

fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(4) [section 101(4) of Pub. L. 105-115, set out above] during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

“(b) FISCAL REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.”

Pub. L. 102-571, title I, §104, Oct. 29, 1992, 106 Stat. 4498, provided that:

“(a) FIRST REPORT.—Within 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration’s progress in achieving the goals identified in section 102(3) of this Act [set out as a note above] during such fiscal year and that agency’s future plans for meeting such goals.

“(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year for which the report is made.

“(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.”

ANIMAL DRUG USER FEE STUDY

Pub. L. 102-571, title I, §108, Oct. 29, 1992, 106 Stat. 4500, directed Secretary, in consultation with manufacturers of animal drug products and other interested persons, to undertake study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 360b of this title, and further provided for submission of study to Congress no later than Jan. 4, 1994.

§ 379h. Authority to assess and use drug fees

(a) Types of fees

Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Human drug application and supplement fee

(A) In general

Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

(i) A fee established under subsection (c)(4) of this section for a human drug ap-

plication for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(4) of this section for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required. Such fee shall be half of the amount of the fee established under clause (i).

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the application or supplement.

(C) Exception for previously filed application or supplement

If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person’s licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) Refund of fee if application refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

(E) Fees for applications previously refused for filing or withdrawn before filing

A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) Exception for designated orphan drug or indication

A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 360bb of this title shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 360bb of this title as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

(G) Refund of fee if application withdrawn

If an application or supplement is withdrawn after the application or supplement

was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) Prescription drug establishment fee

(A) In general

Except as provided in subparagraphs (B) and (C), each person that—

(i) is named as the applicant in a human drug application; and

(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be assessed an annual fee established under subsection (c)(4) of this section for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

(B) Exception

If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

(i) that did not manufacture the product in the previous fiscal year; and

(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.

(C) Special rules for positron emission tomography drugs

(i) In general

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

(ii) Exception from annual establishment fee

Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

(I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

(II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

(iii) Definition

For purposes of this subparagraph, the term “positron emission tomography drug” has the meaning given to the term “compounded positron emission tomography drug” in section 321(ii) of this title, except that paragraph (1)(B) of such section shall not apply.

(3) Prescription drug product fee

(A) In general

Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4) of this section. Such fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(B) Exception

A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

(i) identified on the list compiled under section 355(j)(7) of this title with a potency described in terms of per 100 mL;

(ii) the same product as another product that—

(I) was approved under an application filed under section 355(b) or 355(j) of this title; and

(II) is not in the list of discontinued products compiled under section 355(j)(7) of this title;

(iii) the same product as another product that was approved under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997); or

(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

(b) Fee revenue amounts

(1) In general

For each of the fiscal years 2013 through 2017, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

(A) \$693,099,000;

(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).

(2) Types of fees

Of the total revenue amount determined for a fiscal year under paragraph (1)—

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

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

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

(3) Fiscal year 2013 inflation and workload adjustments

For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

(A) Inflation adjustment

The inflation adjustment for fiscal year 2013 shall be the sum of—

(i) \$652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

(ii) \$652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

(B) Workload adjustment

Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

(i) \$652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the meth-

odology described in subsection (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

(C) Limitation

Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).

(c) Adjustments

(1) Inflation adjustment

For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

(A) one;

(B) the average annual percent 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 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 379g(6) of this title) for the first 3 years of the preceding 4 fiscal years, and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 379g(6) of this title) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

(2) Workload adjustment

For fiscal year 2014 and subsequent fiscal years, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice

that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

(3) Final year adjustment

For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

(4) Annual fee setting

The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on

the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(5) Limit

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

(d) Fee waiver or reduction

(1) In general

The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) of this section where the Secretary finds that—

(A) such waiver or reduction is necessary to protect the public health,

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(C) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

(D) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) Considerations

In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) Use of standard costs

In making the finding in paragraph (1)(C), the Secretary may use standard costs.

(4) Rules relating to small businesses

(A) “Small business” defined

In paragraph (1)(D), the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

(B) Waiver of application fee

The Secretary shall waive under paragraph (1)(D) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

(e) Effect of failure to pay fees

A human drug application or supplement submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

(f) Limitations**(1) In general**

Fees under subsection (a) of this section shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) Authority

If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.

(g) Crediting and availability of fees**(1) In general**

Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) Collections and appropriation acts**(A) In general**

The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of

Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

(C) Provision for early payments

Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) Authorization of appropriations

For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this subsection.

(4) Offset

If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of fees estimated to be collected under this section for fiscal year 2016 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2013 through 2016, the 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 2017.

(h) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) of this section within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) Written requests for waivers, reductions, and refunds

To qualify for consideration for a waiver or reduction under subsection (d) of this section, or for a refund of any fee collected in accordance with subsection (a) of this section, a person shall submit to the Secretary a written request

for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) Construction

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) Orphan drugs

(1) Exemption

A drug designated under section 360bb of this title for a rare disease or condition and approved under section 355 of this title or under section 262 of title 42 shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:

(A) The drug meets the public health requirements contained in this chapter as such requirements are applied to requests for waivers for product and establishment fees.

(B) The drug is owned or licensed and is marketed by a company that had less than \$50,000,000 in gross worldwide revenue during the previous year.

(2) Evidence of qualification

An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed \$50,000,000 for the preceding 12 months before the exemption was requested.

(June 25, 1938, ch. 675, §736, as added Pub. L. 102-571, title I, §103, Oct. 29, 1992, 106 Stat. 4494; amended Pub. L. 105-115, title I, §103(a)-(g), Nov. 21, 1997, 111 Stat. 2299-2304; Pub. L. 107-109, §5(a), Jan. 4, 2002, 115 Stat. 1413; Pub. L. 107-188, title V, §504, June 12, 2002, 116 Stat. 689; Pub. L. 110-85, title I, §103(a)-(h)(1), Sept. 27, 2007, 121 Stat. 826-832; Pub. L. 112-144, title I, §103, July 9, 2012, 126 Stat. 996.)

TERMINATION OF SECTION

For termination of section by section 105(a) of Pub. L. 112-144, see Termination Date note below.

REFERENCES IN TEXT

Section 357 of this title, referred to in subsec. (a)(3)(B)(iii), was repealed by Pub. L. 105-115, title I, §125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

The Drug Price Competition and Patent Term Restoration Act of 1984, referred to in subsec. (a)(3)(B)(iv), is Pub. L. 98-417, Sept. 24, 1984, 98 Stat. 1585. For complete classification of this Act to the Code, see Short Title of 1984 Amendment note set out under section 301 of this title and Tables.

AMENDMENTS

2012—Subsec. (a). Pub. L. 112-144, §103(1)(A), substituted “fiscal year 2013” for “fiscal year 2008” in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 112-144, §103(1)(B), substituted “(c)(4)” for “(c)(5)” in cls. (i) and (ii).

Subsec. (a)(2)(A). Pub. L. 112-144, §103(1)(C), substituted “(c)(4)” for “(c)(5)” and “due on the later of the first business day on or after October 1 of each fis-

cal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section” for “payable on or before October 1 of each year” in concluding provisions.

Subsec. (a)(3)(A). Pub. L. 112-144, §103(1)(D)(i), substituted “subsection (c)(4)” for “subsection (c)(5)” and “due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.” for “payable on or before October 1 of each year.”

Subsec. (a)(3)(B). Pub. L. 112-144, §103(1)(D)(ii), amended subpar. (B) generally. Prior to amendment, text read as follows: “A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b) or 355(j) of this title, under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.”

Subsec. (b)(1). Pub. L. 112-144, §103(2)(A)(i), substituted “fiscal years 2013 through 2017” for “fiscal years 2008 through 2012” in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 112-144, §103(2)(A)(ii), substituted “\$693,099,000;” for “\$392,783,000; and”.

Subsec. (b)(1)(B), (C). Pub. L. 112-144, §103(2)(A)(iii), added subpars. (B) and (C) and struck out former subpar. (B) which read as follows: “an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).”

Subsec. (b)(3), (4). Pub. L. 112-144, §103(2)(B), added par. (3) and struck out former pars. (3) and (4) which related to the modified workload adjustment factor for fiscal year 2007 and additional fee revenues for drug safety for fiscal years 2008 through 2012, respectively.

Subsec. (c). Pub. L. 112-144, §103(3), added subsec. (c) and struck out former subsec. (c) which related to inflation adjustment for fiscal year 2009 and subsequent fiscal years, workload adjustment for fiscal year 2009 and subsequent fiscal years, rent and rent-related cost adjustment for fiscal year 2010 and each subsequent fiscal year, final year adjustment for fiscal year 2012, annual fee setting for each fiscal year that began after Sept. 30, 2007, and the limit on the total amount of fees charged for a fiscal year.

Subsec. (g)(1). Pub. L. 112-144, §103(4)(A), substituted “Subject to paragraph (2)(C), fees authorized” for “Fees authorized”.

Subsec. (g)(2)(A)(i). Pub. L. 112-144, §103(4)(B)(i), substituted “subject to subparagraph (C), shall be collected and available” for “shall be retained”.

Subsec. (g)(2)(A)(ii). Pub. L. 112-144, §103(4)(B)(ii), substituted “shall be available” for “shall only be collected and available”.

Subsec. (g)(2)(C). Pub. L. 112-144, §103(4)(B)(iii), added subpar. (C).

Subsec. (g)(3). Pub. L. 112-144, §103(4)(C), substituted “fiscal years 2013 through 2017” for “fiscal years 2008 through 2012”.

Subsec. (g)(4). Pub. L. 112-144, §103(4)(D), substituted “fiscal years 2013 through 2015” for “fiscal years 2008 through 2010”, “fiscal year 2016” for “fiscal year 2011”, “fiscal years 2013 through 2016” for “fiscal years 2008 through 2011”, and “fiscal year 2017” for “fiscal year 2012”.

2007—Subsec. (a). Pub. L. 110-85, §103(a)(1), substituted “2008” for “2003” in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 110-85, §103(g), substituted “(c)(5)” for “(c)(4)” in cls. (i) and (ii).

Subsec. (a)(1)(D). Pub. L. 110-85, §103(a)(2)(A), inserted “or withdrawn before filing” after “refused for filing” in heading and “or withdrawn without a waiver before filing” before period at end of text.

Subsec. (a)(1)(E) to (G). Pub. L. 110-85, §103(a)(2)(B), (C), added subpar. (E) and redesignated former subpars. (E) and (F) as (F) and (G), respectively.

Subsec. (a)(2)(A). Pub. L. 110-85, §103(a)(3)(A), (g), substituted “subparagraphs (B) and (C)” for “subparagraph (B)” in introductory provisions and “(c)(5)” for “(c)(4)” in concluding provisions.

Subsec. (a)(2)(C). Pub. L. 110-85, §103(a)(3)(B), added subpar. (C).

Subsec. (a)(3)(A). Pub. L. 110-85, §103(g), substituted “(c)(5)” for “(c)(4)”.

Subsec. (b). Pub. L. 110-85, §103(b), amended subsec. (b) generally, substituting provisions contained in pars. (1) to (4) relating to fee revenue amounts for fiscal years 2008 through 2012 for undesignated provisions relating to fee schedules for fiscal years 2003 to 2007.

Subsec. (c)(1). Pub. L. 110-85, §103(c)(1), amended par. (1) by substituting “For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)” for “The revenues established in subsection (b)” in introductory provisions, adding subpar. (C), and substituting “fiscal year 2008” for “fiscal year 2003” in concluding provisions.

Subsec. (c)(2). Pub. L. 110-85, §103(c)(2)(A), substituted “For fiscal year 2009 and subsequent fiscal years,” for “Beginning with fiscal year 2004,” in introductory provisions.

Subsec. (c)(2)(A). Pub. L. 110-85, §103(c)(2)(B), substituted “human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available.” for “human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary.” in first sentence.

Subsec. (c)(2)(B). Pub. L. 110-85, §103(c)(2)(C), inserted at end “Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities.”

Subsec. (c)(2)(C). Pub. L. 110-85, §103(c)(2)(D), added subpar. (C).

Subsec. (c)(3). Pub. L. 110-85, §103(c)(3), added par. (3). Former par. (3) redesignated (4).

Subsec. (c)(4). Pub. L. 110-85, §103(c)(3)(A), (4), redesignated par. (3) as (4) and amended it generally. Prior to amendment, text read as follows: “For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) of this section if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of human drug applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.” Former par. (4) redesignated (5).

Subsec. (c)(5). Pub. L. 110-85, §103(c)(3)(A), (5), redesignated par. (4) as (5) and substituted “2007” for “2002”. Former par. (5) redesignated (6).

Subsec. (c)(6). Pub. L. 110-85, §103(c)(3)(A), redesignated par. (5) as (6).

Subsec. (d)(1). Pub. L. 110-85, §103(d)(1), inserted “to a person who is named as the applicant in a human drug application” after “The Secretary shall grant” and “to that person” after “one or more fees assessed” in introductory provisions.

Subsec. (d)(2), (3). Pub. L. 110-85, §103(d)(2), (3), added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (d)(4). Pub. L. 110-85, §103(d)(2), redesignated par. (3) as (4).

Subsec. (d)(4)(A). Pub. L. 110-85, §103(d)(4), inserted before period at end “, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce”.

Subsec. (g)(1). Pub. L. 110-85, §103(h)(1), substituted “Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.” for “Fees collected for a fiscal year pursuant to subsection (a) of this section shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.”

Subsec. (g)(3). Pub. L. 110-85, §103(e)(1), amended par. (3) generally. Prior to amendment, par. (3) authorized appropriations for fiscal years 2003 to 2007.

Subsec. (g)(4). Pub. L. 110-85, §103(e)(2), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: “Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year 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 a subsequent fiscal year.”

Subsec. (k). Pub. L. 110-85, §103(f), added subsec. (k). 2002—Subsec. (a). Pub. L. 107-188, §504(a)(1), substituted “fiscal year 2003” for “fiscal year 1998” in introductory provisions.

Subsec. (a)(1)(A)(i). Pub. L. 107-188, §504(a)(2)(A), substituted “under subsection (c)(4)” for “in subsection (b)”.

Subsec. (a)(1)(A)(ii). Pub. L. 107-188, §504(a)(2), substituted “under subsection (c)(4)” for “in subsection (b)” and inserted “Such fee shall be half of the amount of the fee established under clause (i).” at end.

Subsec. (a)(1)(F), (G). Pub. L. 107-109 redesignated subpar. (G) as (F) and struck out heading and text of former subpar. (F). Text read as follows: “A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).”

Subsec. (a)(2)(A). Pub. L. 107-188, §504(a)(3), in concluding provisions, substituted “under subsection (c)(4)” for “in subsection (b)” and “payable on or before October 1” for “payable on or before January 31”.

Subsec. (a)(3)(A). Pub. L. 107-188, §504(a)(4)(A), amended heading and text of subpar. (A) generally. Prior to amendment, text read as follows: “Except as provided in subparagraph (B), each person—

“(i) who is named as the applicant in a human drug application for a prescription drug product which has been submitted for listing under section 360 of this title, and

“(ii) who, after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall pay for each such prescription drug product the annual fee established in subsection (b) of this section. Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.”

Subsec. (a)(3)(B). Pub. L. 107-188, §504(a)(4)(B), substituted “A prescription drug product shall not be as-

essed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b)" for "The listing of a prescription drug product under section 360 of this title shall not require the person who listed such product to pay the fee prescribed by subparagraph (A) if such product is the same product as a product approved under an application filed under section 355(b)(2)".

Subsec. (b). Pub. L. 107-188, § 504(b), amended heading and text of subsec. (b) generally, substituting "Fee revenue amounts" for "Fee amounts" in heading and substituting fee schedules for fiscal years 2003 to 2007 for fee provisions relating to fiscal years 1998 to 2002.

Subsec. (c)(1). Pub. L. 107-188, § 504(c)(1)(A), (D), substituted "revenues" for "fees and total fee revenues" in introductory provisions and "fiscal year 2003" for "fiscal year 1997" in concluding provisions.

Subsec. (c)(1)(A). Pub. L. 107-188, § 504(c)(1)(B), struck out "during the preceding fiscal year" before "in the Consumer Price Index" and substituted "for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or" for " or".

Subsec. (c)(1)(B). Pub. L. 107-188, § 504(c)(1)(C), substituted "for the previous fiscal year" for "for such fiscal year".

Subsec. (c)(2) to (5). Pub. L. 107-188, § 504(c)(2)-(4), added pars. (2) and (3), redesignated former pars. (2) and (3) as (4) and (5), respectively, and amended heading and text of par. (4) generally. Prior to amendment, text of par. (4) read as follows: "Subject to the amount appropriated for a fiscal year under subsection (g) of this section, the Secretary shall, within 60 days after the end of each fiscal year beginning after September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b) of this section."

Subsec. (d)(1)(C) to (E). Pub. L. 107-188, § 504(d)(1), inserted "or" at end of subpar. (C), redesignated subpar. (E) as (D), and struck out former subpar. (D) which read as follows: "assessment of the fee for an application or a supplement filed under section 355(b)(1) of this title pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 355(b)(2) of this title could not be assessed fees under subsection (a)(1) of this section, or".

Subsec. (d)(3)(A), (B). Pub. L. 107-188, § 504(d)(2), substituted "paragraph (1)(D)" for "paragraph (1)(E)".

Subsec. (f). Pub. L. 107-188, § 504(e)(1), substituted "Limitations" for "Assessment of fees" in heading.

Subsec. (f)(1). Pub. L. 107-188, § 504(e)(2), substituted "In general" for "Limitation" in heading and "Fees under subsection (a) of this section shall be refunded for a fiscal year beginning" for "Fees may not be assessed under subsection (a) of this section for a fiscal year beginning" in text.

Subsec. (g)(1). Pub. L. 107-188, § 504(f)(1), which directed the amendment of par. (1) by striking "Fees collected for a fiscal year" and all that follows through "fiscal year limitation." and inserting "Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.", was not executed because the phrase "fiscal year limitation." appeared in two places and because of the corrective amendment by Pub. L. 110-85, § 103(h)(1), which is effective as if included in Pub. L. 107-188, § 504. See 2007 Amendment note above and Effective Date of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 107-188, § 504(f)(2), amended par. (2) by designating existing provisions as subpar. (A), inserting subpar. (A) heading, adding subpar. (B), redesignating former subpars. (A) and (B) as cls. (i) and (ii), respectively, of subpar. (A), substituting "shall be retained in each fiscal year in an amount not to exceed the amount specified" for "shall be collected in each fiscal year in an amount equal to the amount specified" in cl. (i), and realigning margin of cl. (ii).

Subsec. (g)(3)(A) to (E). Pub. L. 107-188, § 504(f)(3), added subpars. (A) to (E) and struck out former subpars. (A) to (E) which read as follows:

- "(A) \$106,800,000 for fiscal year 1998;
- "(B) \$109,200,000 for fiscal year 1999;
- "(C) \$109,200,000 for fiscal year 2000;
- "(D) \$114,000,000 for fiscal year 2001; and
- "(E) \$110,100,000 for fiscal year 2002."

1997—Subsec. (a). Pub. L. 105-115, § 103(a)(1), substituted "Beginning in fiscal year 1998" for "Beginning in fiscal year 1993" in introductory provisions.

Subsec. (a)(1)(B). Pub. L. 105-115, § 103(a)(2)(A), amended heading and text of subpar. (B) generally. Prior to amendment, text read as follows:

"(i) FIRST PAYMENT.—50 percent of the fee required by subparagraph (A) shall be due upon submission of the application or supplement.

"(ii) FINAL PAYMENT.—The remaining 50 percent of the fee required by subparagraph (A) shall be due upon—

"(I) the expiration of 30 days from the date the Secretary sends to the applicant a letter designated by the Secretary as an action letter described in section 379g(6)(B) of this title, or

"(II) the withdrawal of the application or supplement after it is filed unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed.

The designation under subclause (I) or the waiver under subclause (II) shall be solely in the discretion of the Secretary and shall not be reviewable."

Subsec. (a)(1)(D). Pub. L. 105-115, § 103(a)(2)(B), substituted "refused" for "not accepted" in heading and "75 percent" for "50 percent", "subparagraph (B)" for "subparagraph (B)(i)", and "refused" for "not accepted" in text.

Subsec. (a)(1)(E) to (G). Pub. L. 105-115, § 103(a)(2)(C), added subpars. (E) to (G).

Subsec. (a)(2). Pub. L. 105-115, § 103(a)(3), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "Each person that—

"(A) owns a prescription drug establishment, at which is manufactured at least 1 prescription drug product which is not the, or not the same as a, product approved under an application filed under section 355(b)(2) or 355(j) of this title, and

"(B) after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be subject to the annual fee established in subsection (b) of this section for each such establishment, payable on or before January 31 of each year."

Subsec. (a)(3)(A). Pub. L. 105-115, § 103(a)(4)(A), substituted, in cl. (i), "has been submitted for listing" for "is listed" and, in closing provisions, "Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable." for "Such fee shall be payable at the time of the first such listing of such product in each calendar year. Such fee shall be paid only once each year for each listed prescription drug product irrespective of the number of times such product is listed under section 360 of this title."

Subsec. (a)(3)(B). Pub. L. 105-115, § 103(a)(4)(B), substituted "355(j) of this title, under an abbreviated appli-

cation filed under section 357 of this title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.” for “355(j) of this title.”.

Subsec. (b). Pub. L. 105-115, §103(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to fee amounts, including a schedule of fees in par. (1) and fee exceptions for certain small businesses in par. (2).

Subsec. (c). Pub. L. 105-115, §103(c)(1), substituted “Adjustments” for “Increases and adjustments” in heading.

Subsec. (c)(1). Pub. L. 105-115, §103(c)(2), substituted “Inflation adjustment” for “Revenue increase” in heading, “The fees and total fee revenues established in subsection (b) of this section shall be adjusted by the Secretary” for “The total fee revenues established by the schedule in subsection (b)(1) of this section shall be increased by the Secretary” in introductory provisions, and “change” for “increase” after “total percentage” in subpars. (A) and (B), and inserted at end “The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.”

Subsec. (c)(2). Pub. L. 105-115, §103(c)(3), substituted “September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b) of this section.” for “October 1, 1992, adjust the fees established by the schedule in subsection (b)(1) of this section for the following fiscal year to achieve the total fee revenues, as may be increased under paragraph (1). Such fees shall be adjusted under this paragraph to maintain the proportions established in such schedule.”

Subsec. (c)(3). Pub. L. 105-115, §103(c)(4), substituted “this subsection” for “paragraph (2)”.

Subsec. (d). Pub. L. 105-115, §103(d), struck out introductory provisions which read “The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) of this section where the Secretary finds that—” and closing provisions which read “In making the finding in paragraph (3), the Secretary may use standard costs.”, inserted designation, heading, and introductory provisions of par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, of par. (1), and added pars. (1)(E), (2), and (3).

Subsec. (f)(1). Pub. L. 105-115, §103(e), substituted “fiscal year 1997” for “fiscal year 1993” and “fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)” for “fiscal year 1992”.

Subsec. (g)(1). Pub. L. 105-115, §103(f)(1), inserted at end “Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.”

Subsec. (g)(2)(A). Pub. L. 105-115, §103(f)(2)(A), substituted “Acts, or otherwise made available for obligation,” for “Acts”.

Subsec. (g)(2)(B). Pub. L. 105-115, §103(f)(2)(B), substituted “over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997” for “over such costs for fiscal year 1992”.

Subsec. (g)(3), (4). Pub. L. 105-115, §103(f)(3), added pars. (3) and (4) and struck out heading and text of former par. (3). Text read as follows: “There are authorized to be appropriated for fees under this section—

“(A) \$36,000,000 for fiscal year 1993,

“(B) \$54,000,000 for fiscal year 1994,

“(C) \$75,000,000 for fiscal year 1995,

“(D) \$78,000,000 for fiscal year 1996, and

“(E) \$84,000,000 for fiscal year 1997,

as adjusted to reflect increases in the total fee revenues made under subsection (c)(1) of this section.”

Subsecs. (i), (j). Pub. L. 105-115, §103(g), added subsec. (i) and redesignated former subsec. (i) as (j).

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112-144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2012, see section 106 of Pub. L. 112-144, set out as a note under section 379g of this title.

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110-85, title I, §103(h)(2), Sept. 27, 2007, 121 Stat. 832, provided that: “Paragraph (1) [amending this section] shall take effect as if included in section 504 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107-188; 116 Stat. 687) [amending this section].”

Amendment by Pub. L. 110-85 effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, see section 107 of Pub. L. 110-85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379g of this title.

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107-188 effective Oct. 1, 2002, see section 508 of Pub. L. 107-188, set out as a note under section 356b of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective Oct. 1, 1997, see section 106 of Pub. L. 105-115, set out as an Effective and Termination Dates of 1997 Amendment note under section 379g of this title.

TERMINATION DATE

Section to terminate Oct. 1, 2017, see section 105(a) of Pub. L. 112-144, set out as a note under section 379g of this title.

SPECIAL RULE FOR WAIVERS AND REFUNDS

Pub. L. 105-115, title I, §103(h), Nov. 21, 1997, 111 Stat. 2304, provided that: “Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) prior to the date of enactment of this Act [Nov. 21, 1997] shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998, shall be evaluated according to the terms of the Prescription Drug User Fee Act of 1992 [see section 101(a) of Pub. L. 102-571, set out as a Short Title of 1992 Amendment note under section 301 of this title] (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379g et seq.] (as in effect on September 30, 1997). The term “person” in such Acts shall continue to include an affiliate thereof.”

§ 379h-1. Fees relating to advisory review of prescription-drug television advertising

(a) Types of direct-to-consumer television advertisement review fees

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

(1) Advisory review fee

(A) In general

With respect to a proposed direct-to-consumer television advertisement (referred to