

[COMMITTEE PRINT]

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE
ON HEALTH ON JUNE 19, 2007]

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

1 provision of law are amendments to such section or other
2 provision of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 301 et seq.).

4 **SEC. 2. DEFINITIONS.**

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

6 (1) in paragraph (1)—

7 (A) in subparagraph (A), by striking
8 “505(b)(1),” and inserting “505(b), or”;

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

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

12 (2) in paragraph (3)(C)—

13 (A) by striking “505(j)(7)(A)” and insert-
14 ing “505(j)(7)(A) (not including the discon-
15 tinued section of such list),”;

16 (B) by inserting before the period “(not in-
17 cluding the discontinued section of such list)”;

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

22 (4) by amending paragraph (6)(F) to read as
23 follows:

24 “(F) Postmarket safety activities with re-
25 spect to drugs approved under human drug ap-

1 plications or supplements, including the fol-
2 lowing activities:

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

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

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

13 (5) in paragraph (8)—

14 (A) by striking “April of the preceding fis-
15 cal year” and inserting “October of the pre-
16 ceding fiscal year”; and

17 (B) by striking “April 1997” and inserting
18 “October 1996”;

19 (6) by redesignating paragraph (9) as para-
20 graph (10); and

21 (7) by inserting after paragraph (8) the fol-
22 lowing paragraphs:

23 “(9) The term ‘person’ includes an affiliate
24 thereof.

1 “(10) The term ‘active’, with respect to a com-
2 mercial investigational new drug application, means
3 such an application to which information was sub-
4 mitted during the relevant period.”.

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 POSITRON EMIS-
14 SION 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 positron
19 emission tomography drug shall be subject
20 under subparagraph (A) to one-sixth of an
21 annual establishment fee with respect to
22 each such establishment identified in the
23 application as producing positron emission
24 tomography drugs under the approved ap-
25 plication.

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
13 positron emission tomography drugs;
14 and

15 “(II) at least 95 percent of the
16 total number of doses of each positron
17 emission tomography drug produced
18 by such establishment during such fis-
19 cal year will be used within the med-
20 ical center.

21 “(iii) DEFINITION.—For purposes of
22 this subparagraph, the term ‘positron
23 emission tomography drug’ has the mean-
24 ing given such term in section 201(ii) with-

1 out regard to subparagraph (1)(B) of such
2 section.”.

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

5 “(b) FEE REVENUE AMOUNTS.—

6 “(1) IN GENERAL.—For each of the fiscal years
7 2008 through 2012, fees under subsection (a) shall,
8 except as provided in subsections (c), (d), (f), and
9 (g), be established to generate a total revenue
10 amount under such subsection that is equal to the
11 sum of—

12 “(A) \$392,783,000; and

13 “(B) an amount equal to the modified
14 workload adjustment factor for fiscal year 2007
15 (as determined under paragraph (3)).

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

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

22 “(B) one-third shall be derived from fees
23 under subsection (a)(2) (relating to prescription
24 drug establishments); and

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

4 “(3) MODIFIED WORKLOAD ADJUSTMENT FAC-
5 TOR FOR FISCAL YEAR 2007.—For purposes of
6 paragraph (1)(B), the Secretary shall determine the
7 modified workload adjustment factor by determining
8 the dollar amount that results from applying the
9 methodology that was in effect under subsection
10 (c)(2) for fiscal year 2007 to the amount
11 \$354,893,000, except that, with respect to the por-
12 tion of such determination that is based on the
13 change in the total number of commercial investiga-
14 tional new drug applications, the Secretary shall
15 count the number of such applications that were ac-
16 tive during the most recent 12-month period for
17 which data on such submissions is available.

18 “(4) ADDITIONAL FEE REVENUES FOR DRUG
19 SAFETY.—

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

1 “(B) AMOUNT DETERMINED.—For each of
2 the fiscal years 2008 through 2012, the amount
3 determined under this subparagraph is the sum
4 of—

5 “(i) \$392,783,000; plus

6 “(ii) an amount equal to—

7 “(I)(aa) for fiscal year 2008,
8 \$25,000,000;

9 “(bb) for fiscal year 2009,
10 \$35,000,000;

11 “(cc) for fiscal year 2010,
12 \$45,000,000;

13 “(dd) for fiscal year 2011,
14 \$55,000,000; and

15 “(ee) for fiscal year 2012,
16 \$65,000,000; minus

17 “(II) the amount equal to one-
18 fifth of the excess amount in item
19 (bb), provided that—

20 “(aa) the amount of the
21 total appropriation for the Food
22 and Drug Administration for
23 such fiscal year (excluding the
24 amount of fees appropriated for
25 such fiscal year) exceeds the

1 amount of the total appropriation
2 for the Food and Drug Adminis-
3 tration for fiscal year 2007 (ex-
4 cluding the amount of fees appro-
5 priated for such fiscal year), ad-
6 justed as provided under sub-
7 section (c)(1); and

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

23 In making the adjustment under sub-
24 clause (II) for any fiscal year 2008
25 through 2012, subsection (c)(1) shall

1 be applied by substituting ‘2007’ for
2 ‘2008.’

3 “(C) LIMITATION.—This paragraph shall
4 not apply for any fiscal year if the amount de-
5 scribed under subparagraph (B)(ii) is less than
6 0.”.

7 (c) ADJUSTMENTS TO FEES.—

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

10 (A) in the matter preceding subparagraph
11 (A), by striking “The revenues established in
12 subsection (b)” and inserting “For fiscal year
13 2009 and subsequent fiscal years, the revenues
14 established in subsection (b)”;

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

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

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

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

1 such positions for the first 5 years of the pre-
2 ceding 6 fiscal years.”; and

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

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

9 (A) in the matter preceding subparagraph
10 (A), by striking “Beginning with fiscal year
11 2004,” and inserting “For fiscal year 2009 and
12 subsequent fiscal years,”;

13 (B) in subparagraph (A), in the first sen-
14 tence—

15 (i) by striking “human drug applica-
16 tions,” and inserting “human drug applica-
17 tions (adjusted for changes in review ac-
18 tivities, as described in the notice that the
19 Secretary is required to publish in the
20 Federal Register pursuant to subsection
21 (c)(2)(A)),”;

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

24 (iii) by inserting before the period the
25 following: “, and the change in the total

1 number of active commercial investiga-
2 tional new drug applications (adjusted for
3 changes in review activities, as so described
4) during the most recent 12-month period
5 for which data on such submissions is
6 available”;

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

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

16 “(C) The Secretary shall contract with an
17 independent accounting firm to study the ad-
18 justment for changes in review activities applied
19 in setting fees and revenue amounts for fiscal
20 year 2009 and to make recommendations, if
21 warranted, for future changes in the method-
22 ology for calculating the adjustment. After re-
23 view of the recommendations, the Secretary
24 shall, if warranted, make appropriate changes
25 to the methodology, and the changes shall be ef-

1 fective for each of the fiscal years 2010 through
2 2012. The Secretary shall not make any adjust-
3 ment for changes in review activities for any
4 fiscal year after 2009 unless such study has
5 been completed.”.

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

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

12 (B) by inserting after paragraph (2) the
13 following:

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

1 year, and shall not exceed \$11,721,000 for any fiscal
2 year.”.

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

5 (A) in paragraph (4) (as redesignated by
6 paragraph (3)(A))—

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

9 (ii) by striking “paragraphs (1) and
10 (2)” and inserting “paragraphs (1), (2),
11 and (3)”;

12 (iii) by striking “2008” and inserting
13 “2013”;

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

16 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
17 (21 U.S.C. 379h(d)) is amended—

18 (1) in paragraph (1), in the matter preceding
19 subparagraph (A)—

20 (A) by inserting after “The Secretary shall
21 grant” the following: “to a person who is
22 named as the applicant in a human drug appli-
23 cation”;

24 (B) by inserting “to that person” after
25 “one or more fees assessed”;

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

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

5 “(2) CONSIDERATIONS.—In determining wheth-
6 er to grant a waiver or reduction of a fee under
7 paragraph (1), the Secretary shall consider only the
8 circumstances and assets of the applicant involved
9 and any affiliate of the applicant.”; and

10 (4) in paragraph (4) (as redesignated by para-
11 graph (2)), in subparagraph (A), by inserting before
12 the period the following: “, and that does not have
13 a drug product that has been approved under a
14 human drug application and introduced or delivered
15 for introduction into interstate commerce”.

16 (e) CREDITING AND AVAILABILITY OF FEES.—

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

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 or otherwise affected under

1 subsection (c) and paragraph (4) of this sub-
2 section.”.

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

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

18 (f) CONFORMING AMENDMENT.—Section 736(a) of
19 the Federal Food, Drug and Cosmetic Act (21 U.S.C.
20 379h) is amended in paragraphs (1)(A)(i), (1)(A)(ii),
21 (2)(A), and (3)(A) by striking “(c)(4)” each place such
22 term appears and inserting “(c)(5)”.

1 **SEC. 4. FEES RELATING TO ADVISORY REVIEW OF PRE-**
2 **SCRIPTION-DRUG TELEVISION ADVERTISING.**

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

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

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

12 “(1) ADVISORY REVIEW FEE.—

13 “(A) IN GENERAL.—With respect to a pro-
14 posed direct-to-consumer television advertise-
15 ment (referred to in this section as a ‘DTC ad-
16 vertisement’), each person that on or after Oc-
17 tober 1, 2007, submits such an advertisement
18 for advisory review by the Secretary prior to its
19 initial public broadcast (referred to in this sec-
20 tion as ‘prebroadcast advisory review’) shall, ex-
21 cept as provided in subparagraph (B), be sub-
22 ject to a fee established under subsection (c)(3).

23 “(B) EXCEPTION FOR REQUIRED SUBMIS-
24 SIONS.—A DTC advertisement that is required
25 under section 502(n) to be submitted to the
26 Secretary prior to initial public broadcast is not

1 subject to a fee under subparagraph (A) unless
2 the sponsor designates the submission as a sub-
3 mission for prebroadcast advisory review.

4 “(C) NOTICE TO SECRETARY OF NUMBER
5 OF ADVERTISEMENTS.—Not later than June 1
6 of each fiscal year, the Secretary shall publish
7 a notice in the Federal Register requesting any
8 person to notify the Secretary within 30 days of
9 the number of DTC advertisements the person
10 intends to submit for prebroadcast advisory re-
11 view in the next fiscal year.

12 “(D) PAYMENT.—

13 “(i) IN GENERAL.—The fee required
14 by subparagraph (A) (referred to in this
15 section as ‘an advisory review fee’) shall be
16 due not later than October 1 of the fiscal
17 year in which the DTC advertisement in-
18 volved is intended be submitted for
19 prebroadcast advisory review, subject to
20 subparagraph (E)(i).

21 “(ii) EFFECT OF SUBMISSION.—Noti-
22 fication of the Secretary under subpara-
23 graph (C) of the number of DTC adver-
24 tisements a person intends to submit for
25 prebroadcast advisory review is a legally

1 binding commitment by that person to pay
2 the annual advisory review fee for that
3 number of submissions on or before Octo-
4 ber 1 of the fiscal year in which the adver-
5 tisement is intended to be submitted.

6 “(iii) NOTICE REGARDING CARRYOVER
7 SUBMISSIONS.—In making a notification
8 under subparagraph (C), the person in-
9 volved shall in addition notify the Sec-
10 retary if under subparagraph (E)(i) the
11 person intends to submit a DTC advertise-
12 ment for which the advisory review fee has
13 already been paid. If the person does not
14 so notify the Secretary, each DTC adver-
15 tisement submitted by the person for
16 prebroadcast advisory review in the fiscal
17 year involved shall be subject to the advi-
18 sory review fee.

19 “(E) MODIFICATION OF ADVISORY REVIEW
20 FEE.—

21 “(i) LATE PAYMENT.—If a person has
22 submitted a notification under subpara-
23 graph (C) with respect to a fiscal year and
24 has not paid all advisory review fees due
25 under subparagraph (D) on or before No-

1 vember 1 of such fiscal year, the fees are
2 regarded as late and a revised due date
3 and an increase in the amount of fees ap-
4 plies in accordance with this clause, not-
5 withstanding any other provision of this
6 section. For such person, the advisory re-
7 view fee for each DTC advertisement sub-
8 mitted in such fiscal year for prebroadcast
9 advisory review shall be due and payable
10 20 days before the advertisement is sub-
11 mitted to the Secretary, and each such fee
12 shall be revised to be equal to 150 percent
13 of the fee that otherwise would have ap-
14 plied pursuant to subsection (c)(3).

15 “(ii) EXCEEDING IDENTIFIED NUM-
16 BER OF SUBMISSIONS.—If a person sub-
17 mits a number of DTC ads for
18 prebroadcast advisory review in a fiscal
19 year that exceeds the number identified by
20 the person under subparagraph (C), a re-
21 vised due date and an increase in the
22 amount of fees applies under this clause
23 for each submission in excess of such num-
24 ber, notwithstanding any other provision of
25 this section. For each such DTC ad, the

1 advisory review fee shall be due and pay-
2 able 20 days before the advertisement is
3 submitted to the Secretary, and the fee
4 shall be revised to be equal to 150 percent
5 of the fee that otherwise would have ap-
6 plied pursuant to subsection (c)(3).

7 “(F) LIMITS.—

8 “(i) SUBMISSIONS.—For each advi-
9 sory review fee paid by a person for a fis-
10 cal year, the person is entitled to accept-
11 ance for advisory review by the Secretary
12 of one DTC advertisement and acceptance
13 of one resubmission for advisory review of
14 the same advertisement. The advertisement
15 shall be submitted for review in the fiscal
16 year for which the fee was assessed, except
17 that a person may carry over not more
18 than one paid advisory review submission
19 to the next fiscal year. Resubmissions may
20 be submitted without regard to the fiscal
21 year of the initial advisory review submis-
22 sion.

23 “(ii) NO REFUNDS.—Except as pro-
24 vided by subsection (f), fees paid under
25 subparagraph (A) shall not be refunded.

1 “(iii) NO WAIVERS, EXEMPTIONS, OR
2 REDUCTIONS.—The Secretary shall not
3 grant a waiver, exemption, or reduction of
4 any fees due or payable under this section.

5 “(iv) RIGHT TO ADVISORY REVIEW
6 NOT TRANSFERABLE.—The right to an ad-
7 visory review under this paragraph is not
8 transferable, except to a successor in inter-
9 est.

10 “(2) OPERATING RESERVE FEE.—

11 “(A) IN GENERAL.—Each person that on
12 or after October 1, 2007, is assessed an advi-
13 sory review fee under paragraph (1) shall be
14 subject to fee established under subsection
15 (d)(2) referred to in this section as an ‘oper-
16 ating reserve fee’ for the first fiscal year in
17 which an advisory review fee is assessed to such
18 person. The person is not subject to an oper-
19 ating reserve fee for any other fiscal year.

20 “(B) PAYMENT.—Except as provided in
21 subparagraph (C), the operating reserve fee
22 shall be due no later than October 1 of the first
23 fiscal year in which the person is required to
24 pay an advisory review fee under paragraph (1).

1 “(C) LATE NOTICE OF SUBMISSION.—If, in
2 the first fiscal year of a person’s participation
3 in the program under this section, that person
4 submits any DTC advertisements for
5 prebroadcast advisory review that are in excess
6 of the number identified by that person in re-
7 sponse to the Federal Register notice described
8 in subsection (a)(1)(C), that person shall pay
9 an operating reserve fee for each of those advi-
10 sory reviews equal to the advisory review fee for
11 each submission established under paragraph
12 (1)(D)(ii). Fees required by this subparagraph
13 shall be in addition to any fees required by sub-
14 paragraph (A). Fees under this subparagraph
15 shall be due 20 days before any DTC advertise-
16 ment is submitted by such person to the Sec-
17 retary for prebroadcast advisory review.

18 “(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—
19 Fees under subsection (a)(1) shall be established to gen-
20 erate revenue amounts of \$6,250,000 for each of fiscal
21 years 2008 through 2012, as adjusted pursuant to sub-
22 sections (c) and (g)(4).

23 “(c) ADJUSTMENTS.—

24 “(1) INFLATION ADJUSTMENT.—Beginning
25 with fiscal year 2009, the revenues established in

1 subsection (b) shall be adjusted by the Secretary by
2 notice, published in the Federal Register, for a fiscal
3 year to reflect the greater of—

4 “(A) the total percentage change that oc-
5 curred in the Consumer Price Index for all
6 urban consumers (all items; U.S. city average),
7 for the 12 month period ending June 30 pre-
8 ceeding the fiscal year for which fees are being
9 established;

10 “(B) the total percentage change for the
11 previous fiscal year in basic pay under the Gen-
12 eral Schedule in accordance with section 5332
13 of title 5, United States Code, as adjusted by
14 any locality-based comparability payment pur-
15 suant to section 5304 of such title for Federal
16 employees stationed in the District of Columbia;
17 or

18 “(C) the average annual change in the
19 cost, per full-time equivalent position of the
20 Food and Drug Administration, of all personnel
21 compensation and benefits paid with respect to
22 such positions for the first 5 fiscal years of the
23 previous 6 fiscal years.

24 The adjustment made each fiscal year by this sub-
25 section will be added on a compounded basis to the

1 sum of all adjustments made each fiscal year after
2 fiscal year 2008 under this subsection.

3 “(2) WORKLOAD ADJUSTMENT.—Beginning
4 with fiscal year 2009, after the fee revenues estab-
5 lished in subsection (b) are adjusted for a fiscal year
6 for inflation in accordance with paragraph (1), the
7 fee revenues shall be adjusted further for such fiscal
8 year to reflect changes in the workload of the Sec-
9 retary with respect to the submission of DTC adver-
10 tisements for advisory review prior to initial broad-
11 cast. With respect to such adjustment:

12 “(A) The adjustment shall be determined
13 by the Secretary based upon the number of
14 DTC advertisements identified pursuant to sub-
15 section (a)(1)(C) for the upcoming fiscal year,
16 excluding allowable previously paid carry over
17 submissions. The adjustment shall be deter-
18 mined by multiplying the number of such adver-
19 tisements projected for that fiscal year that ex-
20 ceeds 150 by \$27,600 (adjusted each year be-
21 ginning with fiscal year 2009 for inflation in
22 accordance with paragraph (1)). The Secretary
23 shall publish in the Federal Register the fee
24 revenues and fees resulting from the adjust-
25 ment and the supporting methodologies.

1 “(B) Under no circumstances shall the ad-
2 justment result in fee revenues for a fiscal year
3 that are less than the fee revenues established
4 for the prior fiscal year.

5 “(3) ANNUAL FEE SETTING FOR ADVISORY RE-
6 VIEW.—

7 “(A) IN GENERAL.—Not later than August
8 1 of each fiscal year, the Secretary shall estab-
9 lish for the next fiscal year the DTC advertise-
10 ment advisory review fee under subsection
11 (a)(1), based on the revenue amounts estab-
12 lished under subsection (b), the adjustments
13 provided under paragraphs (1) and (2), and the
14 number of DTC advertisements identified pur-
15 suant to subsection (a)(1)(C), excluding allow-
16 able previously-paid carry over submissions.
17 The annual advisory review fee shall be estab-
18 lished by dividing the fee revenue for a fiscal
19 year (as adjusted pursuant to this subsection)
20 by the number of DTC advertisements so iden-
21 tified, excluding allowable previously-paid carry
22 over submissions.

23 “(B) FISCAL YEAR 2008 FEE LIMIT.—Not-
24 withstanding subsection (b) and the adjust-
25 ments pursuant to this subsection, the fee es-

1 tablished under subparagraph (A) for fiscal
2 year 2008 may not be more than \$83,000 per
3 submission for advisory review.

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

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

16 “(d) OPERATING RESERVES.—

17 “(1) IN GENERAL.—The Secretary shall estab-
18 lish in the Food and Drug Administration salaries
19 and expenses appropriation account without fiscal
20 year limitation a Direct-to-Consumer Advisory Re-
21 view Operating Reserve, of at least \$6,250,000 in
22 fiscal year 2008, to continue the program under this
23 section in the event the fees collected in any subse-
24 quent fiscal year pursuant to subsection (a)(1) do

1 not generate the fee revenue amount established for
2 that fiscal year.

3 “(2) **FEE SETTING.**—The Secretary shall estab-
4 lish the operating reserve fee under subsection
5 (a)(2)(A) for each person required to pay the fee by
6 multiplying the number of DTC advertisements iden-
7 tified by that person pursuant to subsection
8 (a)(1)(C) by the advisory review fee established pur-
9 suant to subsection (c)(3) for that fiscal year, except
10 that in no case shall the operating reserve fee as-
11 sessed be less than the operating reserve fee as-
12 sessed if the person had first participated in the pro-
13 gram under this section in fiscal year 2008.

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

24 “(4) **REFUND OF OPERATING RESERVES.**—
25 Within 120 days of the end of fiscal year 2012, or

1 if the program under this section ends early pursu-
2 ant to subsection (f), the Secretary, after setting
3 aside sufficient operating reserve amounts to termi-
4 nate the program under this section, shall refund all
5 amounts remaining in the operating reserve on a pro
6 rata basis to each person that paid an operating re-
7 serve fee assessment. In no event shall the refund to
8 any person exceed the total amount of operating re-
9 serve fees paid by such person pursuant to sub-
10 section (a)(2).

11 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
12 standing any other requirement, a submission for
13 prebroadcast advisory review of a DTC advertisement sub-
14 mitted by a person subject to fees under subsection (a)
15 shall be considered incomplete and shall not be accepted
16 for review by the Secretary until all fees owed by such
17 person under this section have been paid.

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

20 “(1) INITIAL FUNDING.—If on November 1,
21 2007, or 120 days after enactment of this provision,
22 whichever is later, the Secretary has not received at
23 least \$11,250,000 in advisory review fees and oper-
24 ating reserve fees combined, the program under this

1 section shall not commence and all collected fees
2 shall be refunded.

3 “(2) LATER FISCAL YEARS.—Beginning in fis-
4 cal year 2009, if, on November 1 of the 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 falls below
8 \$9,000,000, adjusted for inflation (as described in
9 subsection (c)(1)), the program under this section
10 shall cease to exist, and the Secretary shall notify all
11 participants, retain any money from the unused ad-
12 visory review fees and the operating reserves needed
13 to close down the program under this section, and
14 refund the remainder of the unused fees and oper-
15 ating reserves. To the extent required to close down
16 the program under this section, the Secretary shall
17 first use unobligated advisory review fee revenues
18 from prior fiscal years, then the operating reserves,
19 and finally, unused advisory review fees from the rel-
20 evant fiscal year.

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

22 “(1) IN GENERAL.—Fees authorized under sub-
23 section (a) of this section shall be collected and
24 available for obligation only to the extent and in the
25 amount provided in advance in appropriations Acts.

1 Such fees are authorized to remain available until
2 expended. Such sums as may be necessary may be
3 transferred from the Food and Drug Administration
4 salaries and expenses appropriation account without
5 fiscal year limitation to such appropriation account
6 for salaries and expenses with such fiscal year limi-
7 tation. The sums transferred shall be available solely
8 for the process for the advisory review of prescrip-
9 tion drug advertising.

10 “(2) COLLECTIONS AND APPROPRIATION
11 ACTS.—

12 “(A) IN GENERAL.—The fees authorized
13 by this section—

14 “(i) shall be retained in each fiscal
15 year in an amount not to exceed the
16 amount specified in appropriation Acts, or
17 otherwise made available for obligation for
18 such fiscal year; and

19 “(ii) shall be available for obligation
20 only if the amounts appropriated as budget
21 authority for such fiscal year are sufficient
22 to support a number of full-time equivalent
23 review employees that is not fewer than the
24 number of such employees supported in fis-
25 cal year 2007.

1 “(B) REVIEW EMPLOYEES.—For purposes
2 of subparagraph (A)(ii), the term ‘full-time
3 equivalent review employees’ means the total
4 combined number of full-time equivalent em-
5 ployees in—

6 “(i) the Center for Drug Evaluation
7 and Research, Division of Drug Marketing,
8 Advertising, and Communications, Food
9 and Drug Administration; and

10 “(ii) the Center for Biologics Evalua-
11 tion and Research, Advertising and Pro-
12 motional Labeling Branch, Food and Drug
13 Administration.

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 pursuant to subsection (c) and
20 paragraph (4) of this subsection, plus amounts col-
21 lected for the reserve fund under subsection (d).

22 “(4) OFFSET.—Any amount of fees collected
23 for a fiscal year under this section that exceeds the
24 amount of fees specified in appropriation Acts for
25 such fiscal year shall be credited to the appropria-

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

6 “(h) DEFINITIONS.—For purposes of this sub-
7 chapter:

8 “(1) The term ‘advisory review’ means review-
9 ing and providing advisory comments on a proposed
10 advertisement prior to its initial public broadcast.

11 “(2) The term ‘advisory review fee’ has the
12 meaning indicated for such term in subsection
13 (a)(1)(D).

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

18 “(4) 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 3 minutes.

23 “(5) The term ‘DTC advertisement’ has the
24 meaning indicated for such term in subsection
25 (a)(1)(A).

1 “(6) The term ‘operating reserve fee’ has the
2 meaning indicated for such term in subsection
3 (a)(2)(A).

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

7 “(8) The term ‘prebroadcast advisory review’
8 has the meaning indicated for such term in sub-
9 section (a)(1)(A).

10 “(9) 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 DTC advertisements prior to public broadcast
14 and, to the extent the Secretary has additional staff
15 resources available under the program under this
16 section that are not necessary for the advisory re-
17 view of DTC advertisements, the activities necessary
18 to review and provide advisory comments on other
19 proposed advertisements and promotional material
20 prior to public broadcast.

21 “(10) The term ‘resources allocated for the
22 process for the advisory review of prescription drug
23 advertising’ means the expenses incurred in connec-
24 tion with the process for the advisory review of pre-
25 scription drug advertising for—

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

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

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

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

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

21 “(11) The term ‘resubmission’ means a subse-
22 quent submission for advisory review of a direct-to-
23 consumer television advertisement that has been re-
24 vised in response to the Secretary’s comments on an
25 original submission. A resubmission may not intro-

1 duce significant new concepts or creative themes into
2 the television advertisement.

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

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

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

1 (b) FISCAL REPORT.—Beginning with fiscal year
2 2008, not later than 120 days after the end of each fiscal
3 year for which fees are collected under the part described
4 in subsection (a), the Secretary shall prepare and submit
5 to the Committee on Energy and Commerce of the House
6 of Representatives and the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate a report on the
8 implementation of the authority for such fees during such
9 fiscal year and the use, by the Food and Drug Administra-
10 tion, of the fees collected for such fiscal year.

11 (c) REAUTHORIZATION.—

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

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

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

23 (C) scientific and academic experts;

24 (D) health care professionals;

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

3 (F) the regulated industry.

4 (2) PUBLIC REVIEW OF RECOMMENDATIONS.—

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

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

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

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

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

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

22 (3) TRANSMITTAL OF RECOMMENDATIONS.—

23 Not later than January 15, 2012, the Secretary
24 shall transmit to Congress the revised recommenda-
25 tions under paragraph (2), a summary of the views

1 and comments received under such paragraph, and
2 any changes made to the recommendations in re-
3 sponse to such views and comments.

4 **SEC. 6. SUNSET DATES.**

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