

110TH CONGRESS
1ST SESSION

S. 1082

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

IN THE SENATE OF THE UNITED STATES

APRIL 10, 2007

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

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, whenever in this Act an amendment is expressed in
8 terms of an amendment to a section or other provision,
9 the reference shall be considered to be made to a section

1 or other provision of the Federal Food, Drug, and Cos-
 2 metic Act (21 U.S.C. 301 et seq.).

3 **SEC. 2. DRUG FEES.**

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

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

8 **“SEC. 735. DRUG FEES.**

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

20 “(b) REPORTS.—

21 “(1) PERFORMANCE REPORT.—For fiscal years
 22 2008 through 2012, not later than 120 days after
 23 the end of each fiscal year during which fees are col-
 24 lected under this part, the Secretary shall prepare
 25 and submit to the Committee on Health, Education,

1 Labor, and Pensions of the Senate and the Com-
2 mittee on Energy and Commerce of the House of
3 Representatives, a report concerning the progress of
4 the Food and Drug Administration in achieving the
5 goals identified in the letters described in subsection
6 (a) during such fiscal year and the future plans of
7 the Food and Drug Administration for meeting the
8 goals. The report for a fiscal year shall include infor-
9 mation on all previous cohorts for which the Sec-
10 retary has not given a complete response on all
11 human drug applications and supplements in the co-
12 hort.

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

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

5 “(c) REAUTHORIZATION.—

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

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

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

17 “(C) scientific and academic experts;

18 “(D) health care professionals;

19 “(E) representatives of patient and con-
20 sumer advocacy groups; and

21 “(F) the regulated industry.

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

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

4 “(B) publish such recommendations in the
5 Federal Register;

6 “(C) provide for a period of 30 days for
7 the public to provide written comments on such
8 recommendations;

9 “(D) hold a meeting at which the public
10 may present its views on such recommenda-
11 tions; and

12 “(E) after consideration of such public
13 views and comments, revise such recommenda-
14 tions as necessary.

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

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

23 (2) in subsection (d)—

24 (A) in paragraph (1)—

1 (i) in subparagraph (A), by striking
2 “505(b)(1),” and inserting “505(b), or”;

3 (ii) by striking subparagraph (B);

4 (iii) by redesignating subparagraph
5 (C) as subparagraph (B); and

6 (iv) in the matter following subpara-
7 graph (B), as so redesignated, by striking
8 “subparagraph (C)” and inserting “sub-
9 paragraph (B)”;

10 (B) in paragraph (3)(C), by—

11 (i) striking “the list” and inserting
12 “the list (not including the discontinued
13 section of such list)”; and

14 (ii) striking “a list” and inserting “a
15 list (not including the discontinued section
16 of such a list)”;

17 (C) in paragraph (4), by inserting before
18 the period at the end the following: “(such as
19 capsules, tablets, and lyophilized products be-
20 fore reconstitution)”;

21 (D) by amending paragraph (6)(F) to read
22 as follows:

23 “(F) In the case of drugs approved under
24 human drug applications or supplements,
25 postmarket safety activities, including—

1 “(i) collecting, developing, and review-
2 ing safety information on approved drugs
3 (including adverse event reports);

4 “(ii) developing and using improved
5 adverse event data collection systems (in-
6 cluding information technology systems);
7 and

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

12 (E) in paragraph (8)—

13 (i) by striking “April of the preceding
14 fiscal year” and inserting “October of the
15 preceding fiscal year”; and

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

18 (F) by redesignating paragraph (9) as
19 paragraph (10); and

20 (G) by inserting after paragraph (8) the
21 following:

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

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

2 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
3 379h(a)) is amended—

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

6 (2) in paragraph (1)—

7 (A) in subparagraph (D)—

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

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

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

18 (C) by inserting after subparagraph (D)
19 the following:

20 “(E) FEE FOR APPLICATION PREVIOUSLY
21 REFUSED FOR FILING OR WITHDRAWN BEFORE
22 FILING.—An application or supplement that
23 has been refused for filing or that was with-
24 drawn before filing, if filed under protest or re-
25 submitted, shall be subject to the fee under sub-
26 paragraph (A) (unless an exception under sub-

paragraph (C) or (F) applies or the fee is
 waived or reduced under subsection (d)), with-
 out regard to previous payment of such a fee
 and the refund of 75 percent of that fee under
 subparagraph (D).”; and
 (3) in paragraph (2)—

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

(B) by adding at the end the following:

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

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

“(ii) EXCEPTION FROM ANNUAL ES-
 TABLISHMENT FEE.—Each person who is

1 named as the applicant in an application
2 described in clause (i) shall not be assessed
3 an annual establishment fee for a fiscal
4 year if the person certifies to the Sec-
5 retary, at a time specified by the Secretary
6 and using procedures specified by the Sec-
7 retary, that—

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

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

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

21 “(b) FEE REVENUE AMOUNTS.—Except as provided
22 in subsections (c), (d), (f), and (g), fees under subsection
23 (a) shall be established to generate the following revenue
24 amounts, in each fiscal year beginning with fiscal year
25 2008 and continuing through fiscal year 2012:

1 \$392,783,000, plus an adjustment for workload on
 2 \$354,893,000 of this amount. Such adjustment shall be
 3 made in accordance with the workload adjustment provi-
 4 sions in effect for fiscal year 2007, except that instead
 5 of commercial investigational new drug applications sub-
 6 mitted to the Secretary, all commercial investigational new
 7 drug applications with a submission during the previous
 8 12-month period shall be used in the determination. One-
 9 third of the revenue amount shall be derived from applica-
 10 tion fees, one-third from establishment fees, and one-third
 11 from product fees.”.

12 (c) ADJUSTMENTS TO FEES.—

13 (1) INFLATION ADJUSTMENT.—Section
 14 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

15 (A) in the matter preceding subparagraph

16 (A) by striking “The revenues established in
 17 subsection (b)” and inserting “Beginning with
 18 fiscal year 2009, the revenues established in
 19 subsection (b)”;

20 (B) in subparagraph (A) by striking “or”
 21 at the end;

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

24 (D) by inserting after subparagraph (B)
 25 the following:

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

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

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

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

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

(i) by striking “, commercial investigational new drug applications” and inserting “(adjusted for changes in review activities)”;

(ii) by inserting before the period at the end “, and the change in the number of commercial investigational new drug applications with a submission during the

1 previous 12-month period (adjusted for
2 changes in review activities)”;

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

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

13 “(C) The Secretary shall contract with an
14 independent accounting firm to study the ad-
15 justment for changes in review activities applied
16 in setting fees for fiscal year 2009 and to make
17 recommendations, if warranted, on future
18 changes in the methodology for calculating the
19 adjustment for changes in review activity. After
20 review of the recommendations by the inde-
21 pendent accounting firm, the Secretary shall
22 make appropriate changes to the workload ad-
23 justment methodology in setting fees for fiscal
24 years 2010 through 2012. If the study is not

1 conducted, no adjustment for changes in review
2 activities shall be made after fiscal year 2009.”.

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

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

9 (B) by inserting after paragraph (2) the
10 following:

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

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

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

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

3 (ii) by striking “2008” and inserting
4 “2013”; and

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

8 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
9 (21 U.S.C. 379h(d)) is amended—

10 (1) in paragraph (1), in the matter preceding
11 subparagraph (A), by—

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

15 (B) inserting “to that person” after “a
16 waiver from or a reduction of one or more fees
17 assessed”; and

18 (C) striking “finds” and inserting “deter-
19 mines”;

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) EVALUATION.—For the purpose of deter-
25 mining whether to grant a waiver or reduction of a

1 fee under paragraph (1), the Secretary shall con-
 2 sider only the circumstances and assets of the appli-
 3 cant and any affiliate of the applicant.”; and

4 (4) in paragraph (4), as redesignated by this
 5 subsection, in subparagraph (A), by inserting before
 6 the period at the end “, and that does not have a
 7 drug product that has been approved under a human
 8 drug application and introduced or delivered for in-
 9 troduction 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 There are authorized to be appropriated for fees
 16 under this section such sums as are authorized to be
 17 assessed and collected under this section in each of
 18 fiscal years 2008 through 2012.”.

19 (2) OFFSET.—Section 736(g)(4) (21 U.S.C.

20 379h(g)(4)) is amended to read as follows:

21 “(4) OFFSET.—If the cumulative amount of

22 fees collected during fiscal years 2008, 2009, and
 23 2010, plus the amount estimated to be collected for
 24 fiscal year 2011, exceeds the amount of fees speci-
 25 fied in aggregate in appropriation Acts for such fis-

cal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.”.

(f) CONFORMING AMENDMENTS.—

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

(A) in paragraph (1)(A), by striking “subsection (c)(4)” each place it appears and inserting “subsection (c)(5)”;

(B) in paragraph (2), by striking “subsection (c)(4)” and inserting “subsection (c)(5)”; and

(C) in paragraph (3), by striking “subsection (c)(4)” and inserting “subsection (c)(5)”.

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

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

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

6 **“SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE**
 7 **ADVISORY REVIEW OF PRESCRIPTION DRUG**
 8 **ADVERTISING.**

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

13 “(1) **ADVISORY REVIEW FEE.**—

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

21 “(B) **EXCEPTION FOR REQUIRED SUBMIS-**
 22 **SIONS.**—A direct-to-consumer television adver-
 23 tisement that is required to be submitted to the
 24 Secretary prior to initial public dissemination
 25 shall not be assessed a fee unless the sponsor

1 designates it as a submission for advisory re-
2 view.

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

8 “(D) MODIFICATION OF ADVISORY REVIEW
9 FEE.—

10 “(i) LATE PAYMENT.—If, on or before
11 November 1 of the fiscal year in which the
12 fees are due, a person has not paid all fees
13 that were due and payable for advisory re-
14 views identified in response to the Federal
15 Register notice described in subsection
16 (c)(3)(A), the fees shall be regarded as
17 late. Such fees shall be due and payable 20
18 days before any direct-to-consumer tele-
19 vision advertisement is submitted by such
20 person to the Secretary for advisory re-
21 view. Notwithstanding any other provision
22 of this section, such fees shall be due and
23 payable for each of those advisory reviews
24 in the amount of 150 percent of the advi-

sory review fee established for that fiscal year pursuant to subsection (c)(3).

“(ii) LATE NOTICE OF SUBMISSION.—

If any person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay a fee for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3). Fees under this subparagraph shall be due 20 days before the direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review.

“(E) LIMITS.—

“(i) IN GENERAL.—The payment of a fee under this paragraph for a fiscal year entitles the person that pays the fee to acceptance for advisory review by the Secretary of 1 direct-to-consumer television advertisement and acceptance of 1 resubmission for advisory review of the same ad-

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

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

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

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

19 “(2) OPERATING RESERVE FEE.—

20 “(A) IN GENERAL.—Each person that, on
 21 or after October 1, 2007, is assessed an advi-
 22 sory review fee under paragraph (1) shall be
 23 subject to an operating reserve fee established
 24 under subsection (d)(2) only in the first fiscal
 25 year in which an advisory review fee is assessed.

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

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

1 “(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—
 2 Fees under subsection (a)(1) shall be established to gen-
 3 erate revenue amounts of \$6,250,000 for each of fiscal
 4 years 2008 through 2012, as adjusted pursuant to sub-
 5 section (c).

6 “(c) ADJUSTMENTS.—

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

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

18 “(B) the total percentage change for the
 19 previous fiscal year in basic pay under the Gen-
 20 eral Schedule in accordance with section 5332
 21 of title 5, as adjusted by any locality-based
 22 comparability payment pursuant to section
 23 5304 of such title for Federal employees sta-
 24 tioned in the District of Columbia; or

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

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

11 “(2) WORKLOAD ADJUSTMENT.—

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

22 “(B) DETERMINATION OF WORKLOAD AD-
 23 JUSTMENT.—

24 “(i) IN GENERAL.—The workload ad-
 25 justment under this paragraph for a fiscal

1 year shall be determined by the Sec-
2 retary—

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

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

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

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

1 “(3) ANNUAL FEE SETTING.—

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

24 “(B) ANNUAL FEE.—The Secretary shall,
25 60 days before the start of each fiscal year, es-

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

17 “(C) FISCAL YEAR 2008 FEE LIMIT.—Not-
18 withstanding subsection (b), the fee established
19 under subparagraph (B) for fiscal year 2008
20 may not be more than \$83,000 per submission
21 for advisory review.

22 “(D) ANNUAL FEE LIMIT.—Notwith-
23 standing subsection (b), the fee established
24 under subparagraph (B) for a fiscal year after
25 fiscal year 2008 may not be more than 50 per-

1 cent more than the fee established for the prior
2 fiscal year.

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

8 “(d) OPERATING RESERVES.—

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

18 “(2) FEE SETTING.—The Secretary shall estab-
19 lish the operating reserve fee under subsection
20 (a)(2)(A) for each person required to pay the fee by
21 multiplying the number of direct-to-consumer tele-
22 vision advertisements identified by that person pur-
23 suant to subsection (c)(3)(A) by the advisory review
24 fee established pursuant to subsection (c)(3) for that
25 fiscal year. In no case shall the operating reserve fee

1 assessed be less than the operating reserve fee as-
2 sessed if the person had first participated in the
3 Program in fiscal year 2008.

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

14 “(4) REFUND OF OPERATING RESERVES.—
15 Within 120 days of the end of fiscal year 2012, or
16 if the Program is terminated pursuant to subsection
17 (f), the Secretary, after setting aside sufficient oper-
18 ating reserve amounts to terminate the Program,
19 shall refund all amounts remaining in the operating
20 reserve on a pro rata basis to each person that paid
21 an operating reserve fee assessment. In no event
22 shall the refund to any person exceed the total
23 amount of operating reserve fees paid by such per-
24 son pursuant to subsection (a)(2).

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

9 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
10 GRAM.—

11 “(1) FIRST FISCAL YEAR.—If on November 1,
12 2007, or 120 days after enactment of the Prescrip-
13 tion Drug User Fee Amendments of 2007, whichever
14 is later, the Secretary has received less than
15 \$11,250,000 in advisory review fees and operating
16 reserve fees combined, the Program shall be termi-
17 nated and all collected fees shall be refunded.

18 “(2) SUBSEQUENT FISCAL YEARS.—Beginning
19 in fiscal year 2009, if, on November 1 of a fiscal
20 year, the combination of the operating reserves, an-
21 nual fee revenues from that fiscal year, and unobli-
22 gated fee revenues from prior fiscal years is less
23 than \$9,000,000, adjusted for inflation (in accord-
24 ance with subsection (c)(1)), the Program shall be
25 terminated, and the Secretary shall notify all partici-

1 pants, retain any money from the unused advisory
 2 review fees and the operating reserves needed to ter-
 3 minate the Program, and refund the remainder of
 4 the unused fees and operating reserves. To the ex-
 5 tent required to terminate the Program, the Sec-
 6 retary shall first use unobligated advisory review fee
 7 revenues from prior fiscal years, then the operating
 8 reserves, and then unused advisory review fees from
 9 the relevant fiscal year.

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

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

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

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

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

15 “(3) AUTHORIZATION OF APPROPRIATIONS.—
 16 There are authorized to be appropriated for fees
 17 under this section not less than \$6,250,000 for each
 18 of fiscal years 2008, 2009, 2010, 2011, and 2012,
 19 as adjusted to reflect adjustments in the total fee
 20 revenues made under this section, 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 section:

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

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

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

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

24 “(5) The term ‘Program’ means the Program
 25 to assess, collect, and use fees for the advisory re-

1 view of prescription drug advertising established by
2 this section.

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

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

20 “(A) officers and employees of the Food
21 and Drug Administration, contractors of the
22 Food and Drug Administration, advisory com-
23 mittees, and costs related to such officers, em-
24 ployees, and committees, and to contracts with
25 such contractors;

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

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

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

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

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

22 “(9) The term ‘submission for advisory review’
23 means an original submission of a direct-to-con-
24 sumer television advertisement for which the sponsor

1 voluntarily requests advisory comments before the
2 advertisement is publicly disseminated.”.

3 **SEC. 5. SAVINGS CLAUSE.**

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

17 **SEC. 6. TECHNICAL AMENDMENTS.**

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

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

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

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

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

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

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

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