

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO THE COMMITTEE PRINT
OFFERED BY _____

[Prescription Drug User Fee Act]

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; REFERENCES IN ACT.

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

4 (b) REFERENCES IN ACT.—Except as otherwise spec-
5 ified, amendments made by this Act to a section or other
6 provision of law are amendments to such section or other
7 provision of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 301 et seq.).

9 SEC. 2. DEFINITIONS.

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

11 (1) in paragraph (1)—

12 (A) in subparagraph (A), by striking
13 “505(b)(1),” and inserting “505(b), or”;

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

15 (C) by redesignating subparagraph (C) as
16 subparagraph (B);

17 (2) in paragraph (3)(C)—

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

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

6 (3) in paragraph (4), by inserting before the pe-
7 riod at the end the following: “(such as capsules,
8 tablets, or lyophilized products before reconstitu-
9 tion)”;

10 (4) by amending paragraph (6)(F) to read as
11 follows:

12 “(F) Postmarket safety activities with re-
13 spect to drugs approved under human drug ap-
14 plications or supplements, including the fol-
15 lowing activities:

16 “(i) Collecting, developing, and re-
17 viewing safety information on approved
18 drugs, including adverse event reports.

19 “(ii) Developing and using improved
20 adverse-event data-collection systems, in-
21 cluding information technology systems.

22 “(iii) Developing and using improved
23 analytical tools to assess potential safety
24 problems, including access to external data
25 bases.”;

1 (5) in paragraph (8)—

2 (A) by striking “April of the preceding fis-
3 cal year” and inserting “October of the pre-
4 ceding fiscal year”; and

5 (B) by striking “April 1997” and inserting
6 “October 1996”;

7 (6) by redesignating paragraph (9) as para-
8 graph (10); and

9 (7) by inserting after paragraph (8) the fol-
10 lowing paragraphs:

11 “(9) The term ‘person’ includes an affiliate
12 thereof.

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

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

18 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
19 379h(a)) is amended—

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

22 (2) in paragraph (1)—

23 (A) in subparagraph (D)—

1 (i) in the heading, by inserting “OR
2 WITHDRAWN BEFORE FILING” after “RE-
3 FUSED FOR FILING”; and

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

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

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

12 “(E) FEES FOR APPLICATIONS PRE-
13 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
14 BEFORE FILING.—A human drug application or
15 supplement that was submitted but was refused
16 for filing, or was withdrawn before being ac-
17 cepted or refused for filing, shall be subject to
18 the full fee under subparagraph (A) upon being
19 resubmitted or filed over protest, unless the fee
20 is waived or reduced under subsection (d).”;
21 and

22 (3) in paragraph (2)—

23 (A) in subparagraph (A), by striking “sub-
24 paragraph (B)” and inserting “subparagraphs
25 (B) and (C)”; and

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

2 “(C) SPECIAL RULES FOR POSITRON EMIS-
3 SION TOMOGRAPHY DRUGS.—

4 “(i) IN GENERAL.—Except as pro-
5 vided in clause (ii), each person who is
6 named as the applicant in an approved
7 human drug application for a positron
8 emission tomography drug shall be subject
9 under subparagraph (A) to one-sixth of an
10 annual establishment fee with respect to
11 each such establishment identified in the
12 application as producing positron emission
13 tomography drugs under the approved ap-
14 plication.

15 “(ii) EXCEPTION FROM ANNUAL ES-
16 TABLISHMENT FEE.—Each person who is
17 named as the applicant in an application
18 described in clause (i) shall not be assessed
19 an annual establishment fee for a fiscal
20 year if the person certifies to the Sec-
21 retary, at a time specified by the Secretary
22 and using procedures specified by the Sec-
23 retary, that—

24 “(I) the person is a not-for-profit
25 medical center that has only 1 estab-

1 lishment for the production of
2 positron emission tomography drugs;
3 and

4 “(II) at least 95 percent of the
5 total number of doses of each positron
6 emission tomography drug produced
7 by such establishment during such fis-
8 cal year will be used within the med-
9 ical center.

10 “(iii) DEFINITION.—For purposes of
11 this subparagraph, the term ‘positron
12 emission tomography drug’ has the mean-
13 ing given such term in section 201(ii) with-
14 out regard to subparagraph (1)(B) of such
15 section.”.

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

18 “(b) FEE REVENUE AMOUNTS.—

19 “(1) IN GENERAL.—For each of the fiscal years
20 2008 through 2012, fees under subsection (a) shall,
21 except as provided in subsections (c), (d), (f), and
22 (g), be established to generate a total revenue
23 amount under such subsection that is equal to the
24 sum of—

25 “(A) \$392,783,000; and

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

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

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

10 “(B) one-third shall be derived from fees
11 under subsection (a)(2) (relating to prescription
12 drug establishments); and

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

16 “(3) MODIFIED WORKLOAD ADJUSTMENT FAC-
17 TOR FOR FISCAL YEAR 2007.—For purposes of
18 paragraph (1)(B), the Secretary shall determine the
19 modified workload adjustment factor by determining
20 the dollar amount that results from applying the
21 methodology that was in effect under subsection
22 (c)(2) for fiscal year 2007 to the amount
23 \$354,893,000, except that, with respect to the por-
24 tion of such determination that is based on the
25 change in the total number of commercial investiga-

1 tional new drug applications, the Secretary shall
2 count the number of such applications that were ac-
3 tive during the most recent 12-month period for
4 which data on such submissions is available.

5 “(4) ADDITIONAL FEE REVENUES FOR DRUG
6 SAFETY.—

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

12 “(B) AMOUNT DETERMINED.—For each of
13 the fiscal years 2008 through 2012, the amount
14 determined under this subparagraph is the sum
15 of—

16 “(i) \$392,783,000; plus

17 “(ii) an amount equal to—

18 “(I)(aa) for fiscal year 2008,
19 \$25,000,000;

20 “(bb) for fiscal year 2009,
21 \$35,000,000;

22 “(cc) for fiscal year 2010,
23 \$45,000,000;

24 “(dd) for fiscal year 2011,
25 \$55,000,000; and

1 “(ee) for fiscal year 2012,
2 \$65,000,000; minus

3 “(II) the amount equal to one-
4 fifth of the excess amount in item
5 (bb), provided that—

6 “(aa) the amount of the
7 total appropriation for the Food
8 and Drug Administration for
9 such fiscal year (excluding the
10 amount of fees appropriated for
11 such fiscal year) exceeds the
12 amount of the total appropriation
13 for the Food and Drug Adminis-
14 tration for fiscal year 2007 (ex-
15 cluding the amount of fees appro-
16 priated for such fiscal year), ad-
17 justed as provided under sub-
18 section (c)(1); and

19 “(bb) the amount of the
20 total appropriations for the proc-
21 ess of human drug review at the
22 Food and Drug Administration
23 for such fiscal year (excluding
24 the amount of fees appropriated
25 for such fiscal year) exceeds the

1 amount of appropriations for the
2 process of human drug review at
3 the Food and Drug Administra-
4 tion for fiscal year 2007 (exclud-
5 ing the amount of fees appro-
6 priated for such fiscal year), ad-
7 justed as provided under sub-
8 section (c)(1).

9 In making the adjustment under sub-
10 clause (II) for any fiscal year 2008
11 through 2012, subsection (c)(1) shall
12 be applied by substituting ‘2007’ for
13 ‘2008.’

14 “(C) LIMITATION.—This paragraph shall
15 not apply for any fiscal year if the amount de-
16 scribed under subparagraph (B)(ii) is less than
17 0.”.

18 (c) ADJUSTMENTS TO FEES.—

19 (1) INFLATION ADJUSTMENT.—Section
20 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

21 (A) in the matter preceding subparagraph
22 (A), by striking “The revenues established in
23 subsection (b)” and inserting “For fiscal year
24 2009 and subsequent fiscal years, the revenues
25 established in 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 years of the pre-
12 ceding 6 fiscal years.”; and

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

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

19 (A) in the matter preceding subparagraph
20 (A), by striking “Beginning with fiscal year
21 2004,” and inserting “For fiscal year 2009 and
22 subsequent fiscal years,”;

23 (B) in subparagraph (A), in the first sen-
24 tence—

1 (i) by striking “human drug applica-
2 tions,” and inserting “human drug applica-
3 tions (adjusted for changes in review ac-
4 tivities, as described in the notice that the
5 Secretary is required to publish in the
6 Federal Register pursuant to subsection
7 (c)(2)(A)),”;

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

10 (iii) by inserting before the period the
11 following: “, and the change in the total
12 number of active commercial investiga-
13 tional new drug applications (adjusted for
14 changes in review activities, as so described
15) during the most recent 12-month period
16 for which data on such submissions is
17 available”;

18 (C) in subparagraph (B), by adding at the
19 end the following: “Any adjustment for changes
20 in review activities made in setting fees and rev-
21 enue amounts for fiscal year 2009 may not re-
22 sult in the total workload adjustment being
23 more than 2 percentage points higher than it
24 would have been in the absence of the adjust-
25 ment for changes in review activities.”; and

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

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

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

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

23 (B) by inserting after paragraph (2) the
24 following:

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

14 (4) FINAL YEAR ADJUSTMENT.—Section 736(c)
15 (21 U.S.C. 379h(c)) is amended—

16 (A) in paragraph (4) (as redesignated by
17 paragraph (3)(A))—

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

20 (ii) by striking “paragraphs (1) and
21 (2)” and inserting “paragraphs (1), (2),
22 and (3)”;

23 (iii) by striking “2008” and inserting
24 “2013”;

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

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

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

7 (A) by inserting after “The Secretary shall
8 grant” the following: “to a person who is
9 named as the applicant in a human drug appli-
10 cation”; and

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

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

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

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

22 (4) in paragraph (4) (as redesignated by para-
23 graph (2)), in subparagraph (A), by inserting before
24 the period the following: “, and that does not have
25 a drug product that has been approved under a

1 human drug application and introduced or delivered
2 for introduction into interstate commerce”.

3 (e) CREDITING AND AVAILABILITY OF FEES.—

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

7 “(3) AUTHORIZATION OF APPROPRIATIONS.—
8 For each of the fiscal years 2008 through 2012,
9 there is authorized to be appropriated for fees under
10 this section an amount equal to the total revenue
11 amount determined under subsection (b) for the fis-
12 cal year, as adjusted or otherwise affected under
13 subsection (c) and paragraph (4) of this sub-
14 section.”.

15 (2) OFFSET.—Section 736(g)(4) (21 U.S.C.
16 379h(g)(4)) is amended to read as follows:

17 “(4) OFFSET.—If the sum of the cumulative
18 amount of fees collected under this section for the
19 fiscal years 2008 through 2010 and the amount of
20 fees estimated to be collected under this section for
21 fiscal year 2011 exceeds the cumulative amount ap-
22 propriated under paragraph (3) for the fiscal years
23 2008 through 2011, the excess shall be credited to
24 the appropriation account of the Food and Drug Ad-
25 ministration as provided in paragraph (1), and shall

1 be subtracted from the amount of fees that would
2 otherwise be authorized to be collected under this
3 section pursuant to appropriation Acts for fiscal
4 year 2012.”.

5 (f) CONFORMING AMENDMENT.—Section 736(a) of
6 the Federal Food, Drug and Cosmetic Act (21 U.S.C.
7 379h) is amended in paragraphs (1)(A)(i), (1)(A)(ii),
8 (2)(A), and (3)(A) by striking “(c)(4)” each place such
9 term appears and inserting “(c)(5)”.

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

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

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

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

21 “(1) ADVISORY REVIEW FEE.—

22 “(A) IN GENERAL.—With respect to a pro-
23 posed direct-to-consumer television advertise-
24 ment (referred to in this section as a ‘DTC ad-
25 vertisement’), each person that on or after Oc-

1 tober 1, 2007, submits such an advertisement
2 for advisory review by the Secretary prior to its
3 initial public broadcast (referred to in this sec-
4 tion as ‘prebroadcast advisory review’) shall, ex-
5 cept as provided in subparagraph (B), be sub-
6 ject to a fee established under subsection (c)(3).

7 “(B) EXCEPTION FOR REQUIRED SUBMIS-
8 SIONS.—A DTC advertisement that is required
9 under section 502(n) to be submitted to the
10 Secretary prior to initial public broadcast is not
11 subject to a fee under subparagraph (A) unless
12 the sponsor designates the submission as a sub-
13 mission for prebroadcast advisory review.

14 “(C) NOTICE TO SECRETARY OF NUMBER
15 OF ADVERTISEMENTS.—Not later than June 1
16 of each fiscal year, the Secretary shall publish
17 a notice in the Federal Register requesting any
18 person to notify the Secretary within 30 days of
19 the number of DTC advertisements the person
20 intends to submit for prebroadcast advisory re-
21 view in the next fiscal year.

22 “(D) PAYMENT.—

23 “(i) IN GENERAL.—The fee required
24 by subparagraph (A) (referred to in this
25 section as ‘an advisory review fee’) shall be

1 due not later than October 1 of the fiscal
2 year in which the DTC advertisement in-
3 volved is intended be submitted for
4 prebroadcast advisory review, subject to
5 subparagraph (E)(i).

6 “(ii) EFFECT OF SUBMISSION.—Noti-
7 fication of the Secretary under subpara-
8 graph (C) of the number of DTC adver-
9 tisements a person intends to submit for
10 prebroadcast advisory review is a legally
11 binding commitment by that person to pay
12 the annual advisory review fee for that
13 number of submissions on or before Octo-
14 ber 1 of the fiscal year in which the adver-
15 tisement is intended to be submitted.

16 “(iii) NOTICE REGARDING CARRYOVER
17 SUBMISSIONS.—In making a notification
18 under subparagraph (C), the person in-
19 volved shall in addition notify the Sec-
20 retary if under subparagraph (E)(i) the
21 person intends to submit a DTC advertise-
22 ment for which the advisory review fee has
23 already been paid. If the person does not
24 so notify the Secretary, each DTC adver-
25 tisement submitted by the person for

1 prebroadcast advisory review in the fiscal
2 year involved shall be subject to the advisory
3 review fee.

4 “(E) MODIFICATION OF ADVISORY REVIEW
5 FEE.—

6 “(i) LATE PAYMENT.—If a person has
7 submitted a notification under subpara-
8 graph (C) with respect to a fiscal year and
9 has not paid all advisory review fees due
10 under subparagraph (D) on or before No-
11 vember 1 of such fiscal year, the fees are
12 regarded as late and a revised due date
13 and an increase in the amount of fees ap-
14 plies in accordance with this clause, not-
15 withstanding any other provision of this
16 section. For such person, the advisory re-
17 view fee for each DTC advertisement sub-
18 mitted in such fiscal year for prebroadcast
19 advisory review shall be due and payable
20 20 days before the advertisement is sub-
21 mitted to the Secretary, and each such fee
22 shall be revised to be equal to 150 percent
23 of the fee that otherwise would have ap-
24 plied pursuant to subsection (c)(3).

1 “(ii) EXCEEDING IDENTIFIED NUM-
2 BER OF SUBMISSIONS.—If a person sub-
3 mits a number of DTC ads for
4 prebroadcast advisory review in a fiscal
5 year that exceeds the number identified by
6 the person under subparagraph (C), a re-
7 vised due date and an increase in the
8 amount of fees applies under this clause
9 for each submission in excess of such num-
10 ber, notwithstanding any other provision of
11 this section. For each such DTC ad, the
12 advisory review fee shall be due and pay-
13 able 20 days before the advertisement is
14 submitted to the Secretary, and the fee
15 shall be revised to be equal to 150 percent
16 of the fee that otherwise would have ap-
17 plied pursuant to subsection (c)(3).

18 “(F) LIMITS.—

19 “(i) SUBMISSIONS.—For each advi-
20 sory review fee paid by a person for a fis-
21 cal year, the person is entitled to accept-
22 ance for advisory review by the Secretary
23 of one DTC advertisement and acceptance
24 of one resubmission for advisory review of
25 the same advertisement. The advertisement

1 shall be submitted for review in the fiscal
2 year for which the fee was assessed, except
3 that a person may carry over not more
4 than one paid advisory review submission
5 to the next fiscal year. Resubmissions may
6 be submitted without regard to the fiscal
7 year of the initial advisory review submis-
8 sion.

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

12 “(iii) NO WAIVERS, EXEMPTIONS, OR
13 REDUCTIONS.—The Secretary shall not
14 grant a waiver, exemption, or reduction of
15 any fees due or payable under this section.

16 “(iv) RIGHT TO ADVISORY REVIEW
17 NOT TRANSFERABLE.—The right to an ad-
18 visory review under this paragraph is not
19 transferable, except to a successor in inter-
20 est.

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 fee established under subsection

1 (d)(2) referred to in this section as an ‘oper-
2 ating reserve fee’ for the first fiscal year in
3 which an advisory review fee is assessed to such
4 person. The person is not subject to an oper-
5 ating reserve fee for any other fiscal year.

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

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

1 ment is submitted by such person to the Sec-
2 retary for prebroadcast advisory 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 sections (c) and (g)(4).

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; U.S. city average),
17 for the 12 month period ending June 30 pre-
18 ceding the fiscal year for which fees are being
19 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, United States Code, as adjusted by
24 any locality-based comparability payment pur-
25 suant to section 5304 of such title for Federal

1 employees stationed in the District of Columbia;
2 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 will 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.—Beginning
14 with fiscal year 2009, after the fee revenues estab-
15 lished in subsection (b) are adjusted for a fiscal year
16 for inflation in accordance with paragraph (1), the
17 fee revenues shall be adjusted further for such fiscal
18 year to reflect changes in the workload of the Sec-
19 retary with respect to the submission of DTC adver-
20 tisements for advisory review prior to initial broad-
21 cast. With respect to such adjustment:

22 “(A) The adjustment shall be determined
23 by the Secretary based upon the number of
24 DTC advertisements identified pursuant to sub-
25 section (a)(1)(C) for the upcoming fiscal year,

1 excluding allowable previously paid carry over
2 submissions. The adjustment shall be deter-
3 mined by multiplying the number of such adver-
4 tisements projected for that fiscal year that ex-
5 ceeds 150 by \$27,600 (adjusted each year be-
6 ginning with fiscal year 2009 for inflation in
7 accordance with paragraph (1)). The Secretary
8 shall publish in the Federal Register the fee
9 revenues and fees resulting from the adjust-
10 ment and the supporting methodologies.

11 “(B) Under no circumstances shall the ad-
12 justment result in fee revenues for a fiscal year
13 that are less than the fee revenues established
14 for the prior fiscal year.

15 “(3) ANNUAL FEE SETTING FOR ADVISORY RE-
16 VIEW.—

17 “(A) IN GENERAL.—Not later than August
18 1 of each fiscal year, the Secretary shall estab-
19 lish for the next fiscal year the DTC advertise-
20 ment advisory review fee under subsection
21 (a)(1), based on the revenue amounts estab-
22 lished under subsection (b), the adjustments
23 provided under paragraphs (1) and (2), and the
24 number of DTC advertisements identified pur-
25 suant to subsection (a)(1)(C), excluding allow-

1 able previously-paid carry over submissions.
2 The annual advisory review fee shall be estab-
3 lished by dividing the fee revenue for a fiscal
4 year (as adjusted pursuant to this subsection)
5 by the number of DTC advertisements so iden-
6 tified, excluding allowable previously-paid carry
7 over submissions.

8 “(B) FISCAL YEAR 2008 FEE LIMIT.—Not-
9 withstanding subsection (b) and the adjust-
10 ments pursuant to this subsection, the fee es-
11 tablished under subparagraph (A) for fiscal
12 year 2008 may not be more than \$83,000 per
13 submission for advisory review.

14 “(C) ANNUAL FEE LIMIT.—Notwith-
15 standing subsection (b) and the adjustments
16 pursuant to this subsection, the fee established
17 under subparagraph (A) for a fiscal year after
18 fiscal year 2008 may not be more than 50 per-
19 cent more than the fee established for the prior
20 fiscal year.

21 “(D) LIMIT.—The total amount of fees ob-
22 ligated for a fiscal year may not exceed the
23 total costs for such fiscal year for the resources
24 allocated for the process for the advisory review
25 of prescription drug advertising.

1 “(d) OPERATING RESERVES.—

2 “(1) IN GENERAL.—The Secretary shall estab-
3 lish in the Food and Drug Administration salaries
4 and expenses appropriation account without fiscal
5 year limitation a Direct-to-Consumer Advisory Re-
6 view Operating Reserve, of at least \$6,250,000 in
7 fiscal year 2008, to continue the program under this
8 section in the event the fees collected in any subse-
9 quent fiscal year pursuant to subsection (a)(1) do
10 not generate the fee revenue amount established for
11 that fiscal year.

12 “(2) FEE SETTING.—The Secretary shall estab-
13 lish the operating reserve fee under subsection
14 (a)(2)(A) for each person required to pay the fee by
15 multiplying the number of DTC advertisements iden-
16 tified by that person pursuant to subsection
17 (a)(1)(C) by the advisory review fee established pur-
18 suant to subsection (c)(3) for that fiscal year, except
19 that in no case shall the operating reserve fee as-
20 sessed be less than the operating reserve fee as-
21 sessed if the person had first participated in the pro-
22 gram under this section in fiscal year 2008.

23 “(3) USE OF OPERATING RESERVE.—The Sec-
24 retary may use funds from the reserves only to the
25 extent necessary in any fiscal year to make up the

1 difference between the fee revenue amount estab-
2 lished for that fiscal year under subsections (b) and
3 (c) and the amount of fees actually collected for that
4 fiscal year pursuant to subsection (a)(1), or to pay
5 costs of ending the program under this section if it
6 is terminated pursuant to subsection (f) or not reau-
7 thORIZED beyond fiscal year 2012.

8 “(4) REFUND OF OPERATING RESERVES.—
9 Within 120 days of the end of fiscal year 2012, or
10 if the program under this section ends early pursu-
11 ant to subsection (f), the Secretary, after setting
12 aside sufficient operating reserve amounts to termi-
13 nate the program under this section, shall refund all
14 amounts remaining in the operating reserve on a pro
15 rata basis to each person that paid an operating re-
16 serve fee assessment. In no event shall the refund to
17 any person exceed the total amount of operating re-
18 serve fees paid by such person pursuant to sub-
19 section (a)(2).

20 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
21 standing any other requirement, a submission for
22 prebroadcast advisory review of a DTC advertisement sub-
23 mitted by a person subject to fees under subsection (a)
24 shall be considered incomplete and shall not be accepted

1 for review by the Secretary until all fees owed by such
2 person under this section have been paid.

3 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
4 GRAM.—

5 “(1) INITIAL FUNDING.—If on November 1,
6 2007, or 120 days after enactment of this provision,
7 whichever is later, the Secretary has not received at
8 least \$11,250,000 in advisory review fees and oper-
9 ating reserve fees combined, the program under this
10 section shall not commence and all collected fees
11 shall be refunded.

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

1 first use unobligated advisory review fee revenues
2 from prior fiscal years, then the operating reserves,
3 and finally, unused advisory review fees from the rel-
4 evant fiscal year.

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

6 “(1) IN GENERAL.—Fees authorized under sub-
7 section (a) of this section shall be collected and
8 available for obligation only to the extent and in the
9 amount provided in advance in appropriations Acts.
10 Such fees are authorized to remain available until
11 expended. Such sums as may be necessary may be
12 transferred from the Food and Drug Administration
13 salaries and expenses appropriation account without
14 fiscal year limitation to such appropriation account
15 for salaries and expenses with such fiscal year limi-
16 tation. The sums transferred shall be available solely
17 for the process for the advisory review of prescrip-
18 tion drug advertising.

19 “(2) COLLECTIONS AND APPROPRIATION
20 ACTS.—

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

23 “(i) shall be retained in each fiscal
24 year in an amount not to exceed the
25 amount specified in appropriation Acts, or

1 otherwise made available for obligation for
2 such fiscal year; and

3 “(ii) shall be available for obligation
4 only if the amounts appropriated as budget
5 authority for such fiscal year are sufficient
6 to support a number of full-time equivalent
7 review employees that is not fewer than the
8 number of such employees supported in fis-
9 cal year 2007.

10 “(B) REVIEW EMPLOYEES.—For purposes
11 of subparagraph (A)(ii), the term ‘full-time
12 equivalent review employees’ means the total
13 combined number of full-time equivalent em-
14 ployees in—

15 “(i) the Center for Drug Evaluation
16 and Research, Division of Drug Marketing,
17 Advertising, and Communications, Food
18 and Drug Administration; and

19 “(ii) the Center for Biologics Evalua-
20 tion and Research, Advertising and Pro-
21 motional Labeling Branch, Food and Drug
22 Administration.

23 “(3) AUTHORIZATION OF APPROPRIATIONS.—
24 For each of the fiscal years 2008 through 2012,
25 there is authorized to be appropriated for fees under

1 this section an amount equal to the total revenue
2 amount determined under subsection (b) for the fis-
3 cal year, as adjusted pursuant to subsection (c) and
4 paragraph (4) of this subsection, plus amounts col-
5 lected for the reserve fund under subsection (d).

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

15 “(h) DEFINITIONS.—For purposes of this sub-
16 chapter:

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

20 “(2) The term ‘advisory review fee’ has the
21 meaning indicated for such term in subsection
22 (a)(1)(D).

23 “(3) The term ‘carry over submission’ means a
24 submission for an advisory review for which a fee

1 was paid in one fiscal year that is submitted for re-
2 view in the following fiscal year.

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

8 “(5) The term ‘DTC advertisement’ has the
9 meaning indicated for such term in subsection
10 (a)(1)(A).

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

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

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

20 “(9) The term ‘process for the advisory review
21 of prescription drug advertising’ means the activities
22 necessary to review and provide advisory comments
23 on DTC advertisements prior to public broadcast
24 and, to the extent the Secretary has additional staff
25 resources available under the program under this

1 section that are not necessary for the advisory re-
2 view of DTC advertisements, the activities necessary
3 to review and provide advisory comments on other
4 proposed advertisements and promotional material
5 prior to public broadcast.

6 “(10) The term ‘resources allocated for the
7 process for the advisory review of prescription drug
8 advertising’ means the expenses incurred in connec-
9 tion with the process for the advisory review of pre-
10 scription drug advertising for—

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

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

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

1 “(D) collection of fees under this section
2 and accounting for resources allocated for the
3 advisory review of prescription drug advertising;
4 and

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

7 “(11) The term ‘resubmission’ means a subse-
8 quent submission for advisory review of a direct-to-
9 consumer television advertisement that has been re-
10 vised in response to the Secretary’s comments on an
11 original submission. A resubmission may not intro-
12 duce significant new concepts or creative themes into
13 the television advertisement.

14 “(12) The term ‘submission for advisory review’
15 means an original submission of a direct-to-con-
16 sumer television advertisement for which the sponsor
17 voluntarily requests advisory comments before the
18 advertisement is publicly disseminated.”.

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

20 (a) **PERFORMANCE REPORT.**—Beginning with fiscal
21 year 2008, not later than 120 days after the end of each
22 fiscal year for which fees are collected under part 2 of
23 subchapter C of chapter VII of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary
25 of Health and Human Services (referred to in this section

1 as the “Secretary”) shall prepare and submit to the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives and the Committee on Health, Education,
4 Labor, and Pensions of the Senate a report concerning
5 the progress of the Food and Drug Administration in
6 achieving the goals identified in the letters described in
7 section 502(4) of the Prescription Drug User Fee Amend-
8 ments of 2002 (Subtitle A of title V of Public Law 107–
9 188) during such fiscal year and the future plans of the
10 Food and Drug Administration for meeting the goals.

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

21 (c) REAUTHORIZATION.—

22 (1) CONSULTATION.—In developing rec-
23 ommendations to present to the Congress with re-
24 spect to the goals, and plans for meeting the goals,
25 for the process for the review of human drug appli-

1 cations for the first 5 fiscal years after fiscal year
2 2012, and for the reauthorization of this part for
3 such fiscal years, the Secretary shall consult with—

4 (A) the Committee on Energy and Com-
5 merce of the House of Representatives;

6 (B) the Committee on Health, Education,
7 Labor, and Pensions of the Senate;

8 (C) scientific and academic experts;

9 (D) health care professionals;

10 (E) representatives of patient and con-
11 sumer advocacy groups; and

12 (F) the regulated industry.

13 (2) PUBLIC REVIEW OF RECOMMENDATIONS.—

14 After negotiations with the regulated industry and
15 representatives of patient and consumer advocacy
16 groups, the Secretary shall—

17 (A) present the recommendations devel-
18 oped under paragraph (1) to the Congressional
19 committees specified in such paragraph;

20 (B) publish such recommendations in the
21 Federal Register;

22 (C) provide for a period of 30 days for the
23 public to provide written comments on such rec-
24 ommendations;

1 (D) hold a meeting at which the public
2 may present its views on such recommenda-
3 tions; and

4 (E) after consideration of such public
5 views and comments, revise such recommenda-
6 tions as necessary.

7 (3) TRANSMITTAL OF RECOMMENDATIONS.—
8 Not later than January 15, 2012, the Secretary
9 shall transmit to Congress the revised recommenda-
10 tions under paragraph (2), a summary of the views
11 and comments received under such paragraph, and
12 any changes made to the recommendations in re-
13 sponse to such views and comments.

14 **SEC. 6. SUNSET DATES.**

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