17 *“(7) ensure that—*

18 *“(A) action is taken as necessary to obtain*
19 *patents for inventions developed by the Founda-*
20 *tion or with funds from the Foundation;*

21 *“(B) action is taken as necessary to enable*
22 *the licensing of inventions developed by the*
23 *Foundation or with funds from the Foundation;*
24 *and*

1 “(C) *executed licenses, memoranda of under-*
2 *standing, material transfer agreements, con-*
3 *tracts, and other such instruments, promote, to*
4 *the maximum extent practicable, the broadest*
5 *conversion to commercial and noncommercial*
6 *applications of licensed and patented inventions*
7 *of the Foundation to further the goals and prior-*
8 *ities established under paragraph (2);*

9 “(8) *provide objective clinical and scientific in-*
10 *formation to the Food and Drug Administration and,*
11 *upon request, to other Federal agencies to assist in*
12 *agency determinations of how to ensure that regu-*
13 *latory policy accommodates scientific advances and*
14 *meets the agency’s public health mission;*

15 “(9) *conduct annual assessments of the unmet*
16 *needs identified in paragraph (1); and*

17 “(10) *carry out such other activities consistent*
18 *with the purposes of the Foundation as the Board de-*
19 *termines appropriate.*

20 “(d) *BOARD OF DIRECTORS.—*

21 “(1) *ESTABLISHMENT.—*

22 “(A) *IN GENERAL.—The Foundation shall*
23 *have a Board of Directors (referred to in this*
24 *subchapter as the ‘Board’), which shall be com-*
25 *posed of ex officio and appointed members in ac-*

1 cordance with this subsection. All appointed
2 members of the Board shall be voting members.

3 “(B) *EX OFFICIO MEMBERS.*—The *ex officio*
4 members of the Board shall be the following indi-
5 viduals or their designees:

6 “(i) *The Commissioner.*

7 “(ii) *The Director of the National In-*
8 *stitutes of Health.*

9 “(iii) *The Director of the Centers for*
10 *Disease Control and Prevention.*

11 “(iv) *The Director of the Agency for*
12 *Healthcare Research and Quality.*

13 “(C) *APPOINTED MEMBERS.*—

14 “(i) *IN GENERAL.*—The *ex officio mem-*
15 *bers of the Board under subparagraph (B)*
16 *shall, by majority vote, appoint to the*
17 *Board 12 individuals, from a list of can-*
18 *didates to be provided by the National*
19 *Academy of Sciences. Of such appointed*
20 *members—*

21 “(I) 4 shall be representatives of
22 the general pharmaceutical, device,
23 food, cosmetic, and biotechnology in-
24 dustries;

1 “(II) 3 shall be representatives of
2 academic research organizations;

3 “(III) 2 shall be representatives of
4 Government agencies, including the
5 Food and Drug Administration and
6 the National Institutes of Health;

7 “(IV) 2 shall be representatives of
8 patient or consumer advocacy organi-
9 zations; and

10 “(V) 1 shall be a representative of
11 health care providers.

12 “(ii) REQUIREMENT.—The *ex officio*
13 members shall ensure the Board membership
14 includes individuals with expertise in areas
15 including the sciences of developing, manu-
16 facturing, and evaluating the safety and ef-
17 fectiveness of devices, including diagnostics,
18 biologics, and drugs, and the safety of food,
19 food ingredients, and cosmetics.

20 “(D) INITIAL MEETING.—

21 “(i) IN GENERAL.—Not later than 30
22 days after the date of the enactment of the
23 Enhancing Drug Safety and Innovation Act
24 of 2007, the Secretary shall convene a meet-

1 *ing of the ex officio members of the Board*
2 *to—*

3 “(I) *incorporate the Foundation;*

4 *and*

5 “(II) *appoint the members of the*
6 *Board in accordance with subpara-*
7 *graph (C).*

8 “(ii) *SERVICE OF EX OFFICIO MEM-*
9 *BERS.—Upon the appointment of the mem-*
10 *bers of the Board under clause (i)(II), the*
11 *terms of service of the ex officio members of*
12 *the Board as members of the Board shall*
13 *terminate.*

14 “(iii) *CHAIR.—The ex officio members*
15 *of the Board under subparagraph (B) shall*
16 *designate an appointed member of the*
17 *Board to serve as the Chair of the Board.*

18 “(2) *DUTIES OF BOARD.—The Board shall—*

19 “(A) *establish bylaws for the Foundation*
20 *that—*

21 “(i) *are published in the Federal Reg-*
22 *ister and available for public comment;*

23 “(ii) *establish policies for the selection*
24 *of the officers, employees, agents, and con-*
25 *tractors of the Foundation;*

1 “(iii) establish policies, including eth-
2 ical standards, for the acceptance, sollicita-
3 tion, and disposition of donations and
4 grants to the Foundation and for the dis-
5 position of the assets of the Foundation, in-
6 cluding strict limits on the ability of donors
7 to include stipulations or restrictions on the
8 use of donated funds;

9 “(iv) establish policies that would sub-
10 ject all employees, fellows, and trainees of
11 the Foundation to the conflict of interest
12 standards under section 208 of title 18,
13 United States Code;

14 “(v) establish licensing, distribution,
15 and publication policies that support the
16 widest and least restrictive use by the public
17 of information and inventions developed by
18 the Foundation or with Foundation funds
19 to carry out the duties described in para-
20 graphs (6) and (7) of subsection (c), and
21 may include charging cost-based fees for
22 published material produced by the Founda-
23 tion;

24 “(vi) specify principles for the review
25 of proposals and awarding of grants and

1 *contracts that include peer review and that*
2 *are consistent with those of the Foundation*
3 *for the National Institutes of Health, to the*
4 *extent determined practicable and appro-*
5 *priate by the Board;*

6 *“(vii) specify a cap on administrative*
7 *expenses for recipients of a grant, contract,*
8 *or cooperative agreement from the Founda-*
9 *tion;*

10 *“(viii) establish policies for the execu-*
11 *tion of memoranda of understanding and*
12 *cooperative agreements between the Founda-*
13 *tion and other entities, including the Food*
14 *and Drug Administration;*

15 *“(ix) establish policies for funding*
16 *training fellowships, whether at the Foun-*
17 *dation, academic or scientific institutions,*
18 *or the Food and Drug Administration, for*
19 *scientists, doctors, and other professionals*
20 *who are not employees of regulated indus-*
21 *try, to foster greater understanding of and*
22 *expertise in new scientific tools, diagnostics,*
23 *manufacturing techniques, and potential*
24 *barriers to translating basic research into*
25 *clinical and regulatory practice;*

1 “(x) specify a process for annual
2 Board review of the operations of the Foun-
3 dation; and

4 “(xi) establish specific duties of the Ex-
5 ecutive Director;

6 “(B) prioritize and provide overall direc-
7 tion to the activities of the Foundation;

8 “(C) evaluate the performance of the Execu-
9 tive Director; and

10 “(D) carry out any other necessary activi-
11 ties regarding the functioning of the Foundation.

12 “(3) TERMS AND VACANCIES.—

13 “(A) TERM.—The term of office of each
14 member of the Board appointed under para-
15 graph (1)(C) shall be 4 years, except that the
16 terms of offices for the initial appointed members
17 of the Board shall expire on a staggered basis as
18 determined by the *ex officio* members.

19 “(B) VACANCY.—Any vacancy in the mem-
20 bership of the Board—

21 “(i) shall not affect the power of the re-
22 maining members to execute the duties of
23 the Board; and

1 “(ii) shall be filled by appointment by
2 the appointed members described in para-
3 graph (1)(C) by majority vote.

4 “(C) *PARTIAL TERM.*—If a member of the
5 Board does not serve the full term applicable
6 under subparagraph (A), the individual ap-
7 pointed under subparagraph (B) to fill the re-
8 sulting vacancy shall be appointed for the re-
9 mainder of the term of the predecessor of the in-
10 dividual.

11 “(D) *SERVING PAST TERM.*—A member of
12 the Board may continue to serve after the expi-
13 ration of the term of the member until a suc-
14 cessor is appointed.

15 “(4) *COMPENSATION.*—Members of the Board
16 may not receive compensation for service on the
17 Board. Such members may be reimbursed for travel,
18 subsistence, and other necessary expenses incurred in
19 carrying out the duties of the Board, as set forth in
20 the bylaws issued by the Board.

21 “(e) *INCORPORATION.*—The *ex officio* members of the
22 Board shall serve as incorporators and shall take whatever
23 actions necessary to incorporate the Foundation.

24 “(f) *NONPROFIT STATUS.*—The Foundation shall be
25 considered to be a corporation under section 501(c) of the

1 *Internal Revenue Code of 1986, and shall be subject to the*
 2 *provisions of such section.*

3 “(g) *EXECUTIVE DIRECTOR.*—

4 “(1) *IN GENERAL.*—*The Board shall appoint an*
 5 *Executive Director who shall serve at the pleasure of*
 6 *the Board. The Executive Director shall be responsible*
 7 *for the day-to-day operations of the Foundation and*
 8 *shall have such specific duties and responsibilities as*
 9 *the Board shall prescribe.*

10 “(2) *COMPENSATION.*—*The compensation of the*
 11 *Executive Director shall be fixed by the Board but*
 12 *shall not be greater than the compensation of the*
 13 *Commissioner.*

14 “(h) *ADMINISTRATIVE POWERS.*—*In carrying out this*
 15 *subchapter, the Board, acting through the Executive Direc-*
 16 *tor, may—*

17 “(1) *adopt, alter, and use a corporate seal, which*
 18 *shall be judicially noticed;*

19 “(2) *hire, promote, compensate, and discharge 1*
 20 *or more officers, employees, and agents, as may be*
 21 *necessary, and define their duties;*

22 “(3) *prescribe the manner in which—*

23 “(A) *real or personal property of the Foun-*
 24 *ation is acquired, held, and transferred;*

1 “(B) general operations of the Foundation
2 are to be conducted; and

3 “(C) the privileges granted to the Board by
4 law are exercised and enjoyed;

5 “(4) with the consent of the applicable executive
6 department or independent agency, use the informa-
7 tion, services, and facilities of such department or
8 agencies in carrying out this section;

9 “(5) enter into contracts with public and private
10 organizations for the writing, editing, printing, and
11 publishing of books and other material;

12 “(6) hold, administer, invest, and spend any
13 gift, devise, or bequest of real or personal property
14 made to the Foundation under subsection (i);

15 “(7) enter into such other contracts, leases, coop-
16 erative agreements, and other transactions as the
17 Board considers appropriate to conduct the activities
18 of the Foundation;

19 “(8) modify or consent to the modification of
20 any contract or agreement to which it is a party or
21 in which it has an interest under this subchapter;

22 “(9) take such action as may be necessary to ob-
23 tain patents and licenses for devices and procedures
24 developed by the Foundation and its employees;

1 “(10) *sue and be sued in its corporate name, and*
2 *complain and defend in courts of competent jurisdic-*
3 *tion;*

4 “(11) *appoint other groups of advisors as may be*
5 *determined necessary to carry out the functions of the*
6 *Foundation; and*

7 “(12) *exercise other powers as set forth in this*
8 *section, and such other incidental powers as are nec-*
9 *essary to carry out its powers, duties, and functions*
10 *in accordance with this subchapter.*

11 “(i) *ACCEPTANCE OF FUNDS FROM OTHER*
12 *SOURCES.—The Executive Director may solicit and accept*
13 *on behalf of the Foundation, any funds, gifts, grants, de-*
14 *vises, or bequests of real or personal property made to the*
15 *Foundation, including from private entities, for the pur-*
16 *poses of carrying out the duties of the Foundation.*

17 “(j) *SERVICE OF FEDERAL EMPLOYEES.—Federal*
18 *Government employees may serve on committees advisory*
19 *to the Foundation and otherwise cooperate with and assist*
20 *the Foundation in carrying out its functions, so long as*
21 *such employees do not direct or control Foundation activi-*
22 *ties.*

23 “(k) *DETAIL OF GOVERNMENT EMPLOYEES; FELLOW-*
24 *SHIPS.—*

1 “(1) *DETAIL FROM FEDERAL AGENCIES.*—*Fed-*
2 *eral Government employees may be detailed from Fed-*
3 *eral agencies with or without reimbursement to those*
4 *agencies to the Foundation at any time, and such de-*
5 *tail shall be without interruption or loss of civil serv-*
6 *ice status or privilege. Each such employee shall abide*
7 *by the statutory, regulatory, ethical, and procedural*
8 *standards applicable to the employees of the agency*
9 *from which such employee is detailed and those of the*
10 *Foundation.*

11 “(2) *VOLUNTARY SERVICE; ACCEPTANCE OF FED-*
12 *ERAL EMPLOYEES.*—

13 “(A) *FOUNDATION.*—*The Executive Director*
14 *of the Foundation may accept the services of em-*
15 *ployees detailed from Federal agencies with or*
16 *without reimbursement to those agencies.*

17 “(B) *FOOD AND DRUG ADMINISTRATION.*—
18 *The Commissioner may accept the uncompen-*
19 *sated services of Foundation fellows or trainees.*
20 *Such services shall be considered to be under-*
21 *taking an activity under contract with the Sec-*
22 *retary as described in section 708.*

23 “(l) *ANNUAL REPORTS.*—

24 “(1) *REPORTS TO FOUNDATION.*—*Any recipient*
25 *of a grant, contract, fellowship, memorandum of un-*

1 *derstanding, or cooperative agreement from the Foun-*
2 *dation under this section shall submit to the Founda-*
3 *tion a report on an annual basis for the duration of*
4 *such grant, contract, fellowship, memorandum of un-*
5 *derstanding, or cooperative agreement, that describes*
6 *the activities carried out under such grant, contract,*
7 *fellowship, memorandum of understanding, or cooper-*
8 *ative agreement.*

9 “(2) *REPORT TO CONGRESS AND THE FDA.—Be-*
10 *ginning with fiscal year 2009, the Executive Director*
11 *shall submit to Congress and the Commissioner an*
12 *annual report that—*

13 “(A) *describes the activities of the Founda-*
14 *tion and the progress of the Foundation in fur-*
15 *thering the goals and priorities established under*
16 *subsection (c)(2), including the practical impact*
17 *of the Foundation on regulated product develop-*
18 *ment;*

19 “(B) *provides a specific accounting of the*
20 *source and use of all funds used by the Founda-*
21 *tion to carry out such activities; and*

22 “(C) *provides information on how the re-*
23 *sults of Foundation activities could be incor-*
24 *porated into the regulatory and product review*
25 *activities of the Food and Drug Administration.*

1 *under section 770(l)(2) and by other recipients of grants,*
2 *contracts, memoranda of understanding, or cooperative*
3 *agreements into regulatory and product review activities of*
4 *the Food and Drug Administration.*

5 “(c) *EXTRAMURAL GRANTS.*—*The provisions of this*
6 *subchapter shall have no effect on any grant, contract,*
7 *memorandum of understanding, or cooperative agreement*
8 *between the Food and Drug Administration and any other*
9 *entity entered into before, on, or after the date of enactment*
10 *of the Enhancing Drug Safety and Innovation Act of*
11 *2007.”.*

12 (c) *CONFORMING AMENDMENT.*—*Section 742(b) of the*
13 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b))*
14 *is amended by adding at the end the following: “Any such*
15 *fellowships and training programs under this section or*
16 *under section 770(d)(2)(A)(ix) may include provision by*
17 *such scientists and physicians of services on a voluntary*
18 *and uncompensated basis, as the Secretary determines ap-*
19 *propriate. Such scientists and physicians shall be subject*
20 *to all legal and ethical requirements otherwise applicable*
21 *to officers or employees of the Department of Health and*
22 *Human Services.”.*

1 **SEC. 222. OFFICE OF THE CHIEF SCIENTIST.**

2 *Chapter IX of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 391 et seq.) is amended by adding at the*
4 *end the following:*

5 **“SEC. 910. OFFICE OF THE CHIEF SCIENTIST.**

6 *“(a) ESTABLISHMENT; APPOINTMENT.—The Secretary*
7 *shall establish within the Office of the Commissioner an of-*
8 *fice to be known as the Office of the Chief Scientist. The*
9 *Secretary shall appoint a Chief Scientist to lead such Of-*
10 *fice.*

11 *“(b) DUTIES OF THE OFFICE.—The Office of the Chief*
12 *Scientist shall—*

13 *“(1) oversee, coordinate, and ensure quality and*
14 *regulatory focus of the intramural research programs*
15 *of the Food and Drug Administration;*

16 *“(2) track and, to the extent necessary, coordi-*
17 *nate intramural research awards made by each center*
18 *of the Administration or science-based office within*
19 *the Office of the Commissioner, and ensure that there*
20 *is no duplication of research efforts supported by the*
21 *Reagan-Udall Foundation for the Food and Drug Ad-*
22 *ministration;*

23 *“(3) develop and advocate for a budget to sup-*
24 *port intramural research;*

25 *“(4) develop a peer review process by which in-*
26 *tramural research can be evaluated; and*

1 “(5) identify and solicit intramural research
2 proposals from across the Food and Drug Adminis-
3 tration through an advisory board composed of em-
4 ployees of the Administration that shall include—

5 “(A) representatives of each of the centers
6 and the science-based offices within the Office of
7 the Commissioner; and

8 “(B) experts on trial design, epidemiology,
9 demographics, pharmacovigilance, basic science,
10 and public health.”.

11 ***Subtitle C—Clinical Trials***

12 ***SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA***

13 ***BANK.***

14 (a) *IN GENERAL.*—Section 402 of the Public Health
15 Service Act (42 U.S.C. 282) is amended by—

16 (1) redesignating subsections (j) and (k) as sub-
17 sections (k) and (l), respectively; and

18 (2) inserting after subsection (i) the following:

19 “(j) *EXPANDED CLINICAL TRIAL REGISTRY DATA*
20 *BANK.*—

21 “(1) *DEFINITIONS; REQUIREMENT.*—

22 “(A) *DEFINITIONS.*—In this subsection:

23 “(i) *APPLICABLE DEVICE CLINICAL*
24 *TRIAL.*—The term ‘applicable device clinical
25 trial’ means—

1 “(I) a prospective study of health
2 outcomes comparing an intervention
3 against a control in human subjects
4 intended to support an application
5 under section 515 or 520(m), or a re-
6 port under section 510(k), of the Fed-
7 eral Food, Drug, and Cosmetic Act
8 (other than a limited study to gather
9 essential information used to refine the
10 device or design a pivotal trial and
11 that is not intended to determine safety
12 and effectiveness of a device); and

13 “(II) a pediatric postmarket sur-
14 veillance as required under section 522
15 of the Federal Food, Drug, and Cos-
16 metic Act.

17 “(ii) *APPLICABLE DRUG CLINICAL*
18 *TRIAL.*—

19 “(I) *IN GENERAL.*—The term ‘ap-
20 plicable drug clinical trial’ means a
21 controlled clinical investigation, other
22 than a phase I clinical investigation,
23 of a product subject to section 505 of
24 the Federal Food, Drug, and Cosmetic
25 Act or to section 351 of this Act.

1 “(II) *CLINICAL INVESTIGATION*.—
2 *For purposes of subclause (I), the term*
3 *‘clinical investigation’ has the meaning*
4 *given that term in section 312.3 of title*
5 *21, Code of Federal Regulations.*

6 “(III) *PHASE I*.—*The term ‘phase*
7 *I’ has the meaning given that term in*
8 *section 312.21 of title 21, Code of Fed-*
9 *eral Regulations.*

10 “(iii) *CLINICAL TRIAL INFORMATION*.—
11 *The term ‘clinical trial information’ means*
12 *those data elements that are necessary to*
13 *complete an entry in the clinical trial reg-*
14 *istry data bank under paragraph (2).*

15 “(iv) *COMPLETION DATE*.—*The term*
16 *‘completion date’ means, with respect to an*
17 *applicable drug clinical trial or an applica-*
18 *ble device clinical trial, the date on which*
19 *the last patient enrolled in the clinical trial*
20 *has completed his or her last medical visit*
21 *of the clinical trial, whether the clinical*
22 *trial concluded according to the prespecified*
23 *protocol plan or was terminated.*

1 “(v) *DEVICE*.—The term ‘device’ means
2 a device as defined in section 201(h) of the
3 *Federal Food, Drug, and Cosmetic Act*.

4 “(vi) *DRUG*.—The term ‘drug’ means a
5 drug as defined in section 201(g) of the *Fed-*
6 *eral Food, Drug, and Cosmetic Act* or a bio-
7 logical product as defined in section 351 of
8 *this Act*.

9 “(vii) *RESPONSIBLE PARTY*.—The term
10 ‘responsible party’, with respect to a clin-
11 ical trial of a drug or device, means—

12 “(I) the sponsor of the clinical
13 trial (as defined in section 50.3 of title
14 21, *Code of Federal Regulations* (or
15 any successor regulations)) or the prin-
16 cipal investigator of such clinical trial
17 if so designated by such sponsor; or

18 “(II) if no sponsor exists, the
19 grantee, contractor, or awardee for a
20 trial funded by a Federal agency or the
21 principal investigator of such clinical
22 trial if so designated by such grantee,
23 contractor, or awardee.

24 “(B) *REQUIREMENT*.—The Secretary shall
25 develop a mechanism by which—

1 “(i) the responsible party for each ap-
2 plicable drug clinical trial and applicable
3 device clinical trial shall submit the iden-
4 tity and contact information of such respon-
5 sible party to the Secretary at the time of
6 submission of clinical trial information
7 under paragraph (2); and

8 “(ii) other Federal agencies may iden-
9 tify the responsible party for an applicable
10 drug clinical trial or applicable device clin-
11 ical trial.

12 “(2) *EXPANSION OF CLINICAL TRIAL REGISTRY*
13 *DATA BANK WITH RESPECT TO CLINICAL TRIAL INFOR-*
14 *MATION.—*

15 “(A) *IN GENERAL.—*

16 “(i) *EXPANSION OF DATA BANK.—To*
17 *enhance patient enrollment and provide a*
18 *mechanism to track subsequent progress of*
19 *clinical trials, the Secretary, acting through*
20 *the Director of NIH, shall expand, in ac-*
21 *cordance with this subsection, the clinical*
22 *trials registry of the data bank described*
23 *under subsection (i)(3)(A) (referred to in*
24 *this subsection as the ‘registry data bank’).*
25 *The Director of NIH shall ensure that the*

1 registry data bank is made publicly avail-
2 able through the Internet.

3 “(ii) *CONTENT.*—Not later than 18
4 months after the date of enactment of the
5 *Enhancing Drug Safety and Innovation Act*
6 *of 2007*, and after notice and comment, the
7 *Secretary shall promulgate regulations to*
8 *expand the registry data bank to require the*
9 *submission to the registry data bank of clin-*
10 *ical trial information for applicable drug*
11 *clinical trials and applicable device clinical*
12 *trials that—*

13 “(I) *conforms to the International*
14 *Clinical Trials Registry Platform trial*
15 *registration data set of the World*
16 *Health Organization;*

17 “(II) *includes the city, State, and*
18 *zip code for each clinical trial location,*
19 *or a toll-free number through which*
20 *such location information may be*
21 *accessed;*

22 “(III) *if the drug is not approved*
23 *under section 505 of the Federal Food,*
24 *Drug, and Cosmetic Act or licensed*
25 *under section 351 of this Act, specifies*

1 *whether or not there is expanded access*
2 *to the drug under section 561 of the*
3 *Federal Food, Drug, and Cosmetic Act*
4 *for those who do not qualify for enroll-*
5 *ment in the clinical trial and how to*
6 *obtain information about such access;*

7 “(IV) *requires the inclusion of*
8 *such other data elements to the registry*
9 *data bank as appropriate; and*

10 “(V) *becomes effective 90 days*
11 *after issuance of the final rule.*

12 “(B) *FORMAT AND STRUCTURE.—*

13 “(i) *SEARCHABLE CATEGORIES.—The*
14 *Director of NIH shall ensure that the public*
15 *may search the entries in the registry data*
16 *bank by 1 or more of the following criteria:*

17 “(I) *The disease or condition*
18 *being studied in the clinical trial,*
19 *using Medical Subject Headers*
20 *(MeSH) descriptors.*

21 “(II) *The treatment being studied*
22 *in the clinical trial.*

23 “(III) *The location of the clinical*
24 *trial.*

1 “(IV) *The age group studied in*
2 *the clinical trial, including pediatric*
3 *subpopulations.*

4 “(V) *The study phase of the clin-*
5 *ical trial.*

6 “(VI) *The source of support for*
7 *the clinical trial, which may be the*
8 *National Institutes of Health or other*
9 *Federal agency, a private industry*
10 *source, or a university or other organi-*
11 *zation.*

12 “(VII) *The recruitment status of*
13 *the clinical trial.*

14 “(VIII) *The National Clinical*
15 *Trial number or other study identifica-*
16 *tion for the clinical trial.*

17 “(ii) *FORMAT.—The Director of the*
18 *NIH shall ensure that the registry data*
19 *bank is easily used by the public, and that*
20 *entries are easily compared.*

21 “(C) *DATA SUBMISSION.—The responsible*
22 *party for an applicable drug clinical trial shall*
23 *submit to the Director of NIH for inclusion in*
24 *the registry data bank the clinical trial informa-*
25 *tion described in subparagraph (A)(ii).*

1 “(D) *TRUTHFUL CLINICAL TRIAL INFORMA-*
2 *TION.*—

3 “(i) *IN GENERAL.*—*The clinical trial*
4 *information submitted by a responsible*
5 *party under this paragraph shall not be*
6 *false or misleading in any particular.*

7 “(ii) *EFFECT.*—*Clause (i) shall not*
8 *have the effect of requiring clinical trial in-*
9 *formation with respect to an applicable*
10 *drug clinical trial or an applicable device*
11 *clinical trial to include information from*
12 *any source other than such clinical trial in-*
13 *volved.*

14 “(E) *CHANGES IN CLINICAL TRIAL STA-*
15 *TUS.*—

16 “(i) *ENROLLMENT.*—*The responsible*
17 *party for an applicable drug clinical trial*
18 *or an applicable device clinical trial shall*
19 *update the enrollment status not later than*
20 *30 days after the enrollment status of such*
21 *clinical trial changes.*

22 “(ii) *COMPLETION.*—*The responsible*
23 *party for an applicable drug clinical trial*
24 *or applicable device clinical trial shall re-*
25 *port to the Director of NIH that such clin-*

1 ical trial is complete not later than 30 days
2 after the completion date of the clinical
3 trial.

4 “(F) *TIMING OF SUBMISSION.*—The clinical
5 trial information for an applicable drug clinical
6 trial or an applicable device clinical trial re-
7 quired to be submitted under this paragraph
8 shall be submitted not later than 21 days after
9 the first patient is enrolled in such clinical trial.

10 “(G) *POSTING OF DATA.*—

11 “(i) *APPLICABLE DRUG CLINICAL*
12 *TRIAL.*—The Director of NIH shall ensure
13 that clinical trial information for an appli-
14 cable drug clinical trial submitted in ac-
15 cordance with this paragraph is posted pub-
16 licly within 30 days of such submission.

17 “(ii) *APPLICABLE DEVICE CLINICAL*
18 *TRIAL.*—The Director of NIH shall ensure
19 that clinical trial information for an appli-
20 cable device clinical trial submitted in ac-
21 cordance with this paragraph is posted pub-
22 licly within 30 days of clearance under sec-
23 tion 510(k) of the Federal Food, Drug, and
24 Cosmetic Act, or approval under section 515
25 or section 520(m) of such Act, as applicable.

1 “(H) *VOLUNTARY SUBMISSIONS.*—A respon-
2 sible party for a clinical trial that is not an ap-
3 plicable drug clinical trial or an applicable de-
4 vice clinical trial may submit clinical trial in-
5 formation to the registry data bank in accord-
6 ance with this subsection.

7 “(3) *EXPANSION OF REGISTRY DATA BANK TO IN-*
8 *CLUDE RESULTS OF CLINICAL TRIALS.*—

9 “(A) *LINKING REGISTRY DATA BANK TO EX-*
10 *ISTING RESULTS.*—

11 “(i) *IN GENERAL.*—Beginning not later
12 than 90 days after the date of enactment of
13 the *Enhancing Drug Safety and Innovation*
14 *Act of 2007*, for those clinical trials that
15 form the primary basis of an efficacy claim
16 or are conducted after the drug involved is
17 approved or after the device involved is
18 cleared or approved, the Secretary shall en-
19 sure that the registry data bank includes
20 links to results information for such clinical
21 trial—

22 “(I) not earlier than 30 days after
23 the date of the approval of the drug in-
24 volved or clearance or approval of the
25 device involved; or

1 “(II) not later than 30 days after
2 such information becomes publicly
3 available, as applicable.

4 “(i) *REQUIRED INFORMATION.*—

5 “(I) *FDA INFORMATION.*—*The*
6 *Secretary shall ensure that the registry*
7 *data bank includes links to the fol-*
8 *lowing information:*

9 “(aa) *If an advisory com-*
10 *mittee considered at a meeting an*
11 *applicable drug clinical trial or*
12 *an applicable device clinical trial,*
13 *any posted Food and Drug Ad-*
14 *ministration summary document*
15 *regarding such applicable drug*
16 *clinical trial or applicable clin-*
17 *ical device trial.*

18 “(bb) *If an applicable drug*
19 *clinical trial was conducted under*
20 *section 505A or 505B of the Fed-*
21 *eral Food, Drug, and Cosmetic*
22 *Act, a link to the posted Food and*
23 *Drug Administration assessment*
24 *of the results of such trial.*

1 “(cc) *Food and Drug Admin-*
2 *istration public health advisories*
3 *regarding the drug or device that*
4 *is the subject of the applicable*
5 *drug clinical trial or applicable*
6 *device clinical trial, respectively,*
7 *if any.*

8 “(dd) *For an applicable drug*
9 *clinical trial, the Food and Drug*
10 *Administration action package for*
11 *approval document required*
12 *under section 505(l)(2) of the*
13 *Food Drug and Cosmetic Act.*

14 “(ee) *For an applicable de-*
15 *vice clinical trial, in the case of a*
16 *premarket application, the de-*
17 *tailed summary of information re-*
18 *specting the safety and effective-*
19 *ness of the device required under*
20 *section 520(h)(1) of the Federal*
21 *Food, Drug, and Cosmetic Act, or,*
22 *in the case of a report under sec-*
23 *tion 510(k) of such Act, the sec-*
24 *tion 510(k) summary of the safety*
25 *and effectiveness data required*

1 *under section 807.95(d) of title*
2 *21, Code of Federal Regulations*
3 *(or any successor regulations).*

4 *“(II) NIH INFORMATION.—The*
5 *Secretary shall ensure that the registry*
6 *data bank includes links to the fol-*
7 *lowing information:*

8 *“(aa) Medline citations to*
9 *any publications regarding each*
10 *applicable drug clinical trial and*
11 *applicable device clinical trial.*

12 *“(bb) The entry for the drug*
13 *that is the subject of an applicable*
14 *drug clinical trial in the National*
15 *Library of Medicine database of*
16 *structured product labels, if avail-*
17 *able.*

18 *“(iii) RESULTS FOR EXISTING DATA*
19 *BANK ENTRIES.—The Secretary may in-*
20 *clude the links described in clause (i) for*
21 *data bank entries for clinical trials sub-*
22 *mitted to the data bank prior to enactment*
23 *of the Enhancing Drug Safety and Innova-*
24 *tion Act of 2007, as available.*

1 “(B) *FEASIBILITY STUDY.*—*The Director of*
2 *NIH shall—*

3 “(i) *conduct a study to determine the*
4 *best, validated methods of making the re-*
5 *sults of clinical trials publicly available*
6 *after the approval of the drug that is the*
7 *subject of an applicable drug clinical trial;*
8 *and*

9 “(ii) *not later than 18 months after*
10 *initiating such study, submit to the Sec-*
11 *retary any findings and recommendations*
12 *of such study.*

13 “(C) *NEGOTIATED RULEMAKING.*—

14 “(i) *IN GENERAL.*—*The Secretary shall*
15 *establish a negotiated rulemaking process*
16 *pursuant to subchapter IV of chapter 5 of*
17 *title 5, United States Code, to determine, for*
18 *applicable drug clinical trials—*

19 “(I) *how to ensure quality and*
20 *validate methods of expanding the reg-*
21 *istry data bank to include clinical*
22 *trial results information for trials not*
23 *within the scope of this Act;*

24 “(II) *the clinical trials of which*
25 *the results information is appropriate*

1 for adding to the expanded registry
2 data bank; and

3 “(III) the appropriate timing of
4 the posting of such results information.

5 “(ii) *TIME REQUIREMENT.*—The proc-
6 ess described in paragraph (1) shall be con-
7 ducted in a timely manner to ensure that—

8 “(I) any recommendation for a
9 proposed rule—

10 “(aa) is provided to the Sec-
11 retary not later than 21 months
12 after the date of the enactment of
13 the *Enhancing Drug Safety and*
14 *Innovation Act of 2007*; and

15 “(bb) includes an assessment
16 of the benefits and costs of the rec-
17 ommendation; and

18 “(II) a final rule is promulgated
19 not later than 30 months after the date
20 of the enactment of the *Enhancing*
21 *Drug Safety and Innovation Act of*
22 2007, taking into account the rec-
23 ommendations under subclause (I) and
24 the results of the feasibility study con-
25 ducted under subparagraph (B).

1 “(iii) *REPRESENTATION ON NEGOTIATED RULEMAKING COMMITTEE.*—*The negotiated rulemaking committee established by the Secretary pursuant to clause (i) shall include members representing—*

2 “(I) *the Food and Drug Administration;*

3 “(II) *the National Institutes of Health;*

4 “(III) *other Federal agencies as the Secretary determines appropriate;*

5 “(IV) *patient advocacy and health care provider groups;*

6 “(V) *the pharmaceutical industry;*

7 “(VI) *contract clinical research organizations;*

8 “(VII) *the International Committee of Medical Journal Editors; and*

9 “(VIII) *other interested parties, including experts in privacy protection, pediatrics, health information technology, health literacy, communication, clinical trial design and implementation, and health care ethics.*

1 “(iv) *CONTENT OF REGULATIONS.*—*The*
2 *regulations promulgated pursuant to clause*
3 *(i) shall establish—*

4 “(I) *procedures to determine*
5 *which clinical trials results informa-*
6 *tion data elements shall be included in*
7 *the registry data bank, taking into ac-*
8 *count the needs of different populations*
9 *of users of the registry data bank;*

10 “(II) *a standard format for the*
11 *submission of clinical trials results to*
12 *the registry data bank;*

13 “(III) *a standard procedure for*
14 *the submission of clinical trial results*
15 *information, including the timing of*
16 *submission and the timing of posting*
17 *of results information, to the registry*
18 *data bank, taking into account the pos-*
19 *sible impacts on publication of manu-*
20 *scripts based on the clinical trial;*

21 “(IV) *a standard procedure for*
22 *the verification of clinical trial results*
23 *information, including ensuring that*
24 *free text data elements are non-pro-*
25 *motional; and*

1 “(V) *an implementation plan for*
2 *the prompt inclusion of clinical trials*
3 *results information in the registry data*
4 *bank.*

5 “(D) *CONSIDERATION OF WORLD HEALTH*
6 *ORGANIZATION DATA SET.—The Secretary shall*
7 *consider the status of the consensus data elements*
8 *set for reporting clinical trial results of the*
9 *World Health Organization when promulgating*
10 *the regulations under subparagraph (C).*

11 “(E) *TRUTHFUL CLINICAL TRIAL INFORMA-*
12 *TION.—*

13 “(i) *IN GENERAL.—The clinical trial*
14 *information submitted by a responsible*
15 *party under this paragraph shall not be*
16 *false or misleading in any particular.*

17 “(ii) *EFFECT.—Clause (i) shall not*
18 *have the effect of requiring clinical trial in-*
19 *formation with respect to an applicable*
20 *drug clinical trial or an applicable device*
21 *clinical trial to include information from*
22 *any source other than such clinical trial in-*
23 *volved.*

24 “(F) *WAIVERS REGARDING CERTAIN CLIN-*
25 *ICAL TRIAL RESULTS.—The Secretary may waive*

1 *any applicable requirements of this paragraph*
2 *for an applicable drug clinical trial or an appli-*
3 *cable device clinical trial, upon a written request*
4 *from the responsible person, if the Secretary de-*
5 *termines that extraordinary circumstances jus-*
6 *tify the waiver and that providing the waiver is*
7 *in the public interest, consistent with the protec-*
8 *tion of public health, or in the interest of na-*
9 *tional security. Not later than 30 days after any*
10 *part of a waiver is granted, the Secretary shall*
11 *notify, in writing, the appropriate committees of*
12 *Congress of the waiver and provide an expla-*
13 *nation for why the waiver was granted.*

14 “(4) *COORDINATION AND COMPLIANCE.*—

15 “(A) *CLINICAL TRIALS SUPPORTED BY*
16 *GRANTS FROM FEDERAL AGENCIES.*—

17 “(i) *IN GENERAL.*—*No Federal agency*
18 *may release funds under a research grant to*
19 *an awardee who has not complied with*
20 *paragraph (2) for any applicable drug clin-*
21 *ical trial or applicable device clinical trial*
22 *for which such person is the responsible*
23 *party.*

24 “(ii) *GRANTS FROM CERTAIN FEDERAL*
25 *AGENCIES.*—*If an applicable drug clinical*

1 *trial or applicable device clinical trial is*
2 *funded in whole or in part by a grant from*
3 *the Food and Drug Administration, Na-*
4 *tional Institutes of Health, the Agency for*
5 *Healthcare Research and Quality, or the*
6 *Department of Veterans Affairs, any grant*
7 *or progress report forms required under*
8 *such grant shall include a certification that*
9 *the responsible party has made all required*
10 *submissions to the Director of NIH under*
11 *paragraph (2).*

12 “(iii) *VERIFICATION BY FEDERAL*
13 *AGENCIES.—The heads of the agencies re-*
14 *ferred to in clause (ii), as applicable, shall*
15 *verify that the clinical trial information for*
16 *each applicable drug clinical trial or appli-*
17 *cable device clinical trial for which a grant-*
18 *ee is the responsible party has been sub-*
19 *mitted under paragraph (2) before releasing*
20 *any remaining funding for a grant or fund-*
21 *ing for a future grant to such grantee.*

22 “(iv) *NOTICE AND OPPORTUNITY TO*
23 *REMEDY.—If the head of an agency referred*
24 *to in clause (ii), as applicable, verifies that*
25 *a grantee has not submitted clinical trial*

1 *information as described in clause (iii),*
2 *such agency head shall provide notice to*
3 *such grantee of such non-compliance and*
4 *allow such grantee 30 days to correct such*
5 *non-compliance and submit the required*
6 *clinical trial information.*

7 “(v) *CONSULTATION WITH OTHER FED-*
8 *ERAL AGENCIES.—The Secretary shall—*

9 *“(I) consult with other agencies*
10 *that conduct research involving human*
11 *subjects in accordance with any section*
12 *of part 46 of title 45, Code of Federal*
13 *Regulations (or any successor regula-*
14 *tions), to determine if any such re-*
15 *search is an applicable drug clinical*
16 *trial or an applicable device clinical*
17 *trial under paragraph (1); and*

18 *“(II) develop with such agencies*
19 *procedures comparable to those de-*
20 *scribed in clauses (ii), (iii), and (iv) to*
21 *ensure that clinical trial information*
22 *for such applicable drug clinical trials*
23 *and applicable device clinical trial is*
24 *submitted under paragraph (2).*

1 “(B) *CERTIFICATION TO ACCOMPANY DRUG,*
2 *BIOLOGICAL PRODUCT, AND DEVICE SUBMIS-*
3 *SIONS.—At the time of submission of an applica-*
4 *tion under section 505 of the Federal Food,*
5 *Drug, and Cosmetic Act, section 515 of such Act,*
6 *section 520(m) of such Act, or section 351 of this*
7 *Act, or submission of a report under section*
8 *510(k) of such Act, such application or submis-*
9 *sion shall be accompanied by a certification that*
10 *all applicable requirements of this subsection*
11 *have been met. Where available, such certifi-*
12 *cation shall include the appropriate National*
13 *Clinical Trial control numbers.*

14 “(C) *VERIFICATION OF SUBMISSION PRIOR*
15 *TO POSTING.—In the case of clinical trial infor-*
16 *mation that is submitted under paragraph (2),*
17 *but is not made publicly available pending regu-*
18 *latory approval or clearance, as applicable, the*
19 *Director of NIH shall respond to inquiries from*
20 *other Federal agencies and peer-reviewed sci-*
21 *entific journals to confirm that such clinical*
22 *trial information has been submitted but has not*
23 *yet been posted.*

24 “(5) *LIMITATION ON DISCLOSURE OF CLINICAL*
25 *TRIAL INFORMATION.—*

1 “(A) *IN GENERAL.*—*Nothing in this sub-*
2 *section (or under section 552 of title 5, United*
3 *States Code) shall require the Secretary to pub-*
4 *licly disclose, from any record or source other*
5 *than the registry data bank expanded under this*
6 *subsection, information described in subpara-*
7 *graph (B).*

8 “(B) *INFORMATION DESCRIBED.*—*Informa-*
9 *tion described in this subparagraph is—*

10 “(i) *information submitted to the Di-*
11 *rector of NIH under this subsection, or in-*
12 *formation of the same general nature as (or*
13 *integrally associated with) the information*
14 *so submitted; and*

15 “(ii) *not otherwise publicly available,*
16 *including because it is protected from dis-*
17 *closure under section 552 of title 5, United*
18 *States Code.*

19 “(6) *AUTHORIZATION OF APPROPRIATIONS.*—
20 *There are authorized to be appropriated to carry out*
21 *this subsection \$10,000,000 for each fiscal year.”.*

22 (b) *CONFORMING AMENDMENTS.*—

23 (1) *PROHIBITED ACTS.*—*Section 301 of the Fed-*
24 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 331)*
25 *is amended by adding at the end the following:*

1 “(jj)(1) *The failure to submit the certification required*
 2 *by section 402(j)(4)(B) of the Public Health Service Act,*
 3 *or knowingly submitting a false certification under such*
 4 *section.*

5 “(2) *The submission of clinical trial information*
 6 *under subsection (i) or (j) of section 402 of the Public*
 7 *Health Service Act that is promotional or false or mis-*
 8 *leading in any particular under paragraph (2) or (3) of*
 9 *such subsection (j).”.*

10 (2) *CIVIL MONEY PENALTIES.—Section 303(f) of*
 11 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 12 *333(f)), as amended by section 203, is further amend-*
 13 *ed by—*

14 (A) *redesignating paragraphs (4), (5), and*
 15 (i) *as paragraphs (5), (6), and (7), respectively;*

16 (B) *inserting after paragraph (3) the fol-*
 17 *lowing:*

18 “(d) *Any person who violates section 301(jj) shall be*
 19 *subject to a civil monetary penalty of not more than*
 20 *\$10,000 for the first violation, and not more than \$20,000*
 21 *for each subsequent violation.”;*

22 (C) *in paragraph (2)(C), by striking “para-*
 23 *graph (4)(A)” and inserting “paragraph*
 24 *(5)(A)”;*

1 (D) in paragraph (5), as so redesignated, by
2 striking “paragraph (1), (2), or (3)” each place
3 it appears and inserting “paragraph (1), (2),
4 (3), or (4)”; and

5 (E) in paragraph (7), as so redesignated, by
6 striking “paragraph (5)” each place it appears
7 and inserting “paragraph (6)”.

8 (3) *NEW DRUGS AND DEVICES.*—

9 (A) *INVESTIGATIONAL NEW DRUGS.*—Section
10 *505(i) of the Federal Food, Drug, and Cos-*
11 *metic Act (21 U.S.C. 355(i)) is amended in*
12 *paragraph (4), by adding at the end the fol-*
13 *lowing: “The Secretary shall update such regula-*
14 *tions to require inclusion in the informed con-*
15 *sent form a statement that clinical trial infor-*
16 *mation for such clinical investigation has been*
17 *or will be submitted for inclusion in the registry*
18 *data bank pursuant to subsections (i) and (j) of*
19 *section 402 of the Public Health Service Act.”.*

20 (B) *NEW DRUG APPLICATIONS.*—Section
21 *505(b) of the Federal, Food, Drug, and Cosmetic*
22 *Act (21 U.S.C. 355(b)) is amended by adding at*
23 *the end the following:*

24 “(6) An application submitted under this sub-
25 section shall be accompanied by the certification re-

1 *quired under section 402(j)(4)(B) of the Public Health*
2 *Service Act. Such certification shall not be considered*
3 *an element of such application.”.*

4 (C) *DEVICE REPORTS UNDER SECTION*

5 *510(k).—Section 510(k) of the Federal Food,*

6 *Drug, and Cosmetic Act (21 U.S.C. 360(k)) is*

7 *amended by adding at the end the following:*

8 *“A notification submitted under this subsection that con-*
9 *tains clinical trial data for an applicable device clinical*
10 *trial (as defined in section 402(j)(1) of the Public Health*
11 *Service Act) shall be accompanied by the certification re-*
12 *quired under section 402(j)(4)(B) of such Act. Such certifi-*
13 *cation shall not be considered an element of such notifica-*
14 *tion.”.*

15 (D) *DEVICE PREMARKET APPROVAL APPLI-*

16 *CATION.—Section 515(c) of the Federal Food,*

17 *Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is*

18 *amended—*

19 (i) *in subparagraph (F), by striking “;*
20 *and” and inserting a semicolon;*

21 (ii) *by redesignating subparagraph (G)*
22 *as subparagraph (H); and*

23 (iii) *by inserting after subparagraph*
24 *(F) the following:*

1 “(G) the certification required under section
2 402(j)(4)(B) of the Public Health Service Act
3 (which shall not be considered an element of such
4 application); and”.

5 (E) HUMANITARIAN DEVICE EXEMPTION.—
6 Section 520(m)(2) of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 360e(c)) is amend-
8 ed in the first sentence in the matter following
9 subparagraph (C), by inserting at the end before
10 the period “and such application shall include
11 the certification required under section
12 402(j)(4)(B) of the Public Health Service Act
13 (which shall not be considered an element of such
14 application)”.

15 (c) PREEMPTION.—

16 (1) IN GENERAL.—No State or political subdivi-
17 sion of a State may establish or continue in effect any
18 requirement for the registration of clinical trials or
19 for the inclusion of information relating to the results
20 of clinical trials in a database.

21 (2) RULE OF CONSTRUCTION.—The fact of sub-
22 mission of clinical trial information, if submitted in
23 compliance with subsection (i) and (j) of section 402
24 of the Public Health Service Act (as amended by this
25 section), that relates to a use of a drug or device not

1 *included in the official labeling of the approved drug*
2 *or device shall not be construed by the Secretary or*
3 *in any administrative or judicial proceeding, as evi-*
4 *dence of a new intended use of the drug or device that*
5 *is different from the intended use of the drug or device*
6 *set forth in the official labeling of the drug or device.*
7 *The availability of clinical trial information through*
8 *the data bank under such subsections (i) and (j), if*
9 *submitted in compliance with such subsections, shall*
10 *not be considered as labeling, adulteration, or mis-*
11 *branding of the drug or device under the Federal*
12 *Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).*

13 *(d) TRANSITION RULE; EFFECTIVE DATE OF FUNDING*
14 *RESTRICTIONS.—*

15 *(1) TRANSITION RULE FOR CLINICAL TRIALS INI-*
16 *TIATED PRIOR TO EXPANSION OF REGISTRY DATA*
17 *BANK.—The responsible party (as defined in para-*
18 *graph (1) of section 402(j) of the Public Health Serv-*
19 *ice Act (as added by this section)) for an applicable*
20 *drug clinical trial or applicable device clinical trial*
21 *(as defined under such paragraph (1)) that is initi-*
22 *ated after the date of enactment of this subtitle and*
23 *before the effective date of the regulations promulgated*
24 *under paragraph (2) of such section 402(j), shall sub-*
25 *mit required clinical trial information under such*

1 *section not later than 120 days after such effective*
 2 *date.*

3 (2) *FUNDING RESTRICTIONS.*—*Subparagraph (A)*
 4 *of paragraph (4) of such section 402(j) shall take ef-*
 5 *fect 210 days after the effective date of the regulations*
 6 *promulgated under paragraph (2) of such section*
 7 *402(j).*

8 (e) *EFFECTIVE DATE.*—*Beginning 90 days after the*
 9 *date of enactment of this title, the responsible party for an*
 10 *applicable drug clinical trial or an applicable device clin-*
 11 *ical trial (as that term is defined in such section 402(j))*
 12 *that is initiated after the date of enactment of this title and*
 13 *before the effective date of the regulations issued under sub-*
 14 *paragraph (A) of paragraph (2) of such subsection, shall*
 15 *submit clinical trial information under such paragraph (2).*

16 ***Subtitle D—Conflicts of Interest***

17 ***SEC. 241. CONFLICTS OF INTEREST.***

18 (a) *IN GENERAL.*—*Subchapter A of chapter VII of the*
 19 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et*
 20 *seq.) is amended by inserting at the end the following:*

21 ***“SEC. 712. CONFLICTS OF INTEREST.***

22 *“(a) DEFINITIONS.—For purposes of this section:*

23 *“(1) ADVISORY COMMITTEE.—The term ‘advisory*
 24 *committee’ means an advisory committee under the*
 25 *Federal Advisory Committee Act that provides advice*

1 *or recommendations to the Secretary regarding activi-*
2 *ties of the Food and Drug Administration.*

3 “(2) *FINANCIAL INTEREST.*—*The term ‘financial*
4 *interest’ means a financial interest under section*
5 *208(a) of title 18, United States Code.*

6 “(b) *APPOINTMENTS TO ADVISORY COMMITTEES.*—

7 “(1) *RECRUITMENT.*—

8 “(A) *IN GENERAL.*—*Given the importance*
9 *of advisory committees to the review process at*
10 *the Food and Drug Administration, the Sec-*
11 *retary shall carry out informational and recruit-*
12 *ment activities for purposes of recruiting indi-*
13 *viduals to serve as advisory committee members.*
14 *The Secretary shall seek input from professional*
15 *medical and scientific societies to determine the*
16 *most effective informational and recruitment ac-*
17 *tivities. The Secretary shall also take into ac-*
18 *count the advisory committees with the greatest*
19 *number of vacancies.*

20 “(B) *RECRUITMENT ACTIVITIES.*—*The re-*
21 *ruitment activities under subparagraph (A)*
22 *may include—*

23 “(i) *advertising the process for becom-*
24 *ing an advisory committee member at med-*
25 *ical and scientific society conferences;*

1 “(ii) making widely available, includ-
2 ing by using existing electronic communica-
3 tions channels, the contact information for
4 the Food and Drug Administration point of
5 contact regarding advisory committee nomi-
6 nations; and

7 “(iii) developing a method through
8 which an entity receiving National Insti-
9 tutes of Health funding can identify a per-
10 son who the Food and Drug Administration
11 can contact regarding the nomination of in-
12 dividuals to serve on advisory committees.

13 “(2) *EVALUATION AND CRITERIA.*—When consid-
14 ering a term appointment to an advisory committee,
15 the Secretary shall review the expertise of the indi-
16 vidual and the financial disclosure report filed by the
17 individual pursuant to the *Ethics in Government Act*
18 of 1978 for each individual under consideration for
19 the appointment, so as to reduce the likelihood that
20 an appointed individual will later require a written
21 determination as referred to in section 208(b)(1) of
22 title 18, *United States Code*, a written certification as
23 referred to in section 208(b)(3) of title 18, *United*
24 *States Code*, or a waiver as referred to in subsection

1 (c)(3) of this section for service on the committee at
2 a meeting of the committee.

3 “(c) *GRANTING AND DISCLOSURE OF WAIVERS.*—

4 “(1) *IN GENERAL.*—Prior to a meeting of an ad-
5 visory committee regarding a ‘particular matter’ (as
6 that term is used in section 208 of title 18, United
7 States Code), each member of the committee who is a
8 full-time Government employee or special Government
9 employee shall disclose to the Secretary financial in-
10 terests in accordance with subsection (b) of such sec-
11 tion 208.

12 “(2) *FINANCIAL INTEREST OF ADVISORY COM-*
13 *MITTEE MEMBER OR FAMILY MEMBER.*—No member
14 of an advisory committee may vote with respect to
15 any matter considered by the advisory committee if
16 such member (or an immediate family member of
17 such member) has a financial interest that could be
18 affected by the advice given to the Secretary with re-
19 spect to such matter, excluding interests exempted in
20 regulations issued by the Director of the Office of Gov-
21 ernment Ethics as too remote or inconsequential to af-
22 fect the integrity of the services of the Government of-
23 ficers or employees to which such regulations apply.

24 “(3) *WAIVER.*—The Secretary may grant a
25 waiver of the prohibition in paragraph (2) if such

1 *waiver is necessary to afford the advisory committee*
2 *essential expertise.*

3 “(4) *LIMITATION.*—*The Secretary may not grant*
4 *a waiver under paragraph (3) for a member of an ad-*
5 *visory committee when the member’s own scientific*
6 *work is involved.*

7 “(5) *DISCLOSURE OF WAIVER.*—*Notwithstanding*
8 *section 107(a)(2) of the Ethics in Government Act (5*
9 *U.S.C. App.), the following shall apply:*

10 “(A) *15 OR MORE DAYS IN ADVANCE.*—*As*
11 *soon as practicable, but in no case later than 15*
12 *days prior to a meeting of an advisory com-*
13 *mittee to which a written determination as re-*
14 *ferred to in section 208(b)(1) of title 18, United*
15 *States Code, a written certification as referred to*
16 *in section 208(b)(3) of title 18, United States*
17 *Code, or a waiver as referred to in paragraph*
18 *(3) applies, the Secretary shall disclose (other*
19 *than information exempted from disclosure*
20 *under section 552 of title 5, United States Code,*
21 *and section 552a of title 5, United States Code*
22 *(popularly known as the Freedom of Information*
23 *Act and the Privacy Act of 1974, respectively))*
24 *on the Internet website of the Food and Drug*
25 *Administration—*

1 “(i) the type, nature, and magnitude of
2 the financial interests of the advisory com-
3 mittee member to which such determination,
4 certification, or waiver applies; and

5 “(ii) the reasons of the Secretary for
6 such determination, certification, or waiver.

7 “(B) *LESS THAN 30 DAYS IN ADVANCE.*—In
8 the case of a financial interest that becomes
9 known to the Secretary less than 30 days prior
10 to a meeting of an advisory committee to which
11 a written determination as referred to in section
12 208(b)(1) of title 18, United States Code, a writ-
13 ten certification as referred to in section
14 208(b)(3) of title 18, United States Code, or a
15 waiver as referred to in paragraph (3) applies,
16 the Secretary shall disclose (other than informa-
17 tion exempted from disclosure under section 552
18 of title 5, United States Code, and section 552a
19 of title 5, United States Code) on the Internet
20 website of the Food and Drug Administration,
21 the information described in clauses (i) and (ii)
22 of subparagraph (A) as soon as practicable after
23 the Secretary makes such determination, certifi-
24 cation, or waiver, but in no case later than the
25 date of such meeting.

1 “(d) *PUBLIC RECORD.*—*The Secretary shall ensure*
2 *that the public record and transcript of each meeting of an*
3 *advisory committee includes the disclosure required under*
4 *subsection (c)(5) (other than information exempted from*
5 *disclosure under section 552 of title 5, United States Code,*
6 *and section 552a of title 5, United States Code).*

7 “(e) *ANNUAL REPORT.*—*Not later than February 1 of*
8 *each year, the Secretary shall submit to the Inspector Gen-*
9 *eral of the Department of Health and Human Services, the*
10 *Committee on Appropriations and the Committee on*
11 *Health, Education, Labor, and Pensions of the Senate, and*
12 *the Committee on Appropriations and the Committee on*
13 *Energy and Commerce of the House of Representatives, a*
14 *report that describes—*

15 “(1) *with respect to the fiscal year that ended on*
16 *September 30 of the previous year, the number of va-*
17 *cancies on each advisory committee, the number of*
18 *nominees received for each committee, and the number*
19 *of such nominees willing to serve;*

20 “(2) *with respect to such year, the aggregate*
21 *number of disclosures required under subsection (c)(5)*
22 *for each meeting of each advisory committee and the*
23 *percentage of individuals to whom such disclosures*
24 *did not apply who served on such committee for each*
25 *such meeting;*

1 “(3) *with respect to such year, the number of*
2 *times the disclosures required under subsection (c)(5)*
3 *occurred under subparagraph (B) of such subsection;*
4 *and*

5 “(4) *how the Secretary plans to reduce the num-*
6 *ber of vacancies reported under paragraph (1) during*
7 *the fiscal year following such year, and mechanisms*
8 *to encourage the nomination of individuals for service*
9 *on an advisory committee, including those who are*
10 *classified by the Food and Drug Administration as*
11 *academicians or practitioners.*

12 “(f) *PERIODIC REVIEW OF GUIDANCE.—Not less than*
13 *once every 5 years, the Secretary shall review guidance of*
14 *the Food and Drug Administration regarding conflict of in-*
15 *terest waiver determinations with respect to advisory com-*
16 *mittees and update such guidance as necessary.”.*

17 “(b) *CONFORMING AMENDMENT.—Section 505(n) of the*
18 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n))*
19 *is amended by—*

20 (1) *striking paragraph (4); and*

21 (2) *redesignating paragraphs (5), (6), (7), and*
22 (8) *as paragraphs (4), (5), (6), and (7), respectively.*

23 “(c) *EFFECTIVE DATE.—The amendments made by this*
24 *section shall take effect on October 1, 2007.*

1 ***Subtitle E—Other Drug Safety***
2 ***Provisions***

3 **SEC. 251. DATABASE FOR AUTHORIZED GENERIC DRUGS.**

4 *Section 505 of the Federal Food, Drug, and Cosmetic*
5 *Act (21 U.S.C. 355), as amended by this title, is further*
6 *amended by adding at the end the following:*

7 “(q) *DATABASE FOR AUTHORIZED GENERIC DRUGS.—*

8 “(1) *IN GENERAL.—*

9 “(A) *PUBLICATION.—The Commissioner*
10 *shall—*

11 “(i) *not later than 9 months after the*
12 *date of enactment of the Enhancing Drug*
13 *Safety and Innovation Act of 2007, publish*
14 *a complete list on the Internet website of the*
15 *Food and Drug Administration of all au-*
16 *thorized generic drugs (including drug trade*
17 *name, brand company manufacturer, and*
18 *the date the authorized generic drug entered*
19 *the market); and*

20 “(ii) *update the list quarterly to in-*
21 *clude each authorized generic drug included*
22 *in an annual report submitted to the Sec-*
23 *retary by the sponsor of a listed drug dur-*
24 *ing the preceding 3-month period.*

1 “(B) *NOTIFICATION.*—*The Commissioner*
2 *shall notify relevant Federal agencies, including*
3 *the Centers for Medicare & Medicaid Services*
4 *and the Federal Trade Commission, any time the*
5 *Commissioner updates the information described*
6 *in subparagraph (A).*

7 “(2) *INCLUSION.*—*The Commissioner shall in-*
8 *clude in the list described in paragraph (1) each au-*
9 *thorized generic drug included in an annual report*
10 *submitted to the Secretary by the sponsor of a listed*
11 *drug after January 1, 1999.*

12 “(3) *AUTHORIZED GENERIC DRUG.*—*In this sec-*
13 *tion, the term ‘authorized generic drug’ means a list-*
14 *ed drug (as that term is used in subsection (j)) that—*

15 “(A) *has been approved under subsection*
16 *(c); and*

17 “(B) *is marketed, sold, or distributed di-*
18 *rectly or indirectly to retail class of trade under*
19 *a different labeling, packaging (other than re-*
20 *packaging as the listed drug in blister packs,*
21 *unit doses, or similar packaging for use in insti-*
22 *tutions), product code, labeler code, trade name,*
23 *or trade mark than the listed drug.”.*

1 **SEC. 252. MEDICAL MARIJUANA.**

2 *The Secretary shall require that State-legalized med-*
 3 *ical marijuana be subject to the full regulatory requirements*
 4 *of the Food and Drug Administration, including a risk*
 5 *evaluation and mitigation strategy and all other require-*
 6 *ments and penalties of the Federal Food, Drug, and Cos-*
 7 *metic Act (21 U.S.C. 301 et seq.) regarding safe and effec-*
 8 *tive reviews, approval, sale, marketing, and use of pharma-*
 9 *ceuticals.*

10 **TITLE III—MEDICAL DEVICES**

11 **SEC. 301. SHORT TITLE; REFERENCES.**

12 (a) *SHORT TITLE.*—*This title may be cited as the*
 13 *“Medical Device User Fee Amendments of 2007”.*

14 (b) *REFERENCES.*—*Except as otherwise specified,*
 15 *whenever in this title an amendment is expressed in terms*
 16 *of an amendment to a section or other provision, the ref-*
 17 *erence shall be considered to be made to a section or other*
 18 *provision of the Federal Food, Drug, and Cosmetic Act (21*
 19 *U.S.C. 301 et seq.).*

20 **Subtitle A—Device User Fees**

21 **SEC. 302. DEVICE FEES.**

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

23 (1) *by striking the section designation and all*
 24 *that follows through “For purposes of this subchapter”*
 25 *and inserting the following:*

1 **“SEC. 737. DEVICE FEES.**

2 “(a) *PURPOSE.*—*It is the purpose of this part that the*
3 *fees authorized under this part be dedicated toward expe-*
4 *diting the process for the review of device applications and*
5 *for assuring the safety and effectiveness of devices, as set*
6 *forth in the goals identified for purposes of this part in*
7 *the letters from the Secretary to the Chairman of the Com-*
8 *mittee on Health, Education, Labor, and Pensions of the*
9 *Senate and the Chairman of the Committee on Energy and*
10 *Commerce of the House of Representatives, as set forth in*
11 *the Congressional Record.*

12 “(b) *REPORTS.*—

13 “(1) *PERFORMANCE REPORT.*—*For fiscal years*
14 *2008 through 2012, not later than 120 days after the*
15 *end of each fiscal year during which fees are collected*
16 *under this part, the Secretary shall prepare and sub-*
17 *mit to the Committee on Health, Education, Labor,*
18 *and Pensions of the Senate and the Committee on*
19 *Energy and Commerce of the House of Representa-*
20 *tives, a report concerning the progress of the Food*
21 *and Drug Administration in achieving the goals iden-*
22 *tified in the letters described in subsection (a) during*
23 *such fiscal year and the future plans of the Food and*
24 *Drug Administration for meeting the goals. The re-*
25 *port for a fiscal year shall include information on all*
26 *previous cohorts for which the Secretary has not given*

1 *a complete response on all device premarket applica-*
2 *tions, supplements, and premarket notifications in the*
3 *cohort.*

4 “(2) *FISCAL REPORT.*—*For fiscal years 2008*
5 *through 2012, not later than 120 days after the end*
6 *of each fiscal year during which fees are collected*
7 *under this part, the Secretary shall prepare and sub-*
8 *mit to the Committee on Health, Education, Labor,*
9 *and Pensions of the Senate and the Committee on*
10 *Energy and Commerce of the House of Representa-*
11 *tives, a report on the implementation of the authority*
12 *for such fees during such fiscal year and the use, by*
13 *the Food and Drug Administration, of the fees col-*
14 *lected during such fiscal year for which the report is*
15 *made.*

16 “(3) *PUBLIC AVAILABILITY.*—*The Secretary shall*
17 *make the reports required under paragraphs (1) and*
18 *(2) available to the public on the Internet website of*
19 *the Food and Drug Administration.*

20 “(c) *REAUTHORIZATION.*—

21 “(1) *CONSULTATION.*—*In developing rec-*
22 *ommendations to present to Congress with respect to*
23 *the goals, and plans for meeting the goals, for the*
24 *process for the review of device applications for the*
25 *first 5 fiscal years after fiscal year 2012, and for the*

1 *reauthorization of this part for such fiscal years, the*
2 *Secretary shall consult with—*

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

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

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

8 *“(D) health care professionals;*

9 *“(E) representatives of patient and con-*
10 *sumer advocacy groups; and*

11 *“(F) the regulated industry.*

12 *“(2) PUBLIC REVIEW OF RECOMMENDATIONS.—*

13 *After negotiations with the regulated industry, the*
14 *Secretary shall—*

15 *“(A) present the recommendations developed*
16 *under paragraph (1) to the Congressional com-*
17 *mittees specified in such paragraph;*

18 *“(B) publish such recommendations in the*
19 *Federal Register;*

20 *“(C) provide for a period of 30 days for the*
21 *public to provide written comments on such rec-*
22 *ommendations;*

23 *“(D) hold a meeting at which the public*
24 *may present its views on such recommendations;*
25 *and*

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—Not
5 later than January 15, 2012, the Secretary shall
6 transmit to Congress the revised recommendations
7 under paragraph (2), a summary of the views and
8 comments received under such paragraph, and any
9 changes made to the recommendations in response to
10 such views and comments.

11 “(d) DEFINITIONS.—For purposes of this part:”;

12 (2) by redesignating paragraphs (5), (6), (7),
13 and (8), as paragraphs (7), (8), (9), and (11), respec-
14 tively;

15 (3) in paragraph (4)—

16 (A) in subparagraph (A), by striking “or
17 an efficacy supplement,” and inserting “an effi-
18 cacy supplement, or a 30-day notice,”; and

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

20 “(F) The term ‘30-day notice’ means a supple-
21 ment to an approved premarket application or pre-
22 market report under section 515 that is limited to a
23 request to make modifications to manufacturing pro-
24 cedures or methods of manufacture affecting the safety
25 and effectiveness of the device.”;

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

3 “(5) The term ‘request for classification informa-
4 tion’ means a request made under section 513(g) for
5 information respecting the class in which a device has
6 been classified or the requirements applicable to a de-
7 vice.

8 “(6) The term ‘annual fee for periodic reporting
9 concerning a class III device’ means the fee associated
10 with reports imposed by a premarket application ap-
11 proval order (as described in section 814.82(a)(7) of
12 title 21, Code of Federal Regulations), usually re-
13 ferred to as ‘annual reports.’”;

14 (5) in paragraph (9), as redesignated by para-
15 graph (2)—

16 (A) by striking “April of” and inserting
17 “October of”; and

18 (B) by striking “April 2002” and inserting
19 “October 2001”;

20 (6) by inserting after paragraph (9), as redesign-
21 ated by paragraph (2), the following:

22 “(10) The term ‘person’ includes an affiliate of
23 such person.”; and

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

1 “(12) The term ‘establishment subject to a reg-
2 istration fee’ means an establishment required to reg-
3 ister with the Secretary under section 510 at which
4 any of the following types of activities are conducted:

5 “(A) MANUFACTURER.—An establishment
6 that makes by any means any article that is a
7 device including an establishment that sterilizes
8 or otherwise makes such article for or on behalf
9 of a specification developer or any other person.

10 “(B) SINGLE-USE DEVICE REPROCESSOR.—
11 An establishment that performs manufacturing
12 operations on a single-use device.

13 “(C) SPECIFICATION DEVELOPER.—An es-
14 tablishment that develops specifications for a de-
15 vice that is distributed under the establishment’s
16 name but that performs no manufacturing, in-
17 cluding establishments that, in addition to devel-
18 oping specifications, arrange for the manufac-
19 turing of devices labeled with another establish-
20 ment’s name by a contract manufacturer.

21 “(13) The term ‘establishment registration fee’
22 means a fee assessed under section 738(a)(3) for the
23 registration of an establishment subject to a registra-
24 tion fee.

1 “(e) *SUNSET*.—*This part shall cease to be effective on*
2 *October 1, 2012, except that subsection (b) with respect to*
3 *reports shall cease to be effective January 31, 2013.*”.

4 **SEC. 303. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

5 *Section 738 (21 U.S.C. 379j) is amended—*

6 (1) *in subsection (a)—*

7 (A) *in paragraph (2)—*

8 (i) *in the header, by inserting “, AND*
9 *ANNUAL FEE FOR PERIODIC REPORTING*
10 *CONCERNING A CLASS III DEVICE” after*
11 *“FEE”;*

12 (ii) *in subparagraph (A)—*

13 (I) *in clause (iii), by inserting*
14 *“75 percent of” after “a fee equal to”;*

15 (II) *in clause (iv), by striking*
16 *“21.5” and inserting “15”;*

17 (III) *in clause (v), by striking*
18 *“7.2” and inserting “7”;*

19 (IV) *by redesignating clauses (vi)*
20 *and (vii) as clauses (vii) and (viii), re-*
21 *spectively;*

22 (V) *by inserting after clause (v)*
23 *the following:*

1 “(vi) For a 30-day notice, a fee equal
2 to 1.6 percent of the fee that applies under
3 clause (i).”;

4 (VI) in clause (viii), as redesign-
5 nated by subclause (IV)—

6 (aa) by striking “1.42” and
7 inserting “1.84”; and

8 (bb) by striking “, subject to
9 any adjustment under subsection
10 (e)(2)(C)(ii)”;

11 (VII) by adding at the end the fol-
12 lowing:

13 “(ix) For a request for classification
14 information, a fee equal to 1.35 percent of
15 the fee that applies under clause (i).

16 “(x) For periodic reporting concerning
17 a class III device, the annual fee shall be
18 equal to 3.5 percent of the fee that applies
19 under clause (i).”;

20 (iii) in subparagraph (C)—

21 (I) in the first sentence—

22 (aa) by striking “or”; and

23 (bb) by striking “except that”
24 and all that follows through the
25 period and inserting “, 30-day

1 *notice, request for classification*
2 *information, or periodic report*
3 *concerning a class III device.”;*
4 *and*
5 *(II) by striking the third sentence;*
6 *and*
7 *(iv) in subparagraph (D)—*
8 *(I) in clause (iii), by striking the*
9 *last two sentences; and*
10 *(II) by adding at the end the fol-*
11 *lowing:*
12 *“(iv) MODULAR APPLICATION WITH-*
13 *DRAWN BEFORE FIRST ACTION.—The Sec-*
14 *retary shall refund 75 percent of the appli-*
15 *cation fee paid for a modular application*
16 *submitted under section 515(c)(4) that is*
17 *withdrawn before a second module is sub-*
18 *mitted and before a first action on the first*
19 *module. If the modular application is with-*
20 *drawn after a second or subsequent module*
21 *is submitted but before any first action, the*
22 *Secretary may return a portion of the fee.*
23 *The amount of refund, if any, shall be based*
24 *on the level of effort already expended on*
25 *the review of the modules submitted.*

1 “(v) *SOLE DISCRETION TO REFUND.*—
2 *The Secretary shall have sole discretion to*
3 *refund a fee or portion of the fee under this*
4 *subparagraph. A determination by the Sec-*
5 *retary concerning a refund under this para-*
6 *graph shall not be reviewable.”; and*

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

8 “(3) *ANNUAL ESTABLISHMENT REGISTRATION*
9 *FEE.*—

10 “(A) *IN GENERAL.*—*Except as provided in*
11 *subparagraph (B), each establishment subject to*
12 *a registration fee shall be subject to a fee for each*
13 *initial or annual registration beginning with its*
14 *registration for fiscal year 2008.*

15 “(B) *EXCEPTION FOR FEDERAL OR STATE*
16 *GOVERNMENT ESTABLISHMENT.*—*No fee shall be*
17 *required under subparagraph (A) for an estab-*
18 *lishment operated by a Federal or State Govern-*
19 *ment entity unless a device manufactured by the*
20 *establishment is to be distributed commercially.*

21 “(C) *PAYMENT.*—*The annual establishment*
22 *registration fee shall be due once each fiscal year,*
23 *upon the initial registration of the establishment*
24 *or upon the annual registration under section*
25 *510.”;*

1 (2) *by striking subsection (b) and inserting the*
 2 *following:*

3 “(b) *FEE AMOUNTS.—Except as provided in sub-*
 4 *sections (c), (d), and (e), the fees under subsection (a) shall*
 5 *be based on the following fee amounts:*

<i>Fee Type</i>	<i>Fiscal Year 2008</i>	<i>Fiscal Year 2009</i>	<i>Fiscal Year 2010</i>	<i>Fiscal Year 2011</i>	<i>Fiscal Year 2012</i>
<i>Premarket Appli- cation</i>	\$185,000	\$200,725	\$217,787	\$236,298	\$256,384
<i>Establishment Registration Fee</i>	\$1,706	\$1,851	\$2,008	\$2,179	\$2,364.”;

6 (3) *in subsection (c)—*

7 (A) *in the heading, by striking “Annual Fee*
 8 *Setting” and inserting “ANNUAL FEE SETTING”;*

9 (B) *in paragraph (1), by striking the second*
 10 *sentence;*

11 (C) *by redesignating paragraphs (2) and*
 12 *(3) as paragraphs (3) and (4), respectively;*

13 (D) *by inserting after paragraph (1) the fol-*
 14 *lowing:*

15 “(2) *ADJUSTMENT OF ANNUAL ESTABLISHMENT*
 16 *REGISTRATION FEE.—*

17 “(A) *IN GENERAL.—When setting the fees*
 18 *for fiscal year 2010, the Secretary may increase*
 19 *the establishment registration fee specified in*
 20 *subsection (b) only if the Secretary estimates*

1 that the number of establishments submitting fees
2 for fiscal year 2009 is less than 12,250. The per-
3 cent increase shall be the percent by which the
4 estimate of establishments submitting fees in fis-
5 cal year 2009 is less than 12,750, but in no case
6 shall the percent increase be more than 8.5 per-
7 cent over the amount for such fee specified in
8 subsection (b) for fiscal year 2010. If the Sec-
9 retary makes any adjustment to the establish-
10 ment registration fee for fiscal year 2010, then
11 the establishment registration fee for fiscal years
12 2011 and 2012 under subsection (b) shall be ad-
13 justed as follows: the fee for fiscal year 2011 shall
14 be equal to the adjusted fee for fiscal year 2010,
15 increased by 8.5 percent, and the fee for fiscal
16 year 2012 shall be equal to the adjusted fee for
17 fiscal year 2011, increased by 8.5 percent.

18 “(B) PUBLICATION IN THE FEDERAL REG-
19 ISTER.—The Secretary shall publish any deter-
20 mination with respect to any establishment reg-
21 istration fee adjustment made under subpara-
22 graph (A), and the rationale for such determina-
23 tion, in the Federal Register.”; and

24 (E) in paragraph (4)(A), as so redesign-
25 nated—

1 (i) by striking “For fiscal years 2006
2 and 2007, the” and inserting “The”; and

3 (ii) by striking “of fiscal year 2008”
4 and inserting “of the next fiscal year”;

5 (4) in subsection (d)—

6 (A) in paragraph (1), by striking “, part-
7 ners, and parent firms”;

8 (B) in paragraph (2)—

9 (i) in subparagraph (A), by striking “,
10 partners, and parent firms”;

11 (ii) in subparagraph (B)—

12 (I) by striking “An applicant
13 shall” and inserting the following:

14 “(i) *IN GENERAL.*—An applicant
15 shall”;

16 (II) by striking “The applicant
17 shall support” and inserting the fol-
18 lowing:

19 “(ii) *FIRMS SUBMITTING TAX RETURNS*
20 *TO THE UNITED STATES INTERNAL REV-*
21 *ENUE SERVICE.*—The applicant shall sup-
22 port”;

23 (III) by striking “, partners, and
24 parent firms” both places the term ap-
25 pears;

1 (IV) by striking “partners, or
2 parent firms, the” and inserting “the”;

3 (V) by striking “, partners, or
4 parent firms, respectively”; and

5 (VI) by adding at the end the fol-
6 lowing:

7 “(iii) *FIRMS NOT SUBMITTING TAX RE-*
8 *URNS TO THE UNITED STATES INTERNAL*
9 *REVENUE SERVICE.—The applicant shall*
10 *support its claim that it meets the defini-*
11 *tion under subparagraph (A) by submission*
12 *of the following:*

13 “(I) *A signed certification, in*
14 *such form as the Secretary may direct*
15 *through a notice published in the Fed-*
16 *eral Register, that the applicant meets*
17 *the criteria for a small business.*

18 “(II) *A certification, in English,*
19 *from the national taxing authority of*
20 *the country in which it is*
21 *headquartered. Such certification shall*
22 *provide the applicant’s gross receipts*
23 *and sales for the most recent year, in*
24 *both the local currency and in United*
25 *States dollars, the exchange rate used*

1 *in making this conversion to dollars,*
2 *and the dates during which these re-*
3 *ceipts and sales were collected, and it*
4 *shall bear the official seal of the na-*
5 *tional taxing authority.*

6 “(III) *Identical certifications*
7 *shall be provided for each of the appli-*
8 *cant’s affiliates.*

9 “(IV) *A statement signed by the*
10 *head of the applicant or its chief fi-*
11 *nancial officer that it has submitted*
12 *certifications for all of its affiliates, or*
13 *that it had no affiliates, whichever is*
14 *applicable.”; and*

15 *(iii) in subparagraph (C)—*

16 *(I) by striking “reduced rate of”*
17 *and inserting “reduced rate of—”; and*

18 *(II) by striking “38 percent” and*
19 *all that follows through the period and*
20 *inserting the following:*

21 *“(i) 25 percent of the fee established*
22 *under such subsection for a premarket ap-*
23 *plication, a premarket report, a supple-*
24 *ment, or a periodic report concerning a*
25 *class III device; and*

1 “(ii) 50 percent of the fee established
2 under such subsection for a 30-day notice or
3 a request for classification information.”;

4 (5) in subsection (e)—

5 (A) in paragraph (1), by striking “2004”
6 and inserting “2008”; and

7 (B) in paragraph (2)—

8 (i) in subparagraph (A), by striking “,
9 partners, and parent firms”;

10 (ii) by striking subparagraph (B) and
11 inserting the following:

12 “(B) EVIDENCE OF QUALIFICATION.—

13 “(i) IN GENERAL.—An applicant shall
14 pay the higher fees established by the Sec-
15 retary each year unless the applicant sub-
16 mits evidence that it qualifies for the lower
17 fee rate.

18 “(ii) FIRMS SUBMITTING TAX RETURNS
19 TO THE UNITED STATES INTERNAL REV-
20 ENUE SERVICE.—The applicant shall sup-
21 port its claim that it meets the definition
22 under subparagraph (A) by submission of a
23 copy of its most recent Federal income tax
24 return for a taxable year, and a copy of
25 such returns of its affiliates, which show an

1 *amount of gross sales or receipts that is less*
2 *than the maximum established in subpara-*
3 *graph (A). The applicant, and each of such*
4 *affiliates, shall certify that the information*
5 *provided is a true and accurate copy of the*
6 *actual tax forms they submitted to the In-*
7 *ternal Revenue Service. If no tax forms are*
8 *submitted for affiliates, the applicant shall*
9 *certify that the applicant has no affiliates.*

10 *“(iii) FIRMS NOT SUBMITTING TAX RE-*
11 *TURNS TO THE UNITED STATES INTERNAL*
12 *REVENUE SERVICE.—The applicant shall*
13 *support its claim that it meets the defini-*
14 *tion under subparagraph (A) by submission*
15 *of the following:*

16 *“(I) A signed certification, in*
17 *such form as the Secretary may direct*
18 *through a notice published in the Fed-*
19 *eral Register, that the applicant meets*
20 *the criteria for a small business.*

21 *“(II) A certification, in English,*
22 *from the national taxing authority of*
23 *the country in which it is*
24 *headquartered. Such certification shall*
25 *provide the applicant’s gross receipts*

1 *and sales for the most recent year, in*
2 *both the local currency and in United*
3 *States dollars, and the exchange rate*
4 *used in making such conversion to dol-*
5 *lars, and the dates during which such*
6 *receipts and sales were collected, and it*
7 *shall bear the official seal of the na-*
8 *tional taxing authority.*

9 “(III) *Identical certifications*
10 *shall be provided for each of the appli-*
11 *cant’s affiliates.*

12 “(IV) *A statement signed by the*
13 *head of the applicant or its chief fi-*
14 *nancial officer that it has submitted*
15 *certifications for all of its affiliates, or*
16 *that it had no affiliates, whichever is*
17 *applicable.”; and*

18 *(iii) by striking subparagraph (C) and*
19 *inserting the following:*

20 “(C) *REDUCED FEES.—For fiscal year 2008*
21 *and each subsequent fiscal year, where the Sec-*
22 *retary finds that the applicant involved meets*
23 *the definition under subparagraph (A), the fee*
24 *for a premarket notification submission may be*
25 *paid at 50 percent of the fee that applies under*

1 *subsection (a)(2)(A)(viii) and as established*
2 *under subsection (c)(1).”;*

3 *(6) by striking subsection (f) and inserting the*
4 *following:*

5 *“(f) EFFECT OF FAILURE TO PAY FEES.—*

6 *“(1) IN GENERAL.—A premarket application,*
7 *premarket report, supplement, or premarket notifica-*
8 *tion submission, 30-day notice, request for classifica-*
9 *tion information, or periodic report concerning a*
10 *class III device submitted by a person subject to fees*
11 *under paragraphs (2) and (3) of subsection (a) shall*
12 *be considered incomplete and shall not be accepted by*
13 *the Secretary until all fees owed by such person have*
14 *been paid.*

15 *“(2) REGISTRATION INFORMATION.—Registration*
16 *information submitted by an establishment subject to*
17 *a registration fee under subsection (a)(3) shall be con-*
18 *sidered incomplete and shall not be accepted by the*
19 *Secretary until the registration fee owed for the estab-*
20 *lishment has been paid. Until the fee is paid and the*
21 *registration is complete, the establishment shall be*
22 *deemed to have failed to register in accordance with*
23 *section 510.”;*

24 *(7) in subsection (g)—*

1 (A) by striking paragraph (1) and inserting
2 the following:

3 “(1) *PERFORMANCE GOALS; TERMINATION OF*
4 *PROGRAM.*—With respect to the amount that, under
5 the salaries and expenses account of the Food and
6 Drug Administration, is appropriated for a fiscal
7 year for devices and radiological products, fees may
8 not be assessed under subsection (a) for the fiscal
9 year, and the Secretary is not expected to meet any
10 performance goals identified for the fiscal year, if—

11 “(A) the amount so appropriated for the fis-
12 cal year, excluding the amount of fees appro-
13 priated for the fiscal year, is more than 1 per-
14 cent less than \$205,720,000 multiplied by the ad-
15 justment factor applicable to such fiscal year; or

16 “(B) fees were not assessed under subsection
17 (a) for the previous fiscal year.”; and

18 (B) in paragraph (2), by striking “and pre-
19 market notification submissions, and” and in-
20 serting “premarket notification submissions, 30-
21 day notices, requests for classification informa-
22 tion, periodic reports concerning a class III de-
23 vice, and establishment registrations”; and

24 (8) in subsection (h), by striking paragraphs (3)
25 and (4) and inserting the following:

1 “(3) *AUTHORIZATION OF APPROPRIATIONS.—*
2 *There are authorized to be appropriated for fees under*
3 *this section—*

4 “(A) \$48,431,000 for fiscal year 2008;

5 “(B) \$52,547,000 for fiscal year 2009;

6 “(C) \$57,014,000 for fiscal year 2010;

7 “(D) \$61,860,000 for fiscal year 2011; and

8 “(E) \$67,118,000 for fiscal year 2012.

9 “(4) *OFFSET.—If the cumulative amount of fees*
10 *collected during fiscal years 2008, 2009, and 2010,*
11 *added to the amount estimated to be collected for fis-*
12 *cal year 2011 (which estimate shall be based upon the*
13 *amount of fees received by the Secretary through June*
14 *30, 2011), exceeds the amount of fees specified in ag-*
15 *gregate in paragraph (3) for such 4 fiscal years, the*
16 *aggregate amount in excess shall be credited to the ap-*
17 *propriation account of the Food and Drug Adminis-*
18 *tration as provided in paragraph (1), and shall be*
19 *subtracted from the amount of fees that would other-*
20 *wise be authorized to be collected under this section*
21 *pursuant to appropriation Acts for fiscal year 2012.”.*

22 **SEC. 304. SAVINGS CLAUSE.**

23 *Notwithstanding section 107 of the Medical Device*
24 *User Fee and Modernization Act of 2002 (Public Law 107–*
25 *250), and notwithstanding the amendments made by this*

1 subtitle, part 3 of subchapter C of chapter VII of the Federal
2 Food, Drug, and Cosmetic Act, as in effect on the day before
3 the date of enactment of this subtitle, shall continue to be
4 in effect with respect to premarket applications, premarket
5 reports, premarket notification submissions, and supple-
6 ments (as defined in such part as of such day) that on or
7 after October 1, 2002, but before October 1, 2007, were ac-
8 cepted by the Food and Drug Administration for filing with
9 respect to assessing and collecting any fee required by such
10 part for a fiscal year prior to fiscal year 2008.

11 **SEC. 305. EFFECTIVE DATE.**

12 *The amendments made by this subtitle shall take effect*
13 *on the date of the enactment of this subtitle.*

14 ***Subtitle B—Amendments Regarding***
15 ***Regulation of Medical Devices***

16 **SEC. 311. INSPECTIONS BY ACCREDITED PERSONS.**

17 *Section 704(g) (21 U.S.C. 374(g)) is amended—*

18 *(1) in paragraph (1) by striking “not later than*
19 *one year after the date of enactment of this subsection,*
20 *the Secretary” and inserting “The Secretary”;*

21 *(2) in paragraph (3) by adding at the end the*
22 *following:*

23 *“(F) Such person shall notify the Secretary*
24 *of any withdrawal, suspension, restriction, or ex-*
25 *piration of certificate of conformance with the*

1 *quality systems standard referred to in para-*
2 *graph (7) for any manufacturer that such person*
3 *inspects under this subsection not later than 30*
4 *days after such withdrawal, suspension, restric-*
5 *tion, or expiration.*

6 “(G) Such person may conduct audits to es-

7 *tablish conformance with the quality systems*
8 *standard referred to in paragraph (7).”;*

9 *(3) by amending paragraph (6) to read as fol-*
10 *lows:*

11 “(6) A device establishment is eligible for inspec-

12 *tions by persons accredited under paragraph (2) if*
13 *the following conditions are met:*

14 “(A) With respect to inspections to be con-

15 *ducted by an accredited person—*

16 “(i) the owner or operator of the estab-

17 *lishment submits to the Secretary a notice*
18 *indicating the intent to use such a person*
19 *to conduct the inspection, and the date on*
20 *which the inspection is scheduled to begin;*
21 *and*

22 “(ii) the accredited person whom the

23 *establishment selects to conduct the inspec-*
24 *tion is listed on the Internet site of the Food*

1 *and Drug Administration referred to in*
2 *paragraph (4).*

3 “(B) *As requested by the Secretary, the es-*
4 *tablishment or the accredited person identified in*
5 *the notice under subparagraph (A) provides in-*
6 *formation concerning the relationship between*
7 *the establishment and such accredited person.”;*
8 *(4) in paragraph (7)—*

9 *(A) by amending subparagraph (A) to read*
10 *as follows:*

11 “(A) *Persons accredited under paragraph*
12 *(2) to conduct inspections shall record in writing*
13 *their inspection observations and shall present*
14 *the observations to the device establishment’s des-*
15 *ignated representative and describe each observa-*
16 *tion. Additionally, such accredited person shall*
17 *prepare an inspection report in a form and*
18 *manner designated by the Secretary, taking into*
19 *consideration the goals of international harmoni-*
20 *zation of quality systems standards. Any official*
21 *classification of the inspection shall be deter-*
22 *mined by the Secretary.”; and*

23 *(B) by adding at the end the following new*
24 *subparagraph:*

1 “(F) The Secretary shall accept reports of
2 audits assessing conformance with an appro-
3 priate quality systems standard set by the Inter-
4 national Organization for Standardization
5 (ISO) identified by the Secretary in public no-
6 tice for the purpose of setting risk-based
7 inspectional priorities.”.

8 **SEC. 312. EXTENSION OF AUTHORITY FOR THIRD PARTY RE-**
9 **VIEW OF PREMARKET NOTIFICATION.**

10 Section 523(c) (21 U.S.C. 360m(c)) is amended by
11 striking “2007” and inserting “2012”.

12 **SEC. 313. REGISTRATION.**

13 (a) *ANNUAL REGISTRATION OF PRODUCERS OF DRUGS*
14 *AND DEVICES.*—Section 510(b) (21 U.S.C. 359(b)) is
15 amended—

16 (1) by striking “(b) On or before” and inserting
17 “(b)(1) On or before”;

18 (2) in paragraph (1), by striking “or a device or
19 devices”; and

20 (3) by adding at the end the following new para-
21 graph:

22 “(2) Between October 1 and December 31 of each year
23 every person who owns or operates any establishment in
24 any State engaged in the manufacture, preparation, propa-
25 gation, compounding, or processing of a device or devices

1 *shall register with the Secretary his name, places of busi-*
2 *ness, and all such establishments.”.*

3 *(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—*

4 *Section 510(i)(1) (21 U.S.C. 359(i)(1)) is amended—*

5 *(1) by striking “(1) On or before” and inserting*
6 *“(1)(A) On or before”;*

7 *(2) in subparagraph (A)—*

8 *(A) by striking “processing of a drug or a*
9 *device that is imported” and inserting “proc-*
10 *essing of a drug that is imported”;*

11 *(B) by striking “or device” each place it ap-*
12 *pears; and*

13 *(3) by adding after such subparagraph (A) the*
14 *following new subparagraph:*

15 *“(B) Between October 1 and December 31 of each*
16 *year, any establishment within any foreign country*
17 *engaged in the manufacture, preparation, propaga-*
18 *tion, compounding, or processing of a device that is*
19 *imported or offered for import into the United States*
20 *shall, through electronic means in accordance with the*
21 *criteria of the Secretary, register with the Secretary*
22 *the name and place of business of the establishment,*
23 *the name of the United States agent for the establish-*
24 *ment, the name of each importer of such device in the*
25 *United States that is known to the establishment, and*

1 *the name of each person who imports or offers for im-*
2 *port such device to the United States for purposes of*
3 *importation.”.*

4 **SEC. 314. FILING OF LISTS OF DRUGS AND DEVICES MANU-**
5 **FACTURED PREPARED, PROPAGATED AND**
6 **COMPOUNDED BY REGISTRANTS; STATE-**
7 **MENTS; ACCOMPANYING DISCLOSURES.**

8 *Section 510(j)(2) (21 U.S.C. 360(j)(2) is amended, in*
9 *the matter preceding subparagraph (A), to read as follows:*

10 *“(2) Each person who registers with the Secretary*
11 *under this section shall report to the Secretary (i) with re-*
12 *gard to drugs, once during the month of June of each year*
13 *and once during the month of December of each year, and*
14 *(ii) with regard to devices, once each year between October*
15 *1 and December 31, the following information:”.*

16 **SEC. 315. ELECTRONIC REGISTRATION AND LISTING.**

17 *Section 510(p) (21 U.S.C. 360(p)) is amended to read*
18 *as follows:*

19 *“(p)(1) With regard to any establishment engaged in*
20 *the manufacture, preparation, propagation, compounding,*
21 *or processing of a drug, registrations under subsections (b),*
22 *(c), (d), and (i) of this section (including the submission*
23 *of updated information) shall be submitted to the Secretary*
24 *by electronic means, upon a finding by the Secretary that*
25 *the electronic receipt of such registrations is feasible, unless*

1 (A) in paragraph (1)(A)(i), by striking
2 “(D)” both places it appears and inserting
3 “(E)”;

4 (B) in paragraph (1)(A)(ii), by striking
5 “(D)” and inserting “(E)”;

6 (C) by striking “(1)(A)(i)” and inserting
7 “(A)(i)(I)”;

8 (D) by striking “(ii) the” and inserting
9 “(II) the”;

10 (E) by striking “(B) if the drug is des-
11 ignated” and inserting “(ii) if the drug is des-
12 ignated”;

13 (F) by striking “(2)(A)” and inserting
14 “(B)(i)”;

15 (G) by striking “(i) a listed patent” and in-
16 serting “(I) a listed patent”;

17 (H) by striking “(ii) a listed patent” and
18 inserting “(II) a listed patent”;

19 (I) by striking “(B) if the drug is the sub-
20 ject” and inserting “(ii) if the drug is the sub-
21 ject”;

22 (J) by striking “If” and all that follows
23 through “subsection (d)(3)” and inserting the fol-
24 lowing:

1 “(1) *IN GENERAL.*—*Except as provided in para-*
2 *graph (2), if, prior to approval of an application that*
3 *is submitted under section 505(b)(1), the Secretary*
4 *determines that information relating to the use of a*
5 *new drug in the pediatric population may produce*
6 *health benefits in that population, the Secretary*
7 *makes a written request for pediatric studies (which*
8 *shall include a timeframe for completing such stud-*
9 *ies), the applicant agrees to the request, such studies*
10 *are completed using appropriate formulations for*
11 *each age group for which the study is requested with-*
12 *in any such timeframe, and the reports thereof are*
13 *submitted and accepted in accordance with subsection*
14 *(d)(3), and if the Secretary determines that labeling*
15 *changes are appropriate, such changes are made with-*
16 *in the timeframe requested by the Secretary—”;*

17 *(K) by adding at the end the following:*

18 “(2) *EXCEPTION.*—*The Secretary shall not ex-*
19 *tend a period referred to in paragraph (1)(A) or in*
20 *paragraph (1)(B) later than 9 months prior to the ex-*
21 *piration of such period.”;*

22 *(3) in subsection (c)—*

23 *(A) in paragraph (1)(A)(i), by striking*

24 *“(D)” both places it appears and inserting*

25 *“(E)”;*

1 (B) in paragraph (1)(A)(ii), by striking
2 “(D)” and inserting “(E)”;

3 (C) by striking “(1)(A)(i)” and inserting
4 “(A)(i)(I)”;

5 (D) by striking “(ii) the” and inserting
6 “(II) the”;

7 (E) by striking “(B) if the drug is des-
8 ignated” and inserting “(ii) if the drug is des-
9 ignated”;

10 (F) by striking “(2)(A)” and inserting
11 “(B)(i)”;

12 (G) by striking “(i) a listed patent” and in-
13 serting “(I) a listed patent”;

14 (H) by striking “(ii) a listed patent” and
15 inserting “(II) a listed patent”;

16 (I) by striking “(B) if the drug is the sub-
17 ject” and inserting “(ii) if the drug is the sub-
18 ject”;

19 (J) by striking “If” and all that follows
20 through “subsection (d)(3)” and inserting the fol-
21 lowing:

22 “(1) IN GENERAL.—Except as provided in para-
23 graph (2), if the Secretary determines that informa-
24 tion relating to the use of an approved drug in the
25 pediatric population may produce health benefits in

1 *that population and makes a written request to the*
2 *holder of an approved application under section*
3 *505(b)(1) for pediatric studies (which shall include a*
4 *timeframe for completing such studies), the holder*
5 *agrees to the request, such studies are completed using*
6 *appropriate formulations for each age group for*
7 *which the study is requested within any such time-*
8 *frame, and the reports thereof are submitted and ac-*
9 *cepted in accordance with subsection (d)(3), and if*
10 *the Secretary determines that labeling changes are ap-*
11 *propriate, such changes are made within the time-*
12 *frame requested by the Secretary—”;* and

13 *(K) by adding at the end the following:*

14 *“(2) EXCEPTION.—The Secretary shall not ex-*
15 *tend a period referred to in paragraph (1)(A) or in*
16 *paragraph (1)(B) later than 9 months prior to the ex-*
17 *piration of such period.”;*

18 *(4) by striking subsection (d) and inserting the*
19 *following:*

20 *“(d) CONDUCT OF PEDIATRIC STUDIES.—*

21 *“(1) REQUEST FOR STUDIES.—*

22 *“(A) IN GENERAL.—The Secretary may,*
23 *after consultation with the sponsor of an appli-*
24 *cation for an investigational new drug under*
25 *section 505(i), the sponsor of an application for*

1 *a new drug under section 505(b)(1), or the holder*
 2 *of an approved application for a drug under sec-*
 3 *tion 505(b)(1), issue to the sponsor or holder a*
 4 *written request for the conduct of pediatric stud-*
 5 *ies for such drug. In issuing such request, the*
 6 *Secretary shall take into account adequate rep-*
 7 *resentation of children of ethnic and racial mi-*
 8 *norities. Such request to conduct pediatric stud-*
 9 *ies shall be in writing and shall include a time-*
 10 *frame for such studies and a request to the spon-*
 11 *sor or holder to propose pediatric labeling result-*
 12 *ing from such studies.*

13 “(B) *SINGLE WRITTEN REQUEST.*—*A single*
 14 *written request—*

15 “(i) *may relate to more than 1 use of*
 16 *a drug; and*

17 “(ii) *may include uses that are both*
 18 *approved and unapproved.*

19 “(2) *WRITTEN REQUEST FOR PEDIATRIC STUD-*
 20 *IES.*—

21 “(A) *REQUEST AND RESPONSE.*—

22 “(i) *IN GENERAL.*—*If the Secretary*
 23 *makes a written request for pediatric stud-*
 24 *ies (including neonates, as appropriate)*
 25 *under subsection (b) or (c), the applicant or*

1 holder, not later than 180 days after receiv-
2 ing the written request, shall respond to the
3 Secretary as to the intention of the appli-
4 cant or holder to act on the request by—

5 “(I) indicating when the pediatric
6 studies will be initiated, if the appli-
7 cant or holder agrees to the request; or

8 “(II) indicating that the appli-
9 cant or holder does not agree to the re-
10 quest and the reasons for declining the
11 request.

12 “(ii) *DISAGREE WITH REQUEST.*—If,
13 on or after the date of enactment of the *Best*
14 *Pharmaceuticals for Children Amendments*
15 *of 2007*, the applicant or holder does not
16 agree to the request on the grounds that it
17 is not possible to develop the appropriate
18 pediatric formulation, the applicant or
19 holder shall submit to the Secretary the rea-
20 sons such pediatric formulation cannot be
21 developed.

22 “(B) *ADVERSE EVENT REPORTS.*—An ap-
23 plicant or holder that, on or after the date of en-
24 actment of the *Best Pharmaceuticals for Children*
25 *Amendments of 2007*, agrees to the request for

1 *such studies shall provide the Secretary, at the*
2 *same time as submission of the reports of such*
3 *studies, with all postmarket adverse event reports*
4 *regarding the drug that is the subject of such*
5 *studies and are available prior to submission of*
6 *such reports.*

7 “(3) *MEETING THE STUDIES REQUIREMENT.—*
8 *Not later than 180 days after the submission of the*
9 *reports of the studies, the Secretary shall accept or re-*
10 *ject such reports and so notify the sponsor or holder.*
11 *The Secretary’s only responsibility in accepting or re-*
12 *jecting the reports shall be to determine, within the*
13 *180 days, whether the studies fairly respond to the*
14 *written request, have been conducted in accordance*
15 *with commonly accepted scientific principles and pro-*
16 *ocols, and have been reported in accordance with the*
17 *requirements of the Secretary for filing.*

18 “(4) *EFFECT OF SUBSECTION.—Nothing in this*
19 *subsection alters or amends section 301(j) of this Act*
20 *or section 552 of title 5 or section 1905 of title 18,*
21 *United States Code.”;*

22 (5) *by striking subsections (e) and (f) and insert-*
23 *ing the following:*

24 “(e) *NOTICE OF DETERMINATIONS ON STUDIES RE-*
25 *QUIREMENT.—*

1 “(1) *IN GENERAL.*—*The Secretary shall publish*
2 *a notice of any determination, made on or after the*
3 *date of enactment of the Best Pharmaceuticals for*
4 *Children Amendments of 2007, that the requirements*
5 *of subsection (d) have been met and that submissions*
6 *and approvals under subsection (b)(2) or (j) of section*
7 *505 for a drug will be subject to the provisions of this*
8 *section. Such notice shall be published not later than*
9 *30 days after the date of the Secretary’s determina-*
10 *tion regarding market exclusivity and shall include a*
11 *copy of the written request made under subsection (b)*
12 *or (c).*

13 “(2) *IDENTIFICATION OF CERTAIN DRUGS.*—*The*
14 *Secretary shall publish a notice identifying any drug*
15 *for which, on or after the date of enactment of the*
16 *Best Pharmaceuticals for Children Amendments of*
17 *2007, a pediatric formulation was developed, studied,*
18 *and found to be safe and effective in the pediatric*
19 *population (or specified subpopulation) if the pedi-*
20 *atric formulation for such drug is not introduced onto*
21 *the market within 1 year of the date that the Sec-*
22 *retary publishes the notice described in paragraph*
23 *(1). Such notice identifying such drug shall be pub-*
24 *lished not later than 30 days after the date of the ex-*
25 *piration of such 1 year period.*

1 “(f) *INTERNAL REVIEW OF WRITTEN REQUESTS AND*
2 *PEDIATRIC STUDIES.*—

3 “(1) *INTERNAL REVIEW.*—

4 “(A) *IN GENERAL.*—*The Secretary shall cre-*
5 *ate an internal review committee to review all*
6 *written requests issued and all reports submitted*
7 *on or after the date of enactment of the Best*
8 *Pharmaceuticals for Children Amendments of*
9 *2007, in accordance with paragraphs (2) and*
10 *(3).*

11 “(B) *MEMBERS.*—*The committee under sub-*
12 *paragraph (A) shall include individuals, each of*
13 *whom is an employee of the Food and Drug Ad-*
14 *ministration, with the following expertise:*

15 “(i) *Pediatrics.*

16 “(ii) *Biopharmacology.*

17 “(iii) *Statistics.*

18 “(iv) *Drugs and drug formulations.*

19 “(v) *Legal issues.*

20 “(vi) *Appropriate expertise pertaining*
21 *to the pediatric product under review.*

22 “(vii) *One or more experts from the Of-*
23 *fice of Pediatric Therapeutics, including an*
24 *expert in pediatric ethics.*

1 “(viii) *Other individuals as designated*
2 *by the Secretary.*

3 “(2) *REVIEW OF WRITTEN REQUESTS.—All writ-*
4 *ten requests under this section shall be reviewed and*
5 *approved by the committee established under para-*
6 *graph (1) prior to being issued.*

7 “(3) *REVIEW OF PEDIATRIC STUDIES.—The com-*
8 *mittee established under paragraph (1) shall review*
9 *all studies conducted pursuant to this section to deter-*
10 *mine whether to accept or reject such reports under*
11 *subsection (d)(3).*

12 “(4) *TRACKING PEDIATRIC STUDIES AND LABEL-*
13 *ING CHANGES.—The committee established under*
14 *paragraph (1) shall be responsible for tracking and*
15 *making available to the public, in an easily accessible*
16 *manner, including through posting on the website of*
17 *the Food and Drug Administration—*

18 “(A) *the number of studies conducted under*
19 *this section;*

20 “(B) *the specific drugs and drug uses, in-*
21 *cluding labeled and off-labeled indications, stud-*
22 *ied under this section;*

23 “(C) *the types of studies conducted under*
24 *this section, including trial design, the number*

1 *of pediatric patients studied, and the number of*
2 *centers and countries involved;*

3 “(D) *the number of pediatric formulations*
4 *developed and the number of pediatric formula-*
5 *tions not developed and the reasons such formu-*
6 *lations were not developed;*

7 “(E) *the labeling changes made as a result*
8 *of studies conducted under this section;*

9 “(F) *an annual summary of labeling*
10 *changes made as a result of studies conducted*
11 *under this section for distribution pursuant to*
12 *subsection (k)(2); and*

13 “(G) *information regarding reports sub-*
14 *mitted on or after the date of enactment of the*
15 *Best Pharmaceuticals for Children Amendments*
16 *of 2007.”;*

17 (6) *in subsection (g)—*

18 (A) *in paragraph (1)—*

19 (i) *by striking “(c)(1)(A)(ii)” and in-*
20 *serting “(c)(1)(A)(i)(II)”;* and

21 (ii) *by striking “(c)(2)” and inserting*
22 *“(c)(1)(B)”;*

23 (B) *in paragraph (2), by striking*
24 *“(c)(1)(B)” and inserting “(c)(1)(A)(ii)”;*

1 (C) by redesignating paragraphs (1) and
2 (2) as subparagraphs (A) and (B), respectively;
3 (D) by striking “LIMITATIONS.—A drug”
4 and inserting “LIMITATIONS.—
5 “(1) IN GENERAL.—Notwithstanding subsection
6 (c)(2), a drug”; and

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

8 “(2) EXCLUSIVITY ADJUSTMENT.—

9 “(A) ADJUSTMENT.—

10 “(i) IN GENERAL.—With respect to any
11 drug, if the organization designated under
12 subparagraph (B) notifies the Secretary
13 that the combined annual gross sales for all
14 drugs with the same active moiety exceeded
15 \$1,000,000,000 in any calendar year prior
16 to the time the sponsor or holder agrees to
17 the initial written request pursuant to sub-
18 section (d)(2), then each period of market
19 exclusivity deemed or extended under sub-
20 section (b) or (c) shall be reduced by 3
21 months for such drug.

22 “(ii) DETERMINATION.—The deter-
23 mination under clause (i) of the combined
24 annual gross sales shall be determined—

1 “(I) taking into account only
2 those sales within the United States;
3 and

4 “(II) taking into account only the
5 sales of all drugs with the same active
6 moiety of the sponsor or holder and its
7 affiliates.

8 “(B) DESIGNATION.—The Secretary shall
9 designate an organization other than the Food
10 and Drug Administration to evaluate whether
11 the combined annual gross sales for all drugs
12 with the same active moiety exceeded
13 \$1,000,000,000 in a calendar year as described
14 in subparagraph (A). Prior to designating such
15 organization, the Secretary shall determine that
16 such organization is independent and is quali-
17 fied to evaluate the sales of pharmaceutical prod-
18 ucts. The Secretary shall re-evaluate the designa-
19 tion of such organization once every 3 years.

20 “(C) NOTIFICATION.—Once a year at a time
21 designated by the Secretary, the organization
22 designated under subparagraph (B) shall notify
23 the Food and Drug Administration of all drugs
24 with the same active moiety with combined an-

1 *nual gross sales that exceed \$1,000,000,000 dur-*
2 *ing the previous calendar year.”;*

3 *(7) in subsection (i)—*

4 *(A) in the heading, by striking “SUPPLE-*
5 *MENTS” and inserting “CHANGES”;*

6 *(B) in paragraph (1)—*

7 *(i) in the heading, by inserting “AP-*
8 *PLICATIONS AND” after “PEDIATRIC”;*

9 *(ii) by inserting “application or” after*
10 *“Any”;*

11 *(iii) by striking “change pursuant to a*
12 *report on a pediatric study under” and in-*
13 *serting “change as a result of any pediatric*
14 *study conducted pursuant to”; and*

15 *(iv) by inserting “application or” after*
16 *“to be a priority”; and*

17 *(C) in paragraph (2)(A), by—*

18 *(i) striking “If the Commissioner” and*
19 *inserting “If, on or after the date of enact-*
20 *ment of the Best Pharmaceuticals for Chil-*
21 *dren Amendments of 2007, the Commis-*
22 *sioner”; and*

23 *(ii) striking “an application with”*
24 *and all that follows through “on appro-*
25 *priate” and inserting “the sponsor and the*

1 Commissioner have been unable to reach
2 agreement on appropriate”;

3 (8) by striking subsection (m);

4 (9) by redesignating subsections (j), (k), (l), and
5 (n), as subsections (k), (m), (o), and (p), respectively;

6 (10) by inserting after subsection (i) the fol-
7 lowing:

8 “(j) *OTHER LABELING CHANGES.—If, on or after the*
9 *date of enactment of the Best Pharmaceuticals for Children*
10 *Amendments of 2007, the Secretary determines that a pedi-*
11 *atric study conducted under this section does or does not*
12 *demonstrate that the drug that is the subject of the study*
13 *is safe and effective, including whether such study results*
14 *are inconclusive, in pediatric populations or subpopula-*
15 *tions, the Secretary shall order the labeling of such product*
16 *to include information about the results of the study and*
17 *a statement of the Secretary’s determination.”;*

18 (11) in subsection (k), as redesignated by para-
19 graph (9)—

20 (A) in paragraph (1)—

21 (i) by striking “a summary of the med-
22 ical and” and inserting “the medical, sta-
23 tistical, and”; and

1 (ii) by striking “for the supplement”
2 and all that follows through the period and
3 inserting “under subsection (b) or (c).”;

4 (B) by redesignating paragraph (2) as
5 paragraph (3); and

6 (C) by inserting after paragraph (1) the fol-
7 lowing:

8 “(2) *DISSEMINATION OF INFORMATION REGARD-*
9 *ING LABELING CHANGES.—Beginning on the date of*
10 *enactment of the Best Pharmaceuticals for Children*
11 *Amendments of 2007, the Secretary shall require that*
12 *the sponsors of the studies that result in labeling*
13 *changes that are reflected in the annual summary de-*
14 *veloped pursuant to subsection (f)(4)(F) distribute, at*
15 *least annually (or more frequently if the Secretary de-*
16 *termines that it would be beneficial to the public*
17 *health), such information to physicians and other*
18 *health care providers.”;*

19 (12) by inserting after subsection (k), as redesign-
20 ated by paragraph (9), the following:

21 “(l) *ADVERSE EVENT REPORTING.—*

22 “(1) *REPORTING IN YEAR ONE.—Beginning on*
23 *the date of enactment of the Best Pharmaceuticals for*
24 *Children Amendments of 2007, during the 1-year pe-*
25 *riod beginning on the date a labeling change is made*

1 *pursuant to subsection (i), the Secretary shall ensure*
2 *that all adverse event reports that have been received*
3 *for such drug (regardless of when such report was re-*
4 *ceived) are referred to the Office of Pediatric Thera-*
5 *peutics established under section 6 of the Best Phar-*
6 *maceuticals for Children Act (Public Law 107–109).*
7 *In considering such reports, the Director of such Of-*
8 *fice shall provide for the review of the report by the*
9 *Pediatric Advisory Committee, including obtaining*
10 *any recommendations of such Committee regarding*
11 *whether the Secretary should take action under this*
12 *section in response to such reports.*

13 *“(2) REPORTING IN SUBSEQUENT YEARS.—Fol-*
14 *lowing the 1-year period described in paragraph (1),*
15 *the Secretary shall, as appropriate, refer to the Office*
16 *of Pediatric Therapeutics all pediatric adverse event*
17 *reports for a drug for which a pediatric study was*
18 *conducted under this section. In considering such re-*
19 *ports, the Director of such Office may provide for the*
20 *review of such reports by the Pediatric Advisory Com-*
21 *mittee, including obtaining any recommendation of*
22 *such Committee regarding whether the Secretary*
23 *should take action in response to such reports.*

1 “(3) *EFFECT.*—*The requirements of this sub-*
2 *section shall supplement, not supplant, other review of*
3 *such adverse event reports by the Secretary.*”;

4 (13) *by inserting after subsection (m), as redesign-*
5 *ated by paragraph (9), the following:*

6 “(n) *REFERRAL IF PEDIATRIC STUDIES NOT COM-*
7 *PLETED.*—

8 “(1) *IN GENERAL.*—*Beginning on the date of en-*
9 *actment of the Best Pharmaceuticals for Children*
10 *Amendments of 2007, if pediatric studies of a drug*
11 *have not been completed under subsection (d) and if*
12 *the Secretary, through the committee established*
13 *under subsection (f), determines that there is a con-*
14 *tinuing need for information relating to the use of the*
15 *drug in the pediatric population (including neonates,*
16 *as appropriate), the Secretary shall carry out the fol-*
17 *lowing:*

18 “(A) *For a drug for which a listed patent*
19 *has not expired, make a determination regarding*
20 *whether an assessment shall be required to be*
21 *submitted under section 505B. Prior to making*
22 *such determination, the Secretary may take not*
23 *more than 60 days to certify whether the Foun-*
24 *dation for the National Institutes of Health has*
25 *sufficient funding at the time of such certifi-*

1 *cation to initiate 1 or more of the pediatric stud-*
2 *ies of such drug referred to in the sentence pre-*
3 *ceding this paragraph and fund 1 or more of*
4 *such studies in their entirety. Only if the Sec-*
5 *retary makes such certification in the affirma-*
6 *tive, the Secretary shall refer such pediatric*
7 *study or studies to the Foundation for the Na-*
8 *tional Institutes of Health for the conduct of*
9 *such study or studies.*

10 *“(B) For a drug that has no listed patents*
11 *or has 1 or more listed patents that have expired,*
12 *the Secretary shall refer the drug for inclusion*
13 *on the list established under section 409I of the*
14 *Public Health Service Act for the conduct of*
15 *studies.*

16 *“(2) PUBLIC NOTICE.—The Secretary shall give*
17 *the public notice of—*

18 *“(A) a decision under paragraph (1)(A) not*
19 *to require an assessment under section 505B and*
20 *the basis for such decision; and*

21 *“(B) any referral under paragraph (1)(B)*
22 *of a drug for inclusion on the list established*
23 *under section 409I of the Public Health Service*
24 *Act.*

1 “(3) *EFFECT OF SUBSECTION.*—*Nothing in this*
 2 *subsection alters or amends section 301(j) of this Act*
 3 *or section 552 of title 5 or section 1905 of title 18,*
 4 *United States Code.”; and*

5 (14) *in subsection (p), as redesignated by para-*
 6 *graph (9)—*

7 (A) *striking “6-month period” and insert-*
 8 *ing “3-month or 6-month period”;*

9 (B) *by striking “subsection (a)” and insert-*
 10 *ing “subsection (b)”;* and

11 (C) *by striking “2007” both places it ap-*
 12 *pears and inserting “2012”.*

13 (b) *EFFECTIVE DATE.*—*Except as otherwise provided*
 14 *in the amendments made by subsection (a), such amend-*
 15 *ments shall apply to written requests under section 505A*
 16 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 17 *355a) made after the date of enactment of this subtitle.*

18 **SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

19 *Section 409I of the Public Health Service Act (42*
 20 *U.S.C. 284m) is amended—*

21 (1) *by striking subsections (a) and (b) and in-*
 22 *serting the following:*

23 “(a) *LIST OF PRIORITY ISSUES IN PEDIATRIC THERA-*
 24 *PEUTICS.*—

1 “(1) *IN GENERAL.*—Not later than 1 year after
2 the date of enactment of the *Best Pharmaceuticals for*
3 *Children Amendments of 2007*, the Secretary, acting
4 through the Director of the National Institutes of
5 Health and in consultation with the Commissioner of
6 Food and Drugs and experts in pediatric research,
7 shall develop and publish a priority list of needs in
8 pediatric therapeutics, including drugs or indications
9 that require study. The list shall be revised every 3
10 years.

11 “(2) *CONSIDERATION OF AVAILABLE INFORMA-*
12 *TION.*—In developing and prioritizing the list under
13 paragraph (1), the Secretary shall consider—

14 “(A) therapeutic gaps in pediatrics that
15 may include developmental pharmacology,
16 pharmacogenetic determinants of drug response,
17 metabolism of drugs and biologics in children,
18 and pediatric clinical trials;

19 “(B) particular pediatric diseases, disorders
20 or conditions where more complete knowledge
21 and testing of therapeutics, including drugs and
22 biologics, may be beneficial in pediatric popu-
23 lations; and

24 “(C) the adequacy of necessary infrastruc-
25 ture to conduct pediatric pharmacological re-

1 *search, including research networks and trained*
2 *pediatric investigators.*

3 “(b) *PEDIATRIC STUDIES AND RESEARCH.*—*The Sec-*
4 *retary, acting through the National Institutes of Health,*
5 *shall award funds to entities that have the expertise to con-*
6 *duct pediatric clinical trials or other research (including*
7 *qualified universities, hospitals, laboratories, contract re-*
8 *search organizations, practice groups, federally funded pro-*
9 *grams such as pediatric pharmacology research units, other*
10 *public or private institutions, or individuals) to enable the*
11 *entities to conduct the drug studies or other research on the*
12 *issues described in subsection (a). The Secretary may use*
13 *contracts, grants, or other appropriate funding mechanisms*
14 *to award funds under this subsection.”;*

15 (2) *in subsection (c)*—

16 (A) *in the heading, by striking “CON-*
17 *TRACTS” and inserting “PROPOSED PEDIATRIC*
18 *STUDY REQUESTS”;*

19 (B) *by striking paragraphs (4) and (12);*

20 (C) *by redesignating paragraphs (1), (2),*
21 *and (3), as paragraphs (2), (3), and (4);*

22 (D) *by inserting before paragraph (2), as*
23 *redesignated by subparagraph (C), the following:*

24 “(1) *SUBMISSION OF PROPOSED PEDIATRIC*
25 *STUDY REQUEST.*—*The Director of the National Insti-*

1 *tutes of Health shall, as appropriate, submit proposed*
2 *pediatric study requests for consideration by the Com-*
3 *missioner of Food and Drugs for pediatric studies of*
4 *a specific pediatric indication identified under sub-*
5 *section (a). Such a proposed pediatric study request*
6 *shall be made in a manner equivalent to a written re-*
7 *quest made under subsection (b) or (c) of section 505A*
8 *of the Federal Food, Drug, and Cosmetic Act, includ-*
9 *ing with respect to the information provided on the*
10 *pediatric studies to be conducted pursuant to the re-*
11 *quest. The Director of the National Institutes of*
12 *Health may submit a proposed pediatric study re-*
13 *quest for a drug for which—*

14 *“(A)(i) there is an approved application*
15 *under section 505(j) of the Federal Food, Drug,*
16 *and Cosmetic Act; or*

17 *“(i) there is a submitted application that*
18 *could be approved under the criteria of section*
19 *505(j) of the Federal Food, Drug, and Cosmetic*
20 *Act;*

21 *“(B) there is no patent protection or market*
22 *exclusivity protection for at least 1 form of the*
23 *drug under the Federal Food, Drug, and Cos-*
24 *metic Act; and*

1 “(C) additional studies are needed to assess
2 the safety and effectiveness of the use of the drug
3 in the pediatric population.”;

4 (E) in paragraph (2), as redesignated by
5 subparagraph (C)—

6 (i) by inserting “based on the proposed
7 pediatric study request for the indication or
8 indications submitted pursuant to para-
9 graph (1)” after “issue a written request”;

10 (ii) by striking “in the list described in
11 subsection (a)(1)(A) (except clause (iv))”
12 and inserting “under subsection (a)”;

13 (iii) by inserting “and using appro-
14 priate formulations for each age group for
15 which the study is requested” before the pe-
16 riod at the end;

17 (F) in paragraph (3), as redesignated by
18 subparagraph (C)—

19 (i) in the heading, by striking “CON-
20 TRACT”;

21 (ii) by striking “paragraph (1)” and
22 inserting “paragraph (2)”;

23 (iii) by striking “or if a referral de-
24 scribed in subsection (a)(1)(A)(iv) is
25 made,”;

1 (iv) by striking “for contract pro-
2 posals” and inserting “for proposals”; and

3 (v) by inserting “in accordance with
4 subsection (b)” before the period at the end;

5 (G) in paragraph (4), as redesignated by
6 subparagraph (C)—

7 (i) by striking “contract”; and

8 (ii) by striking “paragraph (2)” and
9 inserting “paragraph (3)”; and

10 (H) in paragraph (5)—

11 (i) by striking the heading and insert-
12 ing “CONTRACTS, GRANTS, OR OTHER
13 FUNDING MECHANISMS”; and

14 (ii) by striking “A contract” and all
15 that follows through “is submitted” and in-
16 serting “A contract, grant, or other funding
17 may be awarded under this section only if
18 a proposal is submitted”;

19 (I) in paragraph (6)(A)—

20 (i) by striking “a contract awarded”
21 and inserting “an award”; and

22 (ii) by inserting “, including a written
23 request if issued” after “with the study”;
24 and

1 (3) *by inserting after subsection (c) the fol-*
2 *lowing:*

3 “(d) *DISSEMINATION OF PEDIATRIC INFORMATION.—*
4 *Not later than 1 year after the date of enactment of the*
5 *Best Pharmaceuticals for Children Amendments of 2007,*
6 *the Secretary, acting through the Director of the National*
7 *Institutes of Health, shall study the feasibility of estab-*
8 *lishing a compilation of information on pediatric drug use*
9 *and report the findings to Congress.”*

10 “(e) *AUTHORIZATION OF APPROPRIATIONS.—*

11 “(1) *IN GENERAL.—There are authorized to be*
12 *appropriated to carry out this section—*

13 “(A) *\$200,000,000 for fiscal year 2008; and*

14 “(B) *such sums as are necessary for each of*
15 *the 4 succeeding fiscal years.*

16 “(2) *AVAILABILITY.—Any amount appropriated*
17 *under paragraph (1) shall remain available to carry*
18 *out this section until expended.”.*

19 **SEC. 404. REPORTS AND STUDIES.**

20 “(a) *GAO REPORT.—Not later than January 31, 2011,*
21 *the Comptroller General of the United States, in consulta-*
22 *tion with the Secretary of Health and Human Services,*
23 *shall submit to Congress a report that addresses the effec-*
24 *tiveness of section 505A of the Federal Food, Drug, and Cos-*

1 *metic Act (21 U.S.C. 355a) in ensuring that medicines used*
2 *by children are tested and properly labeled, including—*

3 (1) *the number and importance of drugs for chil-*
4 *dren that are being tested as a result of the amend-*
5 *ments made by this subtitle and the importance for*
6 *children, health care providers, parents, and others of*
7 *labeling changes made as a result of such testing;*

8 (2) *the number and importance of drugs for chil-*
9 *dren that are not being tested for their use notwith-*
10 *standing the provisions of this subtitle and the*
11 *amendments made by this subtitle, and possible rea-*
12 *sons for the lack of testing, including whether the*
13 *number of written requests declined by sponsors or*
14 *holders of drugs subject to section 505A(g)(2) of the*
15 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
16 *355a(g)(2)), has increased or decreased as a result of*
17 *the amendments made by this subtitle;*

18 (3) *the number of drugs for which testing is*
19 *being done and labeling changes required, including*
20 *the date labeling changes are made and which label-*
21 *ing changes required the use of the dispute resolution*
22 *process established pursuant to the amendments made*
23 *by this subtitle, together with a description of the out-*
24 *comes of such process, including a description of the*

1 *disputes and the recommendations of the Pediatric*
2 *Advisory Committee;*

3 *(4) any recommendations for modifications to*
4 *the programs established under section 505A of the*
5 *Federal Food, Drug and Cosmetic Act (21 U.S.C.*
6 *355a) and section 409I of the Public Health Service*
7 *Act (42 U.S.C. 284m) that the Secretary determines*
8 *to be appropriate, including a detailed rationale for*
9 *each recommendation; and*

10 *(5)(A) the efforts made by the Secretary to in-*
11 *crease the number of studies conducted in the neonate*
12 *population; and*

13 *(B) the results of those efforts, including efforts*
14 *made to encourage the conduct of appropriate studies*
15 *in neonates by companies with products that have*
16 *sufficient safety and other information to make the*
17 *conduct of the studies ethical and safe.*

18 *(b) IOM STUDY.—Not later than 3 years after the date*
19 *of enactment of this subtitle, the Secretary of Health and*
20 *Human Services shall enter into a contract with the Insti-*
21 *tute of Medicine to conduct a study and report to Congress*
22 *regarding the written requests made and the studies con-*
23 *ducted pursuant to section 505A of the Federal Food, Drug,*
24 *and Cosmetic Act. The Institute of Medicine may devise an*
25 *appropriate mechanism to review a representative sample*

1 *of requests made and studies conducted pursuant to such*
 2 *section in order to conduct such study. Such study shall—*

3 (1) *review such representative written requests*
 4 *issued by the Secretary since 1997 under subsections*
 5 *(b) and (c) of such section 505A;*

6 (2) *review and assess such representative pedi-*
 7 *atric studies conducted under such subsections (b) and*
 8 *(c) since 1997 and labeling changes made as a result*
 9 *of such studies; and*

10 (3) *review the use of extrapolation for pediatric*
 11 *subpopulations, the use of alternative endpoints for*
 12 *pediatric populations, neonatal assessment tools, and*
 13 *ethical issues in pediatric clinical trials.*

14 **SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

15 (a) *INVESTMENT IN TOMORROW'S PEDIATRIC RE-*
 16 *SEARCHERS.*—*Section 452G(2) of the Public Health Service*
 17 *Act (42 U.S.C. 285g–10(2)) is amended by adding before*
 18 *the period at the end the following: “, including pediatric*
 19 *pharmacological research”.*

20 (b) *PEDIATRIC RESEARCH LOAN REPAYMENT PRO-*
 21 *GRAM.*—*Section 487F(a)(1) of the Public Health Service*
 22 *Act (42 U.S.C. 288–6(a)(1)) is amended by inserting “in-*
 23 *cluding pediatric pharmacological research,” after “pedi-*
 24 *atric research,”.*

1 **SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTES OF**
 2 **HEALTH.**

3 *Section 499(c)(1)(C) of the Public Health Service Act*
 4 *(42 U.S.C. 290b(c)(1)(C)) is amended by striking “and*
 5 *studies listed by the Secretary pursuant to section*
 6 *409I(a)(1)(A) of the is Act and referred under section*
 7 *505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act*
 8 *(21 U.S.C. 355(a)(d)(4)(C))” and inserting “and studies for*
 9 *which the Secretary issues a certification under section*
 10 *505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act*
 11 *(21 U.S.C. 355a(n)(1)(A))”.*

12 **SEC. 407. CONTINUATION OF OPERATION OF COMMITTEE.**

13 *Section 14 of the Best Pharmaceuticals for Children*
 14 *Act (42 U.S.C. 284m note) is amended by adding at the*
 15 *end the following:*

16 *“(d) CONTINUATION OF OPERATION OF COMMITTEE.—*
 17 *Notwithstanding section 14 of the Federal Advisory Com-*
 18 *mittee Act (5 U.S.C. App.), the advisory committee shall*
 19 *continue to operate during the 5-year period beginning on*
 20 *the date of enactment of the Best Pharmaceuticals for Chil-*
 21 *dren Amendments of 2007.”.*

22 **SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**
 23 **DRUGS ADVISORY COMMITTEE.**

24 *Section 15 of the Best Pharmaceuticals for Children*
 25 *Act (42 U.S.C. 284m note) is amended—*

26 *(1) in subsection (a)—*

- 1 (A) in paragraph (1)—
- 2 (i) in subparagraph (B), by striking
- 3 “and” after the semicolon;
- 4 (ii) in subparagraph (C), by striking
- 5 the period at the end and inserting “; and”;
- 6 and
- 7 (iii) by adding at the end the fol-
- 8 lowing:
- 9 “(D) provide recommendations to the inter-
- 10 nal review committee created under section
- 11 505A(f) of the Federal Food, Drug, and Cosmetic
- 12 Act (21 U.S.C. 355a(f)) regarding the implemen-
- 13 tation of amendments to sections 505A and 505B
- 14 of the Federal Food, Drug, and Cosmetic Act (21
- 15 U.S.C. 355a and 355c) with respect to the treat-
- 16 ment of pediatric cancers.”; and
- 17 (B) by adding at the end the following:
- 18 “(3) CONTINUATION OF OPERATION OF SUB-
- 19 COMMITTEE.—Notwithstanding section 14 of the Fed-
- 20 eral Advisory Committee Act (5 U.S.C. App.), the
- 21 Subcommittee shall continue to operate during the 5-
- 22 year period beginning on the date of enactment of the
- 23 Best Pharmaceuticals for Children Amendments of
- 24 2007.”; and

1 (2) *in subsection (d), by striking “2003” and in-*
2 *serting “2009”.*

3 **SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RE-**
4 **LATING TO TOLL-FREE NUMBER FOR AD-**
5 **VERSE EVENTS ON LABELING FOR HUMAN**
6 **DRUG PRODUCTS.**

7 (a) *IN GENERAL.*—*Notwithstanding subchapter II of*
8 *chapter 5, and chapter 7, of title 5, United States Code*
9 *(commonly known as the “Administrative Procedure Act”)*
10 *and any other provision of law, the proposed rule issued*
11 *by the Commissioner of Food and Drugs entitled “Toll-Free*
12 *Number for Reporting Adverse Events on Labeling for*
13 *Human Drug Products”, 69 Fed. Reg. 21778, (April 22,*
14 *2004) shall take effect on January 1, 2008, unless such*
15 *Commissioner issues the final rule before such date.*

16 (b) *LIMITATION.*—*The proposed rule that takes effect*
17 *under subsection (a), or the final rule described under sub-*
18 *section (a), shall, notwithstanding section 17(a) of the Best*
19 *Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not*
20 *apply to a drug—*

21 (1) *for which an application is approved under*
22 *section 505 of the Federal Food, Drug, and Cosmetic*
23 *Act (21 U.S.C. 355);*

24 (2) *that is not described under section 503(b)(1)*
25 *of such Act (21 U.S.C. 353(b)(1)); and*

1 (3) *the packaging of which includes a toll-free*
 2 *number through which consumers can report com-*
 3 *plaints to the manufacturer or distributor of the drug.*

4 ***Subtitle B—Pediatric Research***
 5 ***Improvement***

6 **SEC. 411. SHORT TITLE.**

7 *This subtitle may be cited as the “Pediatric Research*
 8 *Improvement Act”.*

9 **SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPOLATIONS,**
 10 **AND DEFERRALS.**

11 *Section 505B(a) of the Federal Food, Drug, and Cos-*
 12 *metic Act (21 U.S.C. 355c(a)) is amended—*

13 (1) *in paragraph (4)(C), by adding at the end*
 14 *the following: “An applicant seeking either a partial*
 15 *or full waiver on this ground shall submit to the Sec-*
 16 *retary documentation detailing why a pediatric for-*
 17 *mulation cannot be developed, and, if the waiver is*
 18 *granted, the applicant’s submission shall promptly be*
 19 *made available to the public in an easily accessible*
 20 *manner, including through posting on the website of*
 21 *the Food and Drug Administration”;*

22 (2) *in paragraph (2)(B), by adding at the end*
 23 *the following:*

24 “(iii) **INFORMATION ON EXTRAPO-**
 25 **LATION.—***A brief documentation of the sci-*

1 *entific data supporting the conclusion under*
2 *clauses (i) and (ii) shall be included in any*
3 *pertinent reviews for the application under*
4 *section 505 or section 351 of the Public*
5 *Health Service Act.”; and*

6 *(3) by striking paragraph (3) and inserting the*
7 *following:*

8 *“(3) DEFERRAL.—*

9 *“(A) IN GENERAL.—On the initiative of the*
10 *Secretary or at the request of the applicant, the*
11 *Secretary may defer submission of some or all*
12 *assessments required under paragraph (1) until*
13 *a specified date after approval of the drug or*
14 *issuance of the license for a biological product*
15 *if—*

16 *“(i) the Secretary finds that—*

17 *“(I) the drug or biological product*
18 *is ready for approval for use in adults*
19 *before pediatric studies are complete;*

20 *“(II) pediatric studies should be*
21 *delayed until additional safety or effec-*
22 *tiveness data have been collected; or*

23 *“(III) there is another appro-*
24 *prate reason for deferral; and*

1 “(i) the applicant submits to the Sec-
2 retary—

3 “(I) certification of the grounds
4 for deferring the assessments;

5 “(II) a description of the planned
6 or ongoing studies;

7 “(III) evidence that the studies
8 are being conducted or will be con-
9 ducted with due diligence and at the
10 earliest possible time; and

11 “(IV) a timeline for the comple-
12 tion of such studies.

13 “(B) ANNUAL REVIEW.—

14 “(i) IN GENERAL.—On an annual
15 basis following the approval of a deferral
16 under subparagraph (A), the applicant
17 shall submit to the Secretary the following
18 information:

19 “(I) Information detailing the
20 progress made in conducting pediatric
21 studies.

22 “(II) If no progress has been made
23 in conducting such studies, evidence
24 and documentation that such studies

1 *will be conducted with due diligence*
2 *and at the earliest possible time.*

3 “(ii) *PUBLIC AVAILABILITY.—The in-*
4 *formation submitted through the annual re-*
5 *view under clause (i) shall promptly be*
6 *made available to the public in an easily*
7 *accessible manner, including through the*
8 *website of the Food and Drug Administra-*
9 *tion.”.*

10 **SEC. 413. IMPROVING AVAILABILITY OF PEDIATRIC DATA**
11 **FOR ALREADY MARKETED PRODUCTS.**

12 *Section 505B(b) of the Federal Food, Drug, and Cos-*
13 *metic Act (21 U.S.C. 355c(b)) is amended—*

14 *(1) by striking paragraph (1) and inserting the*
15 *following:*

16 “(1) *IN GENERAL.—After providing notice in the*
17 *form of a letter, or a written request under section*
18 *505A that was declined by the sponsor or holder, and*
19 *an opportunity for written response and a meeting,*
20 *which may include an advisory committee meeting,*
21 *the Secretary may (by order in the form of a letter)*
22 *require the sponsor or holder of an approved applica-*
23 *tion for a drug under section 505 or the holder of a*
24 *license for a biological product under section 351 of*
25 *the Public Health Service Act (42 U.S.C. 262) to sub-*

1 *mit by a specified date the assessments described in*
2 *subsection (a)(2) and the written request, as appro-*
3 *priate, if the Secretary finds that—*

4 *“(A)(i) the drug or biological product is*
5 *used for a substantial number of pediatric pa-*
6 *tients for the labeled indications; and*

7 *“(ii) adequate pediatric labeling could con-*
8 *fer a benefit on pediatric patients;*

9 *“(B) there is reason to believe that the drug*
10 *or biological product would represent a meaning-*
11 *ful therapeutic benefit over existing therapies for*
12 *pediatric patients for 1 or more of the claimed*
13 *indications; or*

14 *“(C) the absence of adequate pediatric label-*
15 *ing could pose a risk to pediatric patients.”;*

16 *(2) in paragraph (2)(C), by adding at the end*
17 *the following: “An applicant seeking either a partial*
18 *or full waiver shall submit to the Secretary docu-*
19 *mentation detailing why a pediatric formulation can-*
20 *not be developed, and, if the waiver is granted, the*
21 *applicant’s submission shall promptly be made avail-*
22 *able to the public in an easily accessible manner, in-*
23 *cluding through posting on the website of the Food*
24 *and Drug Administration.”; and*

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

3 “(3) *EFFECT OF SUBSECTION.*—Nothing in this
4 subsection alters or amends section 301(j) of this Act
5 or section 552 of title 5 or section 1905 of title 18,
6 United States Code.”.

7 **SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESSMENTS;**
8 **ADVERSE EVENT REPORTING; LABELING**
9 **CHANGES; AND PEDIATRIC ASSESSMENTS.**

10 Section 505B of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 355c) is amended—

12 (1) redesignating subsection (h) as subsection (j);

13 (2) in subsection (j), as so redesignated, by strik-
14 ing “505A(n)” and inserting “505A(p)”;

15 (3) by redesignating subsection (f) as subsection
16 (k);

17 (4) by redesignating subsection (g) as subsection
18 (l); and

19 (5) by inserting after subsection (e) the following:

20 “(f) *REVIEW OF PEDIATRIC ASSESSMENT REQUESTS,*
21 *PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.*—

22 “(1) *REVIEW.*—The Secretary shall create an in-
23 ternal committee to review all pediatric assessment
24 requests issued under this section, all pediatric assess-
25 ments conducted under this section, and all deferral

1 *and waiver requests made pursuant to this section.*
2 *Such internal committee shall include individuals,*
3 *each of whom is an employee of the Food and Drug*
4 *Administration, with the following expertise:*

5 *“(A) Pediatrics.*

6 *“(B) Biopharmacology.*

7 *“(C) Statistics.*

8 *“(D) Drugs and drug formulations.*

9 *“(E) Pediatric ethics.*

10 *“(F) Legal issues.*

11 *“(G) Appropriate expertise pertaining to*
12 *the pediatric product under review.*

13 *“(H) 1 or more experts from the Office of*
14 *Pediatric Therapeutics.*

15 *“(I) Other individuals as designated by the*
16 *Secretary.*

17 *“(2) REVIEW OF REQUESTS FOR PEDIATRIC AS-*
18 *SESSMENTS, DEFERRALS, AND WAIVERS.—All written*
19 *requests for a pediatric assessment issued pursuant to*
20 *this section and all requests for deferrals and waivers*
21 *from the requirement to conduct a pediatric assess-*
22 *ment under this section shall be reviewed and ap-*
23 *proved by the committee established under paragraph*
24 *(1).*

1 “(3) *REVIEW OF ASSESSMENTS.*—*The committee*
2 *established under paragraph (1) shall review all as-*
3 *sessments conducted under this section to determine*
4 *whether such assessments meet the requirements of*
5 *this section.*

6 “(4) *TRACKING OF ASSESSMENTS AND LABELING*
7 *CHANGES.*—*The committee established under para-*
8 *graph (1) is responsible for tracking and making pub-*
9 *lic in an easily accessible manner, including through*
10 *posting on the website of the Food and Drug Admin-*
11 *istration—*

12 “(A) *the number of assessments conducted*
13 *under this section;*

14 “(B) *the specific drugs and drug uses as-*
15 *essed under this section;*

16 “(C) *the types of assessments conducted*
17 *under this section, including trial design, the*
18 *number of pediatric patients studied, and the*
19 *number of centers and countries involved;*

20 “(D) *the total number of deferrals requested*
21 *and granted under this section, and, if granted,*
22 *the reasons for such deferrals, the timeline for*
23 *completion, and the number completed and pend-*
24 *ing by the specified date, as outlined in sub-*
25 *section (a)(3);*

1 “(E) the number of waivers requested and
2 granted under this section, and, if granted, the
3 reasons for the waivers;

4 “(F) the number of pediatric formulations
5 developed and the number of pediatric formula-
6 tions not developed and the reasons any such for-
7 mulations were not developed;

8 “(G) the labeling changes made as a result
9 of assessments conducted under this section;

10 “(H) an annual summary of labeling
11 changes made as a result of assessments con-
12 ducted under this section for distribution pursu-
13 ant to subsection (i)(2); and

14 “(I) an annual summary of the information
15 submitted pursuant to subsection (a)(3)(B).

16 “(g) LABELING CHANGES.—

17 “(1) PRIORITY STATUS FOR PEDIATRIC SUPPLE-
18 MENT.—Any supplement to an application under sec-
19 tion 505 and section 351 of the Public Health Service
20 Act proposing a labeling change as a result of any pe-
21 diatric assessments conducted pursuant to this sec-
22 tion—

23 “(A) shall be considered a priority supple-
24 ment; and

1 “(B) shall be subject to the performance
2 goals established by the Commissioner for pri-
3 ority drugs.

4 “(2) DISPUTE RESOLUTION.—

5 “(A) REQUEST FOR LABELING CHANGE AND
6 FAILURE TO AGREE.—If the Commissioner deter-
7 mines that a sponsor and the Commissioner have
8 been unable to reach agreement on appropriate
9 changes to the labeling for the drug that is the
10 subject of the application or supplement, not
11 later than 180 days after the date of the submis-
12 sion of the application or supplement—

13 “(i) the Commissioner shall request
14 that the sponsor make any labeling change
15 that the Commissioner determines to be ap-
16 propriate; and

17 “(ii) if the sponsor does not agree to
18 make a labeling change requested by the
19 Commissioner, the Commissioner shall refer
20 the matter to the Pediatric Advisory Com-
21 mittee.

22 “(B) ACTION BY THE PEDIATRIC ADVISORY
23 COMMITTEE.—Not later than 90 days after re-
24 ceiving a referral under subparagraph (A)(ii),
25 the Pediatric Advisory Committee shall—

1 “(i) review the pediatric study reports;

2 and

3 “(ii) make a recommendation to the
4 Commissioner concerning appropriate label-
5 ing changes, if any.

6 “(C) CONSIDERATION OF RECOMMENDA-
7 TIONS.—The Commissioner shall consider the
8 recommendations of the Pediatric Advisory Com-
9 mittee and, if appropriate, not later than 30
10 days after receiving the recommendation, make a
11 request to the sponsor of the application or sup-
12 plement to make any labeling changes that the
13 Commissioner determines to be appropriate.

14 “(D) MISBRANDING.—If the sponsor, within
15 30 days after receiving a request under subpara-
16 graph (C), does not agree to make a labeling
17 change requested by the Commissioner, the Com-
18 missioner may deem the drug that is the subject
19 of the application or supplement to be mis-
20 branded.

21 “(E) NO EFFECT ON AUTHORITY.—Nothing
22 in this subsection limits the authority of the
23 United States to bring an enforcement action
24 under this Act when a drug lacks appropriate
25 pediatric labeling. Neither course of action (the

1 *Pediatric Advisory Committee process or an en-*
2 *forcement action referred to in the preceding sen-*
3 *tence) shall preclude, delay, or serve as the basis*
4 *to stay the other course of action.*

5 “(3) *OTHER LABELING CHANGES.—If the Sec-*
6 *retary makes a determination that a pediatric assess-*
7 *ment conducted under this section does or does not*
8 *demonstrate that the drug that is the subject of such*
9 *assessment is safe and effective, including whether*
10 *such assessment results are inconclusive, in pediatric*
11 *populations or subpopulations, the Secretary shall*
12 *order the labeling of such product to include informa-*
13 *tion about the results of the assessment and a state-*
14 *ment of the Secretary’s determination.*

15 “(h) *DISSEMINATION OF PEDIATRIC INFORMATION.—*

16 “(1) *IN GENERAL.—Not later than 180 days*
17 *after the date of submission of a pediatric assessment*
18 *under this section, the Secretary shall make available*
19 *to the public in an easily accessible manner the med-*
20 *ical, statistical, and clinical pharmacology reviews of*
21 *such pediatric assessments and shall post such assess-*
22 *ments on the website of the Food and Drug Adminis-*
23 *tration.*

24 “(2) *DISSEMINATION OF INFORMATION REGARD-*
25 *ING LABELING CHANGES.—The Secretary shall require*

1 that the sponsors of the assessments that result in la-
2 beling changes that are reflected in the annual sum-
3 mary developed pursuant to subsection (f)(4)(H) dis-
4 tribute such information to physicians and other
5 health care providers.

6 “(3) *EFFECT OF SUBSECTION.*—Nothing in this
7 subsection shall alter or amend section 301(j) of this
8 Act or section 552 of title 5, United States Code, or
9 section 1905 of title 18, United States Code.

10 “(i) *ADVERSE EVENT REPORTING.*—

11 “(1) *REPORTING IN YEAR 1.*—During the 1-year
12 period beginning on the date a labeling change is
13 made pursuant to subsection (g), the Secretary shall
14 ensure that all adverse event reports that have been
15 received for such drug (regardless of when such report
16 was received) are referred to the Office of Pediatric
17 Therapeutics. In considering such reports, the Direc-
18 tor of such Office shall provide for the review of the
19 report by the Pediatric Advisory Committee, includ-
20 ing obtaining any recommendations of such com-
21 mittee regarding whether the Secretary should take
22 action under this Act in response to such report.

23 “(2) *REPORTING IN SUBSEQUENT YEARS.*—Fol-
24 lowing the 1-year period described in paragraph (1),
25 the Secretary shall, as appropriate, refer to the Office

1 *of Pediatric Therapeutics with all pediatric adverse*
2 *event reports for a drug for which a pediatric study*
3 *was conducted under this section. In considering such*
4 *reports, the Director of such Office may provide for*
5 *the review of such reports by the Pediatric Advisory*
6 *Committee, including obtaining any recommendation*
7 *of such Committee regarding whether the Secretary*
8 *should take action in response to such report.*

9 “(3) *EFFECT.*—*The requirements of this sub-*
10 *section shall supplement, not supplant, other review of*
11 *such adverse event reports by the Secretary.”.*

12 **SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.**

13 *Section 505B(c) of the Federal Food, Drug, and Cos-*
14 *metic Act (21 U.S.C. 355c) is amended—*

15 *(1) by striking “estimates” and inserting “deter-*
16 *mines”; and*

17 *(2) by striking “would” and inserting “could”.*

18 **SEC. 416. REPORTS.**

19 *(a) INSTITUTE OF MEDICINE STUDY.—*

20 *(1) IN GENERAL.—Not later than 3 years after*
21 *the date of enactment of this subtitle, the Secretary*
22 *shall contract with the Institute of Medicine to con-*
23 *duct a study and report to Congress regarding the pe-*
24 *diatric studies conducted pursuant to section 505B of*

1 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
2 *355c) since 1997.*

3 (2) *CONTENT OF STUDY.—The study under para-*
4 *graph (1) shall review and assess—*

5 (A) *pediatric studies conducted pursuant to*
6 *section 505B of the Federal Food, Drug, and*
7 *Cosmetic Act (21 U.S.C. 355c) since 1997 and*
8 *labeling changes made as a result of such studies;*
9 *and*

10 (B) *the use of extrapolation for pediatric*
11 *subpopulations, the use of alternative endpoints*
12 *for pediatric populations, neonatal assessment*
13 *tools, number and type of pediatric adverse*
14 *events, and ethical issues in pediatric clinical*
15 *trials.*

16 (3) *REPRESENTATIVE SAMPLE.—The Institute of*
17 *Medicine may devise an appropriate mechanism to*
18 *review a representative sample of studies conducted*
19 *pursuant to section 505B of the Federal Food, Drug,*
20 *and Cosmetic Act (21 U.S.C. 355c) from each review*
21 *division within the Center for Drug Evaluation and*
22 *Research and the Center for Biologics Evaluation and*
23 *Research in order to make the required assessment.*

24 (b) *GAO REPORT.—Not later than September 1, 2010,*
25 *the Comptroller General of the United States, in consulta-*

1 *tion with the Secretary of Health and Human Services,*
2 *shall submit to Congress a report that addresses the effec-*
3 *tiveness of section 505B of the Federal Food, Drug, and Cos-*
4 *metic Act (21 U.S.C. 355a) in ensuring that medicines used*
5 *by children are tested and properly labeled, including—*

6 (1) *the number and importance of drugs for chil-*
7 *dren that are being tested as a result of this provision*
8 *and the importance for children, health care pro-*
9 *viders, parents, and others of labeling changes made*
10 *as a result of such testing;*

11 (2) *the number and importance of drugs for chil-*
12 *dren that are not being tested for their use notwith-*
13 *standing the provisions of such section 505B, and*
14 *possible reasons for the lack of testing; and*

15 (3) *the number of drugs for which testing is*
16 *being done and labeling changes required, including*
17 *the date labeling changes are made and which label-*
18 *ing changes required the use of the dispute resolution*
19 *process established under such section 505B, together*
20 *with a description of the outcomes of such process, in-*
21 *cluding a description of the disputes and the rec-*
22 *ommendations of the Pediatric Advisory Committee.*

1 **SEC. 417. TECHNICAL CORRECTIONS.**

2 *Section 505B(a)(2)(B)(ii) of the Federal Food, Drug,*
3 *and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amended*
4 *by striking “one” and inserting “1”.*

5 ***Subtitle C—Pediatric Medical***
6 ***Devices***

7 **SEC. 421. SHORT TITLE.**

8 *This subtitle may be cited as the “Pediatric Medical*
9 *Device Safety and Improvement Act of 2007”.*

10 **SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.**

11 *Chapter V of the Federal Food, Drug, and Cosmetic*
12 *Act (21 U.S.C. 351 et seq.) is amended by inserting after*
13 *section 515 the following:*

14 **“SEC. 515A. PEDIATRIC USES OF DEVICES.**

15 **“(a) NEW DEVICES.—**

16 **“(1) IN GENERAL.—***A person that submits to the*
17 *Secretary an application under section 520(m), or an*
18 *application (or supplement to an application) or a*
19 *product development protocol under section 515, shall*
20 *include in the application or protocol the information*
21 *described in paragraph (2).*

22 **“(2) REQUIRED INFORMATION.—***The application*
23 *or protocol described in paragraph (1) shall include,*
24 *with respect to the device for which approval is sought*
25 *and if readily available—*

1 “(A) a description of any pediatric sub-
2 populations that suffer from the disease or condi-
3 tion that the device is intended to treat, diag-
4 nose, or cure; and

5 “(B) the number of affected pediatric pa-
6 tients.

7 “(3) ANNUAL REPORT.—Not later than 18
8 months after the date of enactment of this section, and
9 annually thereafter, the Secretary shall submit to the
10 Committee on Health, Education, Labor, and Pen-
11 sions of the Senate and the Committee on Energy and
12 Commerce of the House of Representatives a report
13 that includes—

14 “(A) the number of devices approved in the
15 year preceding the year in which the report is
16 submitted, for which there is a pediatric sub-
17 population that suffers from the disease or condi-
18 tion that the device is intended to treat, diag-
19 nose, or cure;

20 “(B) the number of devices approved in the
21 year preceding the year in which the report is
22 submitted, labeled for use in pediatric patients;

23 “(C) the number of pediatric devices ap-
24 proved in the year preceding the year in which

1 the report is submitted, exempted from a fee pur-
 2 suant to section 738(a)(2)(B)(v); and

3 “(D) the review time for each device de-
 4 scribed in subparagraphs (A), (B), and (C).

5 “(b) *DETERMINATION OF PEDIATRIC EFFECTIVENESS*
 6 *BASED ON SIMILAR COURSE OF DISEASE OR CONDITION*
 7 *OR SIMILAR EFFECT OF DEVICE ON ADULTS.—*

8 “(1) *IN GENERAL.—If the course of the disease or*
 9 *condition and the effects of the device are sufficiently*
 10 *similar in adults and pediatric patients, the Sec-*
 11 *retary may conclude that adult data may be used to*
 12 *support a determination of a reasonable assurance of*
 13 *effectiveness in pediatric populations, as appropriate.*

14 “(2) *EXTRAPOLATION BETWEEN SUBPOPULA-*
 15 *TIONS.—A study may not be needed in each pediatric*
 16 *subpopulation if data from one subpopulation can be*
 17 *extrapolated to another subpopulation.*

18 “(c) *PEDIATRIC SUBPOPULATION.—In this section, the*
 19 *term ‘pediatric subpopulation’ has the meaning given the*
 20 *term in section 520(m)(6)(E)(ii).”.*

21 **SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EX-**
 22 **EMPTION.**

23 (a) *IN GENERAL.—Section 520(m) of the Federal*
 24 *Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is*
 25 *amended—*

1 (1) *in paragraph (3), by striking “No” and in-*
2 *serting “Except as provided in paragraph (6), no”;*

3 (2) *in paragraph (5)—*

4 (A) *by inserting “, if the Secretary has rea-*
5 *son to believe that the requirements of paragraph*
6 *(6) are no longer met,” after “public health”;*
7 *and*

8 (B) *by adding at the end the following: “If*
9 *the person granted an exemption under para-*
10 *graph (2) fails to demonstrate continued compli-*
11 *ance with the requirements of this subsection, the*
12 *Secretary may suspend or withdraw the exemp-*
13 *tion from the effectiveness requirements of sec-*
14 *tions 514 and 515 for a humanitarian device*
15 *only after providing notice and an opportunity*
16 *for an informal hearing.”;*

17 (3) *by striking paragraph (6) and inserting the*
18 *following:*

19 “(6)(A) *Except as provided in subparagraph (D), the*
20 *prohibition in paragraph (3) shall not apply with respect*
21 *to a person granted an exemption under paragraph (2) if*
22 *each of the following conditions apply:*

23 “(i)(I) *The device with respect to which the ex-*
24 *emption is granted is intended for the treatment or*
25 *diagnosis of a disease or condition that occurs in pe-*

1 *diatric patients or in a pediatric subpopulation, and*
2 *such device is labeled for use in pediatric patients or*
3 *in a pediatric subpopulation in which the disease or*
4 *condition occurs.*

5 *“(II) The device was not previously approved*
6 *under this subsection for the pediatric patients or the*
7 *pediatric subpopulation described in subclause (I)*
8 *prior to the date of enactment of the Pediatric Med-*
9 *ical Device Safety and Improvement Act of 2007.*

10 *“(ii) During any calendar year, the number of*
11 *such devices distributed during that year does not ex-*
12 *ceed the annual distribution number specified by the*
13 *Secretary when the Secretary grants such exemption.*
14 *The annual distribution number shall be based on the*
15 *number of individuals affected by the disease or con-*
16 *dition that such device is intended to treat, diagnose,*
17 *or cure, and of that number, the number of individ-*
18 *uals likely to use the device, and the number of de-*
19 *vices reasonably necessary to treat such individuals.*
20 *In no case shall the annual distribution number ex-*
21 *ceed the number identified in paragraph (2)(A).*

22 *“(iii) Such person immediately notifies the Sec-*
23 *retary if the number of such devices distributed dur-*
24 *ing any calendar year exceeds the annual distribution*
25 *number referred to in clause (ii).*

1 “(iv) *The request for such exemption is submitted*
2 *on or before October 1, 2012.*

3 “(B) *The Secretary may inspect the records relating*
4 *to the number of devices distributed during any calendar*
5 *year of a person granted an exemption under paragraph*
6 *(2) for which the prohibition in paragraph (3) does not*
7 *apply.*

8 “(C) *A person may petition the Secretary to modify*
9 *the annual distribution number specified by the Secretary*
10 *under subparagraph (A)(ii) with respect to a device if addi-*
11 *tional information on the number of individuals affected*
12 *by the disease or condition arises, and the Secretary may*
13 *modify such number but in no case shall the annual dis-*
14 *tribution number exceed the number identified in para-*
15 *graph (2)(A).*

16 “(D) *If a person notifies the Secretary, or the Sec-*
17 *retary determines through an inspection under subpara-*
18 *graph (B), that the number of devices distributed during*
19 *any calendar year exceeds the annual distribution number,*
20 *as required under subparagraph (A)(iii), and modified*
21 *under subparagraph (C), if applicable, then the prohibition*
22 *in paragraph (3) shall apply with respect to such person*
23 *for such device for any sales of such device after such notifi-*
24 *cation.*

1 “(E)(i) In this subsection, the term ‘pediatric patients’
2 means patients who are 21 years of age or younger at the
3 time of the diagnosis or treatment.

4 “(ii) In this subsection, the term ‘pediatric subpopula-
5 tion’ means 1 of the following populations:

6 “(I) Neonates.

7 “(II) Infants.

8 “(III) Children.

9 “(IV) Adolescents.”; and

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

11 “(7) The Secretary shall refer any report of an adverse
12 event regarding a device for which the prohibition under
13 paragraph (3) does not apply pursuant to paragraph
14 (6)(A) that the Secretary receives to the Office of Pediatric
15 Therapeutics, established under section 6 of the Best Phar-
16 maceuticals for Children Act (Public Law 107–109)). In
17 considering the report, the Director of the Office of Pediatric
18 Therapeutics, in consultation with experts in the Center for
19 Devices and Radiological Health, shall provide for periodic
20 review of the report by the Pediatric Advisory Committee,
21 including obtaining any recommendations of such com-
22 mittee regarding whether the Secretary should take action
23 under this Act in response to the report.”.

24 (b) REPORT.—Not later than January 1, 2012, the
25 Comptroller General of the United States shall submit to

1 *the Committee on Health, Education, Labor, and Pensions*
2 *of the Senate and the Committee on Energy and Commerce*
3 *of the House of Representatives a report on the impact of*
4 *allowing persons granted an exemption under section*
5 *520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21*
6 *U.S.C. 360j(m)(2)) with respect to a device to profit from*
7 *such device pursuant to section 520(m)(6) of such Act (21*
8 *U.S.C. 360j(m)(6)) (as amended by subsection (a)), includ-*
9 *ing—*

10 (1) *an assessment of whether such section*
11 *520(m)(6) (as amended by subsection (a)) has in-*
12 *creased the availability of pediatric devices for condi-*
13 *tions that occur in small numbers of children, includ-*
14 *ing any increase or decrease in the number of—*

15 (A) *exemptions granted under such section*
16 *520(m)(2) for pediatric devices; and*

17 (B) *applications approved under section*
18 *515 of such Act (21 U.S.C. 360e) for devices in-*
19 *tended to treat, diagnose, or cure conditions that*
20 *occur in pediatric patients or for devices labeled*
21 *for use in a pediatric population;*

22 (2) *the conditions or diseases the pediatric de-*
23 *vices were intended to treat or diagnose and the esti-*
24 *mated size of the pediatric patient population for*
25 *each condition or disease;*

1 (3) *the costs of the pediatric devices, based on a*
2 *survey of children's hospitals;*

3 (4) *the extent to which the costs of such devices*
4 *are covered by health insurance;*

5 (5) *the impact, if any, of allowing profit on ac-*
6 *cess to such devices for patients;*

7 (6) *the profits made by manufacturers for each*
8 *device that receives an exemption;*

9 (7) *an estimate of the extent of the use of the pe-*
10 *diatric devices by both adults and pediatric popu-*
11 *lations for a condition or disease other than the con-*
12 *dition or disease on the label of such devices;*

13 (8) *recommendations of the Comptroller General*
14 *of the United States regarding the effectiveness of such*
15 *section 520(m)(6) (as amended by subsection (a)) and*
16 *whether any modifications to such section 520(m)(6)*
17 *(as amended by subsection (a)) should be made;*

18 (9) *existing obstacles to pediatric device develop-*
19 *ment; and*

20 (10) *an evaluation of the demonstration grants*
21 *described in section 425, which shall include an eval-*
22 *uation of the number of pediatric medical devices—*

23 (A) *that have been or are being studied in*
24 *children; and*

1 (B) that have been submitted to the Food
2 and Drug Administration for approval, clear-
3 ance, or review under such section 520(m) (as
4 amended by this Act) and any regulatory actions
5 taken.

6 (c) *GUIDANCE*.—Not later than 180 days after the date
7 of enactment of this subtitle, the Commissioner of Food and
8 Drugs shall issue guidance for institutional review commit-
9 tees on how to evaluate requests for approval for devices
10 for which a humanitarian device exemption under section
11 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360j(m)(2)) has been granted.

13 **SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.**

14 Section 402(b) of the Public Health Service Act (42
15 U.S.C. 282(b)) is amended—

16 (1) in paragraph (21), by striking “and” after
17 the semicolon at the end;

18 (2) in paragraph (22), by striking the period at
19 the end and inserting “; and”; and

20 (3) by inserting after paragraph (22) the fol-
21 lowing:

22 “(23) shall designate a contact point or office to
23 help innovators and physicians identify sources of
24 funding available for pediatric medical device devel-
25 opment.”.

1 **SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
2 **ATRIC DEVICE AVAILABILITY.**

3 (a) *IN GENERAL.*—

4 (1) *REQUEST FOR PROPOSALS.*—*Not later than*
5 *90 days after the date of enactment of this subtitle,*
6 *the Secretary of Health and Human Services shall*
7 *issue a request for proposals for 1 or more grants or*
8 *contracts to nonprofit consortia for demonstration*
9 *projects to promote pediatric device development.*

10 (2) *DETERMINATION ON GRANTS OR CON-*
11 *TRACTS.*—*Not later than 180 days after the date the*
12 *Secretary of Health and Human Services issues a re-*
13 *quest for proposals under paragraph (1), the Sec-*
14 *retary shall make a determination on the grants or*
15 *contracts under this section.*

16 (b) *APPLICATION.*—*A nonprofit consortium that de-*
17 *sires to receive a grant or contract under this section shall*
18 *submit an application to the Secretary of Health and*
19 *Human Services at such time, in such manner, and con-*
20 *taining such information as the Secretary may require.*

21 (c) *USE OF FUNDS.*—*A nonprofit consortium that re-*
22 *ceives a grant or contract under this section shall facilitate*
23 *the development, production, and distribution of pediatric*
24 *medical devices by—*

1 (1) *encouraging innovation and connecting*
2 *qualified individuals with pediatric device ideas with*
3 *potential manufacturers;*

4 (2) *mentoring and managing pediatric device*
5 *projects through the development process, including*
6 *product identification, prototype design, device devel-*
7 *opment, and marketing;*

8 (3) *connecting innovators and physicians to ex-*
9 *isting Federal and non-Federal resources, including*
10 *resources from the Food and Drug Administration,*
11 *the National Institutes of Health, the Small Business*
12 *Administration, the Department of Energy, the De-*
13 *partment of Education, the National Science Founda-*
14 *tion, the Department of Veterans Affairs, the Agency*
15 *for Healthcare Research and Quality, and the Na-*
16 *tional Institute of Standards and Technology;*

17 (4) *assessing the scientific and medical merit of*
18 *proposed pediatric device projects; and*

19 (5) *providing assistance and advice as needed on*
20 *business development, personnel training, prototype*
21 *development, postmarket needs, and other activities*
22 *consistent with the purposes of this section.*

23 (d) *COORDINATION.—*

1 (1) *NATIONAL INSTITUTES OF HEALTH.*—*Each*
2 *consortium that receives a grant or contract under*
3 *this section shall—*

4 (A) *coordinate with the National Institutes*
5 *of Health’s pediatric device contact point or of-*
6 *fice, designated under section 424; and*

7 (B) *provide to the National Institutes of*
8 *Health any identified pediatric device needs that*
9 *the consortium lacks sufficient capacity to ad-*
10 *dress or those needs in which the consortium has*
11 *been unable to stimulate manufacturer interest.*

12 (2) *FOOD AND DRUG ADMINISTRATION.*—*Each*
13 *consortium that receives a grant or contract under*
14 *this section shall coordinate with the Commissioner of*
15 *Food and Drugs and device companies to facilitate*
16 *the application for approval or clearance of devices*
17 *labeled for pediatric use.*

18 (3) *EFFECTIVENESS AND OUTCOMES.*—*Each con-*
19 *sortium that receives a grant or contract under this*
20 *section shall annually report to the Secretary of*
21 *Health and Human Services on—*

22 (A) *the effectiveness of activities conducted*
23 *under subsection (c);*

1 (B) the impact of activities conducted under
2 subsection (c) on pediatric device development;
3 and

4 (C) the status of pediatric device develop-
5 ment that has been facilitated by the consortium.

6 (e) *AUTHORIZATION OF APPROPRIATIONS.*—There are
7 authorized to be appropriated to carry out this section
8 \$6,000,000 for each of fiscal years 2008 through 2012.

9 **SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**
10 **PEUTICS AND PEDIATRIC ADVISORY COM-**
11 **MITTEE.**

12 (a) *IN GENERAL.*—

13 (1) *OFFICE OF PEDIATRIC THERAPEUTICS.*—Sec-
14 tion 6(b) of the *Best Pharmaceuticals for Children*
15 *Act* (21 U.S.C. 393a(b)) is amended by inserting “,
16 including increasing pediatric access to medical de-
17 vices” after “pediatric issues”.

18 (2) *PLAN FOR PEDIATRIC MEDICAL DEVICE RE-*
19 *SEARCH.*—

20 (A) *IN GENERAL.*—Not later than 270 days
21 after the date of enactment of this subtitle, the
22 Office of Pediatric Therapeutics, in collaboration
23 with the Director of the National Institutes of
24 Health and the Director of the Agency for
25 Healthcare Research and Quality, shall submit

1 to the Committee on Health, Education, Labor,
2 and Pensions of the Senate and the Committee
3 on Energy and Commerce of the House of Rep-
4 resentatives a plan for expanding pediatric med-
5 ical device research and development. In devel-
6 oping such plan, the Commissioner of Food and
7 Drugs shall consult with individuals and organi-
8 zations with appropriate expertise in pediatric
9 medical devices.

10 (B) CONTENTS.—The plan under subpara-
11 graph (A) shall include—

12 (i) the current status of federally fund-
13 ed pediatric medical device research;

14 (ii) any gaps in such research, which
15 may include a survey of pediatric medical
16 providers regarding unmet pediatric med-
17 ical device needs, as needed; and

18 (iii) a research agenda for improving
19 pediatric medical device development and
20 Food and Drug Administration clearance or
21 approval of pediatric medical devices, and
22 for evaluating the short- and long-term safe-
23 ty and effectiveness of pediatric medical de-
24 vices.

1 (b) *PEDIATRIC ADVISORY COMMITTEE*.—Section 14 of
2 *the Best Pharmaceuticals for Children Act (42 U.S.C. 284m*
3 *note) is amended—*

4 (1) *in subsection (a), by inserting “(including*
5 *drugs and biological products) and medical devices”*
6 *after “therapeutics”; and*

7 (2) *in subsection (b)—*

8 (A) *in paragraph (1), by inserting “(in-*
9 *cluding drugs and biological products) and med-*
10 *ical devices” after “therapeutics”; and*

11 (B) *in paragraph (2)—*

12 (i) *in subparagraph (A), by striking*
13 *“and 505B” and inserting “505B, 510(k),*
14 *515, and 520(m)”;*

15 (ii) *by striking subparagraph (B) and*
16 *inserting the following:*

17 “*(B) identification of research priorities re-*
18 *lated to therapeutics (including drugs and bio-*
19 *logical products) and medical devices for pedi-*
20 *atric populations and the need for additional*
21 *diagnostics and treatments for specific pediatric*
22 *diseases or conditions; and”;* and

23 (iii) *in subparagraph (C), by inserting*
24 *“(including drugs and biological products)*
25 *and medical devices” after “therapeutics”.*

1 **SEC. 427. SURVEILLANCES.**

2 (a) *POSTMARKET SURVEILLANCES.*—Section 522 of
3 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l)*
4 *is amended—*

5 (1) *by striking subsection (a) and inserting the*
6 *following:*

7 “(a) *POSTMARKET SURVEILLANCE.*—

8 “(1) *IN GENERAL.*—

9 “(A) *CONDUCT.*—*The Secretary may by*
10 *order require a manufacturer to conduct*
11 *postmarket surveillance for any device of the*
12 *manufacturer that is a class II or class III de-*
13 *vice—*

14 “(i) *the failure of which would be rea-*
15 *sonably likely to have serious adverse health*
16 *consequences;*

17 “(ii) *that is expected to have signifi-*
18 *cant use in pediatric populations; or*

19 “(iii) *that is intended to be implanted*
20 *in the human body for more than 1 year,*
21 *or a life sustaining or life supporting device*
22 *used outside a device user facility.*

23 “(B) *CONDITION.*—*The Secretary may order*
24 *a postmarket surveillance under subparagraph*
25 *(A) as a condition to approval of an application*
26 *(or a supplement to an application) or a product*

1 *development protocol under section 515 or as a*
2 *condition to clearance of a premarket notifica-*
3 *tion under section 510(k) only for a device de-*
4 *scribed in subparagraph (A)(ii).*

5 “(2) *RULE OF CONSTRUCTION.*—*The provisions*
6 *of paragraph (1) shall have no effect on authorities*
7 *otherwise provided under the Act or regulations issued*
8 *under this Act.”; and*

9 (2) *in subsection (b)—*

10 (A) *by striking “(b) SURVEILLANCE AP-*
11 *PROVAL.—Each” and inserting the following:*

12 “(b) *SURVEILLANCE APPROVAL.—*

13 (1) *IN GENERAL.—Each”;*

14 (B) *by striking “The Secretary, in consulta-*
15 *tion” and inserting “Except as provided in*
16 *paragraph (2), the Secretary, in consultation”;*

17 (C) *by striking “Any determination” and*
18 *inserting “Except as provided in paragraph (2),*
19 *any determination”;* and

20 (D) *by adding at the end the following:*

21 “(2) *LONGER SURVEILLANCES FOR PEDIATRIC*
22 *DEVICES.—The Secretary may by order require a pro-*
23 *spective surveillance period of more than 36 months*
24 *with respect to a device that is expected to have sig-*
25 *nificant use in pediatric populations if such period of*

1 *more than 36 months is necessary in order to assess*
2 *the impact of the device on growth and development,*
3 *or the effects of growth, development, activity level, or*
4 *other factors on the safety of the device.”.*

5 **SEC. 428. SEVERABILITY CLAUSE.**

6 *If any provision of this Act, an amendment made this*
7 *Act, or the application of such provision or amendment to*
8 *any person or circumstance is held to be unconstitutional,*
9 *the remainder of this Act, the amendments made by this*
10 *Act, and the application of the provisions of such to any*
11 *person or circumstances shall not be affected thereby.*

Amend the title so as to read: “To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.”.

Calendar No. 120

110TH CONGRESS
1ST Session

S. 1082

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

APRIL 24, 2007

Reported with an amendment and an amendment to the
title