FDCA Sec. 736 [21 USC § 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 application 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by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person's licensee, assignee, or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D. **Refund of fee if application refused for filing or withdrawn before filing**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75 percent of the fee paid under subparagraph (B) for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

E. **Fees for applications previously refused for filing or withdrawn before filing**

A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the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 526 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 526 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—

(I) the first business day after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

iii. 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 201(ii) , 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 paid only once for each product for a

fiscal year in which the fee is payable. Such fee shall due on the later of—

(I) the first business day after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

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 505(j)(7)(A) with a potency described in terms of per 100 mL;

(ii) the same product as another product—

(I) which was approved under an application filed under section 505(b) or 505(j) ;, and

(II) which is not in the list of discontinued products compiled under section 505(j)(7)(A) ;

(iii) under an abbreviated application filed under section 507 (as in effect on the day before the enactment of the Food and Drug Administration Modernization Act of 1997 [enacted November 21, 1997]); or

(iv) 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. $712,808,000; and

B. The dollar amount of the inflation and workload adjustments for fiscal year 2013 (as determined under paragraph (3)).

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)(B), 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. $672,418,000 multiplied by the result of the inflation adjustment calculation described in subsection (c)(1)(A); and

ii. $672,418,000 multiplied by the result of the inflation adjustment calculation described in subsection (c)(1)(B).

B. **Workload Adjustment**. The workload adjustment for fiscal 2013 shall be—

(i) $672,418,000 plus 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 methodology under subsection (c)(2), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012 , if both such adjustment percentages were calculated using the five-year base period consisting of fiscal years 2003-2007.

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 to reflect the sum of one plus —

A. 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 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 735(6))for the first 3 years of the preceding 4 fiscal years, and

B. the average annual 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 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year by this paragraph will 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) of this section 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 fee revenues for the fiscal year established in subsection (b) of this section, 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 studies. 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 will be published for public comment. After review of the reports and 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 subparagraph shall not be made.

4. **Annual fee setting**

The Secretary shall, 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) of this section, based on the revenue amounts established under subsection (b) of this section 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**

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, subject to paragraph (2)(C). 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. shall be retained 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, subject to subparagraph (C), and

ii. shall only be collected and 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 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public Health Service Act 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.

FDCA Sec. 742 [21 USC § 379l]

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(a) by redesignating section 742 as section 742A ; and
(b) by inserting after section 741 the following:

'SEC. 742 Electronic Submission of Applications

"Beginning no earlier than 24 months after the issuance of a final guidance (issued after public notice and opportunity for comment), submissions under sections 505(b) or 505(i) of this Act or section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance. In such guidance, the Secretary may provide a timetable for establishment by the Secretary of further standards for such electronic submission, and set forth criteria for waivers of and exemptions from the requirements of this section. This section shall not apply to submissions described in section 561 of this Act.'.