

[COMMITTEE PRINT]110TH CONGRESS
1ST SESSION**H. R.** _____

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 HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to 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”.

6 (b) **REFERENCES IN ACT.**—Except as otherwise spec-
7 ified, amendments made by this Act to a section or other
8 provision of law are amendments to such section or other

1 provision of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 301 et seq.).

3 **SEC. 2. DEFINITIONS.**

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

5 (1) in paragraph (1)—

6 (A) in subparagraph (A), by striking
7 “505(b)(1),” and inserting “505(b), or”;

8 (B) by striking subparagraph (B); and

9 (C) by redesignating subparagraph (C) as
10 subparagraph (B);

11 (2) in paragraph (3)(C)—

12 (A) by inserting a comma after
13 “505(j)(7)(A)”;

14 (B) by inserting before the period the fol-
15 lowing: “, other than inclusion on a portion of
16 such a list that the Secretary has designated for
17 drugs that are discontinued (or for drugs for
18 which a specific strength, potency, or final dos-
19 age form or combination thereof have been dis-
20 continued)”;

21 (3) in paragraph (4), by inserting before the pe-
22 riod at the end the following: “(such as capsules,
23 tablets, or lyophilized products before reconstitu-
24 tion)”;

1 (4) by amending paragraph (6)(F) to read as
2 follows:

3 “(F) Postmarket safety activities with re-
4 spect to drugs approved under human drug ap-
5 plications or supplements, including the fol-
6 lowing activities:

7 “(i) Collecting, developing, and re-
8 viewing safety information on approved
9 drugs, including adverse event reports.

10 “(ii) Developing and using improved
11 adverse-event data-collection systems, in-
12 cluding information technology systems.

13 “(iii) Developing and using improved
14 analytical tools to assess potential safety
15 problems, including access to external data
16 bases.”;

17 (5) in paragraph (8)—

18 (A) by striking “April of the preceding fis-
19 cal year” and inserting “October of the pre-
20 ceding fiscal year”; and

21 (B) by striking “April 1997” and inserting
22 “October 2006”;

23 (6) by redesignating paragraph (9) as para-
24 graph (10); and

1 (7) by inserting after paragraph (8) the fol-
2 lowing new paragraph:

3 “(9) The term ‘person’ includes an affiliate
4 thereof.”.

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

6 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
7 379h(a)) is amended—

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

10 (2) in paragraph (1)—

11 (A) in subparagraph (D)—

12 (i) in the heading, by inserting “OR
13 WITHDRAWN BEFORE FILING” after “RE-
14 FUSED FOR FILING”; and

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

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

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

23 “(E) FEES FOR APPLICATIONS PRE-
24 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
25 BEFORE FILING.—A human drug application or

1 supplement that was submitted but was refused
2 for filing, or was withdrawn before being ac-
3 cepted or refused for filing, shall be subject to
4 the full fee under subparagraph (A) upon being
5 resubmitted or filed over protest, unless the fee
6 is waived or reduced under subsection (d).”;
7 and

8 (3) in paragraph (2)—

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

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

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

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

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

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

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

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

23 “(b) FEE REVENUE AMOUNTS.—

24 “(1) IN GENERAL.—For each of the fiscal years
25 2008 through 2012, fees under subsection (a) shall,

1 except as provided in subsections (c), (d), (f), and
2 (g), be established to generate a total revenue
3 amount under such subsection that is equal to the
4 sum of—

5 “(A) \$392,783,000; and

6 “(B) an amount equal to the modified
7 workload adjustment factor for fiscal year 2007
8 (as determined under paragraph (3)).

9 “(2) TYPES OF FEES.—Of the total revenue
10 amount determined for a fiscal year under para-
11 graph (1)—

12 “(A) one-third shall be derived from fees
13 under subsection (a)(1) (relating to human
14 drug applications and supplements);

15 “(B) one-third shall be derived from fees
16 under subsection (a)(2) (relating to prescription
17 drug establishments); and

18 “(C) one-third shall be derived from fees
19 under subsection (a)(3) (relating to prescription
20 drug products).

21 “(3) MODIFIED WORKLOAD ADJUSTMENT FAC-
22 TOR FOR FISCAL YEAR 2007.—For purposes of para-
23 graph (1)(B), the Secretary shall determine the
24 modified workload adjustment factor by determining
25 the dollar amount that results from applying the

1 methodology that was in effect under subsection
2 (c)(2) for fiscal year 2007 to the amount
3 \$354,893,000, except that, with respect to the por-
4 tion of such determination that is based on the
5 change in the total number of commercial investiga-
6 tional new drug applications, the Secretary shall
7 count each such application that (relative to October
8 1, 2007) was submitted during the most recent 12-
9 month period for which data on the number of such
10 applications is available.

11 “(4) ADDITIONAL FEE REVENUES FOR DRUG
12 SAFETY.—

13 “(A) IN GENERAL.—For each of the fiscal
14 years 2008 through 2012, paragraph (1)(A)
15 shall, subject to subparagraph (C), be applied
16 by substituting the amount determined under
17 subparagraph (B) for ‘\$392,783,000’.

18 “(B) AMOUNT DETERMINED.—For each of
19 the fiscal years 2008 through 2012, the amount
20 determined under this subparagraph is the sum
21 of—

22 “(i) \$392,783,000; plus

23 “(ii) an amount equal to—

24 “(I)(aa) for fiscal year 2008,
25 \$25,000,000;

1 “(bb) for fiscal year 2009,
2 \$35,000,000;

3 “(cc) for fiscal year 2010,
4 \$45,000,000;

5 “(dd) for fiscal year 2011,
6 \$55,000,000; and

7 “(ee) for fiscal year 2012,
8 \$65,000,000; minus

9 “(II) the amount equal to one-
10 fifth of the excess amount in item
11 (bb), provided that—

12 “(aa) the amount of the
13 total appropriation for the Food
14 and Drug Administration for
15 such fiscal year (excluding the
16 amount of fees appropriated for
17 such fiscal year) exceeds the
18 amount of the total appropriation
19 for the Food and Drug Adminis-
20 tration for fiscal year 2007 (ex-
21 cluding the amount of fees appro-
22 priated for such fiscal year), ad-
23 justed as provided under sub-
24 section (c)(1); and

1 “(bb) the amount of the
2 total appropriations for the proc-
3 ess of human drug review at the
4 Food and Drug Administration
5 for such fiscal year (excluding
6 the amount of fees appropriated
7 for such fiscal year) exceeds the
8 amount of appropriations for the
9 process of human drug review at
10 the Food and Drug Administra-
11 tion for fiscal year 2007 (exclud-
12 ing the amount of fees appro-
13 priated for such fiscal year), ad-
14 justed as provided under sub-
15 section (c)(1).

16 In making the adjustment under sub-
17 clause (II) for any fiscal year 2008
18 through 2012, subsection (c)(1) shall
19 be applied by substituting ‘2007’ for
20 ‘2008.’

21 “(C) LIMITATION.—This paragraph shall
22 not apply for any fiscal year if the amount de-
23 scribed under subparagraph (B)(ii) is less than
24 0.”.

25 (c) ADJUSTMENTS TO FEES.—

1 (1) INFLATION ADJUSTMENT.—Section
2 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

3 (A) in the matter preceding subparagraph
4 (A), by striking “The revenues established in
5 subsection (b)” and inserting “For fiscal year
6 2009 and subsequent fiscal years, the revenues
7 established in subsection (b)”;

8 (B) in subparagraph (A), by striking “or”
9 at the end;

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

12 (D) by inserting after subparagraph (B)
13 the following:

14 “(C) the average annual change in the
15 cost, per full-time equivalent position of the
16 Food and Drug Administration, of all personnel
17 compensation and benefits paid with respect to
18 such positions for the 5-year period ending Sep-
19 tember 30 of the fiscal year preceding the fiscal
20 year for which fees are being established.”; and

21 (E) in the matter following subparagraph
22 (C) (as added under this paragraph), by strik-
23 ing “fiscal year 2003” and inserting “fiscal
24 year 2008”.

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

3 (A) in the matter preceding subparagraph
4 (A), by striking “Beginning with fiscal year
5 2004,” and inserting “For fiscal year 2009 and
6 subsequent fiscal years,”;

7 (B) in subparagraph (A), in the first sen-
8 tence—

9 (i) by striking “human drug applica-
10 tions,” and inserting “human drug applica-
11 tions (adjusted for changes in review ac-
12 tivities),”;

13 (ii) by striking “commercial investiga-
14 tional new drug applications,”; and

15 (iii) by inserting before the period the
16 following: “, and the change in the total
17 number of commercial investigational new
18 drug applications (adjusted for changes in
19 review activities) submitted to the Sec-
20 retary, which change shall be determined
21 by counting each such application that
22 (relative to October 1 of such fiscal
23 year) was submitted during the most recent
24 12-month period for which data on the
25 number of such applications is available”;

1 (C) in subparagraph (B), by adding at the
2 end the following: “Any adjustment for changes
3 in review activities made in setting fees and rev-
4 enue amounts for fiscal year 2009 may not re-
5 sult in the total workload adjustment being
6 more than 2 percentage points higher than it
7 would have been in the absence of the adjust-
8 ment for changes in review activities.”; and

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

10 “(C) The Secretary shall contract with an
11 independent accounting firm to study the ad-
12 justment for changes in review activities applied
13 in setting fees and revenue amounts for fiscal
14 year 2009 and to make recommendations, if
15 warranted, for future changes in the method-
16 ology for calculating the adjustment. After re-
17 view of the recommendations, the Secretary
18 shall, if warranted, make appropriate changes
19 to the methodology, and the changes shall be ef-
20 fective for each of the fiscal years 2010 through
21 2012. The Secretary shall not make any adjust-
22 ment for changes in review activities for any
23 fiscal year after 2009 unless such study has
24 been completed.”.

1 (3) RENT AND RENT-RELATED COST ADJUST-
2 MENT.—Section 736(c) (21 U.S.C. 379h(c)) is
3 amended—

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

7 (B) by inserting after paragraph (2) the
8 following:

9 “(3) RENT AND RENT-RELATED COST ADJUST-
10 MENT.—For fiscal year 2010 and each subsequent
11 fiscal year, the Secretary shall, before making ad-
12 justments under paragraphs (1) and (2), decrease
13 the fee revenue amount established in subsection (b)
14 if actual costs paid for rent and rent-related ex-
15 penses for the preceding fiscal year are less than es-
16 timates made for such year in fiscal year 2006. Any
17 reduction made under this paragraph shall not ex-
18 ceed the amount by which such costs fall below the
19 estimates made in fiscal year 2006 for such fiscal
20 year, and shall not exceed \$11,721,000 for any fiscal
21 year.”.

22 (4) FINAL YEAR ADJUSTMENT.—Section 736(c)
23 (21 U.S.C. 379h(c)) is amended—

24 (A) in paragraph (4) (as redesignated by
25 paragraph (3)(A))—

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

3 (ii) by striking “paragraphs (1) and
4 (2)” and inserting “paragraphs (1), (2),
5 and (3)”; and

6 (iii) by striking “2008” and inserting
7 “2013”; and

8 (B) in paragraph (5) (as so redesignated),
9 by striking “2002” and inserting “2007”.

10 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
11 (21 U.S.C. 379h(d)) is amended—

12 (1) in paragraph (1), in the matter preceding
13 subparagraph (A)—

14 (A) by inserting after “The Secretary shall
15 grant” the following: “to a person who is
16 named as the applicant in a human drug appli-
17 cation”; and

18 (B) by inserting “for that person” after
19 “one or more fees assessed”;

20 (2) by redesignating paragraphs (2) and (3) as
21 paragraphs (3) and (4), respectively;

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

24 “(2) CONSIDERATIONS.—In determining wheth-
25 er to grant a waiver or reduction of a fee under

1 paragraph (1), the Secretary shall consider only the
2 circumstances and assets of the applicant involved
3 and any affiliate of the applicant.”; and

4 (4) in paragraph (4) (as redesignated by para-
5 graph (2)), in subparagraph (A), by inserting before
6 the period the following: “, and that does not have
7 any approved human drug application under which
8 a drug product has been introduced or delivered for
9 introduction into interstate commerce”.

10 (e) CREDITING AND AVAILABILITY OF FEES.—

11 (1) AUTHORIZATION OF APPROPRIATIONS.—

12 Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amend-
13 ed to read as follows:

14 “(3) AUTHORIZATION OF APPROPRIATIONS.—

15 For each of the fiscal years 2008 through 2012,
16 there is authorized to be appropriated for fees under
17 this section an amount equal to the total revenue
18 amount determined under subsection (b) for the fis-
19 cal year, as adjusted or otherwise affected under
20 subsections (c), (d), and (f) and paragraph (4) of
21 this subsection.”.

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

24 “(4) OFFSET.—If the sum of the cumulative
25 amount of fees collected under this section for the

1 fiscal years 2008 through 2010 and the amount of
2 fees estimated to be collected under this section for
3 fiscal year 2011 exceeds the cumulative amount ap-
4 propriated under paragraph (3) for the fiscal years
5 2008 through 2011, the excess shall be credited to
6 the appropriation account of the Food and Drug Ad-
7 ministration as provided in paragraph (1), and shall
8 be subtracted from the amount of fees that would
9 otherwise be authorized to be collected under this
10 section pursuant to appropriation Acts for fiscal
11 year 2012.”.

12 (f) CONFORMING AMENDMENT.—Section 736(a) of
13 the Federal Food, Drug and Cosmetic Act (21 U.S.C.
14 379h) is amended in paragraphs (1)(A)(i), (1)(A)(ii),
15 (2)(A), and (3)(A) by striking “(c)(4)” each place such
16 term appears and inserting “(c)(5)”.

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

19 Part 2 of subchapter C of chapter VII of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.)
21 is amended by adding after section 736 the following:

22 **“SEC. 736A. FEES RELATING TO ADVISORY REVIEW OF PRE-**
23 **SCRIPTION-DRUG TELEVISION ADVERTISING.**

24 “(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION
25 ADVERTISEMENT REVIEW FEES.—Beginning in fiscal

1 year 2008, the Secretary shall assess and collect fees in
2 accordance with this section as follows:

3 “(1) ADVISORY REVIEW FEE.—

4 “(A) IN GENERAL.—Except as provided in
5 subparagraph (B), each person that on or after
6 October 1, 2007, submits a proposed direct-to-
7 consumer television advertisement for advisory
8 review by the Secretary prior to its initial public
9 dissemination shall be subject to a fee estab-
10 lished under subsection (c)(3).

11 “(B) EXCEPTION FOR REQUIRED SUBMIS-
12 SIONS.—A direct-to-consumer television adver-
13 tisement that is required to be submitted to the
14 Secretary prior to initial public dissemination is
15 not subject to a fee under this paragraph unless
16 the sponsor designates the submission as a sub-
17 mission for advisory review.

18 “(C) NOTICE TO SECRETARY OF NUMBER
19 OF ADVERTISEMENTS; PAYMENT.—Not later
20 than July 1 of each fiscal year, the Secretary
21 shall publish a notice in the Federal Register
22 requesting a person to notify the Secretary
23 within 30 days of the number of direct-to-con-
24 sumer television advertisements the person in-
25 tends to submit for advisory review by the Sec-

1 retary during the next fiscal year. Notification
2 of the Secretary of the number of advertise-
3 ments a person intends to submit for advisory
4 review prior to initial broadcast of the adver-
5 tisements is a legally binding commitment by
6 that person to pay the annual advisory review
7 fee for that number of submissions on or before
8 October 1 of such next fiscal year. A person
9 shall at the same time also notify the Secretary
10 if such person intends to use a paid submission
11 from the previous fiscal year under subpara-
12 graph (E)(i). If such person does not so notify
13 the Secretary, all submissions for advisory re-
14 view shall be subject to advisory review fees.

15 “(D) MODIFICATION OF ADVISORY REVIEW
16 FEE.—

17 “(i) LATE PAYMENT.—If on or before
18 November 1 of the fiscal year in which the
19 fees are due, a person has not paid all fees
20 that were due and payable for advisory re-
21 views identified in response to the Federal
22 Register notice described in subsection
23 (c)(3)(A), the fees are regarded as late.
24 Such fees shall be due and payable 20 days
25 before any direct-to-consumer television

1 advertisement is submitted by such person
2 to the Secretary for advisory review. Not-
3 withstanding any other provision of this
4 section, such fees shall be due and payable
5 for each of those advisory reviews in the
6 amount of 150 percent of the advisory re-
7 view fee established for that fiscal year
8 pursuant to subsection (c)(3).

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

24 “(E) LIMITS.—

1 “(i) SUBMISSIONS.—For each advisory
2 sory review fee paid by a person under this
3 paragraph for a fiscal year, such person is
4 entitled to acceptance for advisory review
5 by the Secretary of one direct-to-consumer
6 television advertisement and acceptance of
7 one resubmission for advisory review of the
8 same advertisement. The advertisement
9 shall be submitted for review in the fiscal
10 year for which the fee was assessed, except
11 that a person may carry over no more than
12 one paid advisory review submission to the
13 next fiscal year. Resubmissions may be
14 submitted without regard to the fiscal year
15 of the initial advisory review submission.

16 “(ii) NO REFUNDS.—Except as provided
17 by subsection (f), fees paid under
18 this paragraph will not be refunded.

19 “(iii) NO WAIVERS, EXEMPTIONS, OR
20 REDUCTIONS.—The Secretary shall not
21 grant a waiver, exemption, or reduction of
22 any fees due or payable under this section.

23 “(iv) RIGHT TO ADVISORY REVIEW
24 NOT TRANSFERABLE.—The right to an ad-

1 visory review is not transferable, except to
2 a successor in interest.

3 “(2) OPERATING RESERVE FEE.—

4 “(A) IN GENERAL.—Each person that on
5 or after October 1, 2007, is assessed an advisory
6 review fee under paragraph (1) shall be
7 subject to an operating reserve fee established
8 under subsection (d)(2) only in the first fiscal
9 year in which an advisory review fee is assessed
10 to such person.

11 “(B) PAYMENT.—Except as provided in
12 subparagraph (C), the fee required by subpara-
13 graph (A) shall be due no later than October 1
14 of the first fiscal year in which the person is re-
15 quired to pay an advisory review fee under
16 paragraph (1).

17 “(C) LATE NOTICE OF SUBMISSION.—If, in
18 the first fiscal year of a person’s participation
19 in this Program, that person submits any di-
20 rect-to-consumer television advertisements for
21 advisory review that are in excess of the num-
22 ber identified by that person in response to the
23 Federal Register notice described in subsection
24 (c)(3)(A), that person must pay an operating
25 reserve fee for each of those advisory reviews

1 equal to the advisory review fee for each sub-
2 mission established under paragraph (1)(D)(ii).
3 Fees required by this subparagraph shall be in
4 addition to any fees required by subparagraph
5 (A). Fees under this subparagraph shall be due
6 20 days before any direct-to-consumer television
7 advertisement is submitted by such person to
8 the Secretary for advisory review.

9 “(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—
10 Except as provided in subsections (c) and (g), fees under
11 subsection (a)(1) shall be established to generate revenue
12 amounts of \$6,250,000 for each of fiscal years 2008
13 through 2012.

14 “(c) ADJUSTMENTS.—

15 “(1) INFLATION ADJUSTMENT.—Beginning
16 with fiscal year 2009, the revenues established in
17 subsection (b) shall be adjusted by the Secretary by
18 notice, published in the Federal Register, for a fiscal
19 year to reflect the greater of—

20 “(A) the total percentage change that oc-
21 curred in the Consumer Price Index for all
22 urban consumers (all items; U.S. city average),
23 for the 12 month period ending June 30 pre-
24 ceding the fiscal year for which fees are being
25 established;

1 “(B) the total percentage change for the
2 previous fiscal year in basic pay under the Gen-
3 eral Schedule in accordance with section 5332
4 of title 5, United States Code, as adjusted by
5 any locality-based comparability payment pur-
6 suant to section 5304 of such title for Federal
7 employees stationed in the District of Columbia;
8 or

9 “(C) the average annual change in the
10 cost, per full-time equivalent position of the
11 Food and Drug Administration, of all personnel
12 compensation and benefits paid with respect to
13 such positions, for the most recent 5-year pe-
14 riod ending on September 30, 12 months and 1
15 day prior to the year for which fees are being
16 established.

17 The adjustment made each fiscal year by this sub-
18 section will be added on a compounded basis to the
19 sum of all adjustments made each fiscal year after
20 fiscal year 2008 under this subsection.

21 “(2) WORKLOAD ADJUSTMENT.—Beginning
22 with fiscal year 2009, after the fee revenues estab-
23 lished in subsection (b) of this section are adjusted
24 for a fiscal year for inflation in accordance with
25 paragraph (1), the fee revenues shall be adjusted

1 further for such fiscal year to reflect changes in the
2 workload of the Secretary with respect to the sub-
3 mission of proposed direct-to-consumer television ad-
4 vertisements for advisory review prior to initial
5 broadcast. With respect to such adjustment:

6 “(A) The adjustment shall be determined
7 by the Secretary based upon the number of di-
8 rect-to-consumer television advertisements iden-
9 tified pursuant to paragraph (3)(A) for the up-
10 coming fiscal year, excluding allowable pre-
11 viously paid carry over submissions. The adjust-
12 ment shall be determined by multiplying the
13 number of such advertisements projected for
14 that fiscal year that exceeds 150 by \$27,600
15 (adjusted each year beginning with fiscal year
16 2009 for inflation in accordance with paragraph
17 (1)). The Secretary shall publish in the Federal
18 Register the fee revenues and fees resulting
19 from the adjustment and the supporting meth-
20 odologies.

21 “(B) Under no circumstances shall the ad-
22 justment result in fee revenues for a fiscal year
23 that are less than the fee revenues established
24 for the prior fiscal year.

1 “(3) ANNUAL FEE SETTING FOR ADVISORY RE-
2 VIEW.—

3 “(A) IN GENERAL.—Not later than August
4 1 of each fiscal year, establish, the Secretary
5 shall establish for the next fiscal year the di-
6 rect-to-consumer television advertisement advi-
7 sory review fee under subsection (a)(1), based
8 on the revenue amounts established under sub-
9 section (b), the adjustments provided under
10 paragraphs (1) and (2), and the number of di-
11 rect-to-consumer television advertisements iden-
12 tified pursuant to subsection (a)(1)(C), exclud-
13 ing allowable previously paid carry over submis-
14 sions. The annual advisory review fee shall be
15 established by dividing the fee revenue for a fis-
16 cal year (as adjusted pursuant to this sub-
17 section) by the number of direct-to-consumer
18 television advertisements identified pursuant to
19 subparagraph (A), excluding allowable pre-
20 viously paid carry over submissions.

21 “(B) FISCAL YEAR 2008 FEE LIMIT.—Not-
22 withstanding subsection (b) and the adjust-
23 ments pursuant to this subsection, the fee es-
24 tablished under subparagraph (B) for fiscal

1 year 2008 may not be more than \$83,000 per
2 submission for advisory review.

3 “(C) ANNUAL FEE LIMIT.—Notwith-
4 standing subsection (b) and the adjustments
5 pursuant to this subsection, the fee established
6 under subparagraph (B) for a fiscal year after
7 fiscal year 2008 may not be more than 50 per-
8 cent more than the fee established for the prior
9 fiscal year.

10 “(D) LIMIT.—The total amount of fees ob-
11 ligated for a fiscal year may not exceed the
12 total costs for such fiscal year for the resources
13 allocated for the process for the advisory review
14 of prescription drug advertising.

15 “(d) OPERATING RESERVES.—

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

1 “(2) FEE SETTING.—The Secretary shall estab-
2 lish the operating reserve fee under subsection
3 (a)(2)(A) for each person required to pay the fee by
4 multiplying the number of direct-to-consumer tele-
5 vision advertisements identified by that person pur-
6 suant to subsection (c)(3)(A) by the advisory review
7 fee established pursuant to subsection (c)(3) for that
8 fiscal year. However, in no case shall the operating
9 reserve fee assessed be less than the operating re-
10 serve fee assessed if the person had first participated
11 in the Program in fiscal year 2008.

12 “(3) USE OF OPERATING RESERVE.—The Sec-
13 retary may use funds from the reserves only to the
14 extent necessary in any fiscal year to make up the
15 difference between the fee revenue amount estab-
16 lished for that fiscal year under subsections (b) and
17 (c) and the amount of fees actually collected for that
18 fiscal year pursuant to subsection (a)(1), or to pay
19 costs of ending the Program if it is terminated pur-
20 suant to subsection (f) or not reauthorized beyond
21 fiscal year 2012.

22 “(4) REFUND OF OPERATING RESERVES.—
23 Within 120 days of the end of fiscal year 2012, or
24 if the Program ends early pursuant to subsection
25 (f), the Secretary, after setting aside sufficient oper-

1 ating reserve amounts to terminate the Program,
2 shall refund all amounts remaining in the operating
3 reserve on a pro rata basis to each person that paid
4 an operating reserve fee assessment. In no event
5 shall the refund to any person exceed the total
6 amount of operating reserve fees paid by such per-
7 son pursuant to subsection (a)(2).

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

15 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
16 GRAM.—

17 “(1) INITIAL FUNDING.—If on November 1,
18 2007, or 120 days after enactment of this provision,
19 whichever is later, the Secretary has not received at
20 least \$11,250,000 in advisory review fees and oper-
21 ating reserve fees combined, the Program shall not
22 commence and all collected fees shall be refunded.

23 “(2) LATER FISCAL YEARS.—Beginning in fis-
24 cal year 2009, if, on November 1 of the fiscal year,
25 the combination of the operating reserves, annual fee

1 revenues from that fiscal year, and unobligated fee
2 revenues from prior fiscal years falls below
3 \$9,000,000, adjusted for inflation (as described in
4 subsection (c)(1)), the Program shall cease to exist,
5 and the Secretary shall notify all participants, retain
6 any money from the unused advisory review fees and
7 the operating reserves needed to close down the Pro-
8 gram, and refund the remainder of the unused fees
9 and operating reserves. To the extent required to
10 close down the Program, the Secretary shall first use
11 unobligated advisory review fee revenues from prior
12 fiscal years, then the operating reserves, and finally,
13 unused advisory review fees from the relevant fiscal
14 year.

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

16 “(1) IN GENERAL.—Fees authorized under sub-
17 section (a) of this section shall be collected and
18 available for obligation only to the extent and in the
19 amount provided in advance in appropriations Acts.
20 Such fees are authorized to remain available until
21 expended. Such sums as may be necessary may be
22 transferred from the Food and Drug Administration
23 salaries and expenses appropriation account without
24 fiscal year limitation to such appropriation account
25 for salaries and expenses with such fiscal year limi-

1 tation. The sums transferred shall be available solely
2 for the process for the advisory review of prescrip-
3 tion drug advertising.

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

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

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

20 “(3) AUTHORIZATION OF APPROPRIATIONS.—
21 For each of the fiscal years 2008 through 2012,
22 there is authorized to be appropriated for fees under
23 this section an amount equal to the total revenue
24 amount determined under subsection (b) for the fis-
25 cal year, as adjusted pursuant to subsection (c) and

1 paragraph (4) of this subsection, plus any amount
2 necessary for ending the program under this section
3 pursuant to subsection (d).

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

13 “(h) DEFINITIONS.—For purposes of this sub-
14 chapter:

15 “(1) The term ‘advisory review’ means review-
16 ing and providing advisory comments on a proposed
17 advertisement prior to its initial public dissemina-
18 tion.

19 “(2) The term ‘carry over submission’ means a
20 submission for an advisory review for which a fee
21 was paid in one fiscal year that is submitted for re-
22 view in the following fiscal year.

23 “(3) The term ‘direct-to-consumer television ad-
24 vertisement’ means an advertisement for a prescrip-
25 tion drug product as defined in section 735(3) in-

1 tended to be displayed on any television channel for
2 less than 2 minutes.

3 “(4) The term ‘person’ includes individual,
4 partnership, corporation, and association, and any
5 affiliate thereof or successor in interest.

6 “(5) The term ‘Program’ means the program to
7 assess, collect, and use fees for the advisory review
8 of prescription drug advertising established by this
9 section.

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

22 “(7) The term ‘resources allocated for the proc-
23 ess for the advisory review of prescription drug ad-
24 vertising’ means the expenses incurred in connection

1 with the process for the advisory review of prescrip-
2 tion drug advertising for—

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

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

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

17 “(D) collection of fees under this section
18 and accounting for resources allocated for the
19 advisory review of prescription drug advertising;
20 and

21 “(E) closing down the Program under sub-
22 section (f)(2) if that becomes necessary.

23 “(8) The term ‘resubmission’ means a subse-
24 quent submission for advisory review of a direct-to-
25 consumer television advertisement that has been re-

1 vised in response to the Secretary’s comments on an
2 original submission. A resubmission may not intro-
3 duce significant new concepts or creative themes into
4 the television advertisement.

5 “(9) The term ‘submission for advisory review’
6 means an original submission of a direct-to-con-
7 sumer television advertisement for which the sponsor
8 voluntarily requests advisory comments before the
9 advertisement is publicly disseminated.”.

10 **SEC. 5. REAUTHORIZATION; REPORTING REQUIREMENTS.**

11 (a) PERFORMANCE REPORT.—Beginning with fiscal
12 year 2008, not later than 120 days after the end of each
13 fiscal year for which fees are collected under part 2 of
14 subchapter C of chapter VII of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary
16 of Health and Human Services (referred to in this section
17 as the “Secretary”) shall prepare and submit to the Com-
18 mittee on Energy and Commerce of the House of Rep-
19 resentatives and the Committee on Health, Education,
20 Labor, and Pensions of the Senate a report concerning
21 the progress of the Food and Drug Administration in
22 achieving the goals identified in the letters described in
23 section 502(4) of the Prescription Drug User Fee Amend-
24 ments of 2002 (Subtitle A of title V of Public Law 107–

1 188) during such fiscal year and the future plans of the
2 Food and Drug Administration for meeting the goals.

3 (b) FISCAL REPORT.—Beginning with fiscal year
4 2008, not later than 120 days after the end of each fiscal
5 year for which fees are collected under the part described
6 in subsection (a), the Secretary shall prepare and submit
7 to the Committee on Energy and Commerce of the House
8 of Representatives and the Committee on Health, Edu-
9 cation, Labor, and Pensions of the Senate a report on the
10 implementation of the authority for such fees during such
11 fiscal year and the use, by the Food and Drug Administra-
12 tion, of the fees collected for such fiscal year.

13 (c) REAUTHORIZATION.—

14 (1) CONSULTATION.—In developing rec-
15 ommendations to present to the Congress with re-
16 spect to the goals, and plans for meeting the goals,
17 for the process for the review of human drug appli-
18 cations for the first 5 fiscal years after fiscal year
19 2012, and for the reauthorization of this part for
20 such fiscal years, the Secretary shall consult with—

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

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

25 (C) scientific and academic experts;

1 (D) health care professionals;

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

4 (F) the regulated industry.

5 (2) PUBLIC REVIEW OF RECOMMENDATIONS.—

6 After negotiations with the regulated industry and
7 representatives of patient and consumer advocacy
8 groups, the Secretary shall—

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

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

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

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

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

23 (3) TRANSMITTAL OF RECOMMENDATIONS.—

24 Not later than January 15, 2012, the Secretary
25 shall transmit to Congress the revised recommenda-

1 tions under paragraph (2), a summary of the views
2 and comments received under such paragraph, and
3 any changes made to the recommendations in re-
4 sponse to such views and comments.

5 **SEC. 6. SUNSET DATES.**

6 The amendments made by sections 2, 3, and 4 cease
7 to be effective October 1, 2012.