Part 3--Fees Relating to Devices (Redline of proposed amendments)

SEC. 737. [21 USC §379i] Definitions

For purposes of this part:

(1) The term "premarket application" means-- (A) an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act [42 USC § 262]; or (B) a product development protocol described in section 515(f). Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term "premarket report" means a report submitted under section 515(c)(2).

(3) The term "premarket notification submission" means a report submitted under section 510(k).

(4)(A) The term "supplement", with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which--

(i) an application or report has been approved under section 515(d), or an application has been approved under section 351 of the Public Health Service Act [42 USC § 262]; or

(ii) a notice of completion has become effective under section 515(f).

(B) The term "panel-track supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term "180-day supplement" means a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term "real-time supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term "efficacy supplement" means a supplement to an approved premarket application under section 351 of the Public Health Service Act [42 USC § 262] that requires substantive clinical data.

(5) The term "30-day notice" means a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(6) The term "request for classification information" means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

(7) The term "annual fee", for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.

(8) The term "process for the review of device applications" means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 351 of the Public Health Service Act [42 USC § 262] for an investigational new drug application under section 505(i) or for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) or 520(g).

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

(9) The term "costs of resources allocated for the process for the review of device applications" means the expenses ~~incurred~~ in connection with the process for the review of device applications for--

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

(10) The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October ~~2001~~2011.

(11) The term "person" includes an affiliate thereof.

(12) The term "affiliate" means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly--

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(13) The term "establishment subject to a registration fee" means an establishment that ~~—~~

~~(A)~~ is registered (or is required to register) with the Secretary under section 510~~; and is one of the following types of establishments:~~

~~(B)~~ because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

~~(A) Manufacturer. An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.~~

~~(B) Single-use device reprocessor. An establishment that, within the meaning of section 201(ll)(2)(A) [21 USC § 321(ll)(2)(A)], performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.~~

~~(C) Specification developer. An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.~~

SEC. 738. [21 USC §379j] Authority to Assess and Use Device Fees

(a) Types of fees.

(1) In general. Beginning in fiscal year ~~2008~~2013, the Secretary shall assess and collect fees in accordance with this section.

(2) Premarket application, premarket report, supplement, and submission fee, and annual fee for periodic reporting concerning a class III device.

(A) In general. Except as provided in subparagraph (B) and subsections (d), ~~and~~ (e), and (f), each person who submits any of the following, on or after October 1, ~~2002~~2012, shall be subject to a fee established under subsection (c)~~(1)~~ for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to 75 percent of the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).

(vi) a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).

(vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(viii) For a premarket notification submission, a fee equal to 2~~1.84~~ percent of the fee that applies under clause (i).

(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

(B) Exceptions.

(i) Humanitarian device exemption. An application under section 520(m) is not subject to any fee under subparagraph (A).

(ii) Further manufacturing use. No fee shall be required under subparagraph (A) for the submission of a premarket application under section 351 of the Public Health Service Act [42 USCS § 262] for a product licensed for further manufacturing use only.

(iii) State or Federal Government sponsors. No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, or premarket notification submission submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) Premarket notifications by third parties. No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 523.

(v) Pediatric conditions of use.

(I) In general. No fee shall be required under subparagraph (A) for a premarket application, premarket report, or premarket notification submission if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) Subsequent proposal of adult conditions of use. In the case of a person who submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

(C) Payment. The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.

(D) Refunds.

(i) Application refused for filing. The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

(ii) Application withdrawn before filing. The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) Application withdrawn before first action. After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement. The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(iv) Modular applications withdrawn before first action. The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 515(c)(4) [21 USC § 360e(c)(4)] that is withdrawn before a second portion is submitted and before a first action on the first portion.

(v) Later withdrawn modular applications. If an application submitted under section 515(c)(4) [21 USC § 360e(c)(4)] is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

(vi) Sole discretion to refund. The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

(3) Annual establishment registration fee.

(A) In general. Except as provided in subparagraph (B) and subsection (f), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

(B) Exception. No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

(C) Payment. The fee required under subparagraph (A) shall be due once each fiscal year, upon the later of—

(i) the initial or annual registration (as applicable) of the establishment ~~or~~

~~or upon the annual registration under section 510~~; or

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

(b) Fee amounts. ~~Except as provided in subsections (c), (d), (e), and (h) the —~~

(1) In General.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be ~~based on~~ derived from the ~~following~~ base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3)~~:~~.

(2) Base fee amounts specified.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

Fee Type	Fiscal Year ~~2008~~ 2013	Fiscal Year ~~2009~~2014	Fiscal Year ~~2010~~2015	Fiscal Year ~~2011~~2016	Fiscal Year ~~2012~~2017
Premarket Application	$~~185,000~~248,000	$~~200,725~~252,960	$~~217,787~~258,019	$~~236,298~~263,180	$~~256,384~~268,443
Establishment Registration	$~~1,706~~2,575	$~~1,851~~3,200	$~~2,008~~3,750	$~~2,179~~3,872	$~~2,364~~3,872

(3) Total Revenue Amounts.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

(A) $~~95,429,314~~97,722,301 for fiscal year 2013;

(B) $~~112,171,877~~112,580,497 for fiscal year 2014;

(C) $~~127,537,959~~125,767,107 for fiscal year 2015;

(D) $~~129,997,509~~129,339,949 for fiscal year 2016; and

(E) $~~130,328,967~~130,184,348 for fiscal year 2017.

(c) Annual fee setting; adjustments.

(1) In general. The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012 ~~2002~~, establish ~~and publish in the Federal Register~~ fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

(2) Inflation adjustments.

(A) Adjustment to total revenue amounts.—For fiscal year 2014 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b) for such fiscal year by multiplying such amount by the inflation adjustment described in subparagraph (B) for such year.

(B) Inflation adjustment described.—The inflation adjustment described in this subparagraph for a fiscal year is:

(i) subject to clauses (ii) through (iv), the sum of one plus —

(I) 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 0.60, and

(II) 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 0.40;.

(ii) for fiscal year 2014, the inflation adjustment under this subparagraph is the sum described in clause (i).

(iii) for fiscal year 2015 and each subsequent fiscal year, the inflation adjustment under this subparagraph is the product of—

(I) the sum calculated under clause (i) for such fiscal year; and

(II) the product of the sums calculated under clause (i) with respect to all preceding fiscal years beginning with fiscal year 2014.

(iv) For purposes of clauses (ii) and (iii), if any sum under clause (i)—

(I) is less than 1, such sum shall be considered 1; or

(II) is greater than 1.04, such sum shall be considered 1.04.

(C) Adjustment to base fee amounts.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the inflation-adjusted total revenue amounts provided for under this paragraph.

(3) Adjustments to establishment registration base fees.—For each of fiscal years 2014 through 2017, after the base fee amounts specified in subsection (b)(2) are adjusted for inflation under paragraph (2)(C), the base establishment registration fee amounts specified in such subsection shall be further adjusted, as the Secretary estimates necessary for total fee collections for such fiscal year to generate the total revenue amounts as adjusted under paragraph (2).

~~(2) Adjustment. (A) In general. When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.~~

~~(B) Publication. For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination.~~

(4~~3~~) 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 device applications.

(5~~4~~) Supplement.

(A) In general. The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

(B) Notice to Congress. Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(d) Small businesses; fee waiver and fee reduction regarding premarket approval fees.

(1) In general. The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. For the purposes of this paragraph, the term "small business" means an entity that reported $~~-~~30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vi) and clauses (vii), (ix), and (x) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) Rules relating to premarket approval fees.

(A) Definition. For purposes of this paragraph, the term "small business" means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) Evidence of qualification.

(i) In general. An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

(ii) Firms submitting tax returns to the United States Internal Revenue Service. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

(iii) Firms not submitting tax returns to the United States Internal Revenue Service. In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) Reduced fees. Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of--

(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, or a supplement.

(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.

(D) Request for fee waiver or reduction. An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before

the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) Small businesses; fee reduction regarding premarket notification submissions.

(1) In general. For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) Rules relating to premarket notification submissions.

(A) Definition. For purposes of this subsection, the term "small business" means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) Evidence of qualification.

(i) In general. An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

(ii) Firms submitting tax returns to the United States Internal Revenue Service. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) Firms not submitting tax returns to the United States Internal Revenue Service. In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) Reduced fees. For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

(D) Request for reduction. An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) Fee waiver or reduction.

(1) In General. The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

(2) Limitation. The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

(3) Duration. The authority provided by this subsection terminates October 1, 2017.

(g) Effect of failure to pay fees.

(1) No acceptance of submissions. A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

(2) No registration. Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.

(h~~g~~) Conditions.

(1) Performance goals; termination of program. With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if--

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $~~205,720,000~~280,587,000 multiplied by the adjustment factor applicable to such fiscal year ; or

(B) fees were not assessed under subsection (a) for the previous fiscal year

(2) Authority. If the Secretary does not assess fees under subsection (a) 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 premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment

registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(i~~h~~) 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 appropriation Acts, subject to subparagraph (2)(C). Such fees are authorized to be appropriated 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 device applications.

(2) Collections and appropriation acts.

(A) In general. The fees authorized by this section--

(i) shall be collected and available ~~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 device 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 ~~2002~~ 2009 multiplied by the adjustment factor.

(B) Compliance.

(i) In general. 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 device applications--

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

(II) (aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a 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

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

(ii) More than 5 percent. To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(C) Provision for early year 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) Authorizations 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 specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c) and paragraph (4). ~~There are authorized to be appropriated for fees under this section –~~

~~(A) $ 48,431,000 for fiscal year 2008;~~

~~(B) $ 52,547,000 for fiscal year 2009;~~

~~(C) $ 57,014,000 for fiscal year 2010;~~

~~(D) $ 61,860,000 for fiscal year 2011; and~~

~~(E) $ 67,118,000 for fiscal year 2012.~~

(4) Offset. If the cumulative amount of fees collected during fiscal years ~~2008, 2009, and 2010~~2013, 2014, and 2015, added to the amount estimated to be collected for fiscal year ~~2011~~2016, which estimate shall be based upon the amount of fees received by the Secretary through June 30, ~~2011~~2016, exceeds the cumulative amount appropriated under ~~of fees specified in aggregate in~~ paragraph (3) for these four fiscal 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~~2017.

(j~~i~~) Collection of unpaid fees. In any case where the Secretary does not receive payment of a fee assessed under subsection (a) 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, United States Code [31 USC §§ 3711 et seq.].

(k~~j~~) Written requests for refunds. To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

(l~~k~~) 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, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

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Subchapter D--Information and Education

SEC. 74x.

Beginning after the issuance of final guidance implementing this provision, pre-submissions and submissions for devices under sections 510(k), 515(c), 515(d), 515(f), 520(g), 520(m), 564, or under section 351 of the Public Health Service Act, and any supplements to such submissions, shall include an electronic copy of such pre-submissions or submissions. In such guidance, the Secretary may provide standards for such electronic copy, and set forth criteria for waivers of and exemptions from the requirements of this section.

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STREAMLINED HIRING AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

SEC. 7xx. STREAMLINED HIRING AUTHORITY.

(a) In general.---In addition to any other personnel authorities, the Secretary may, without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

(b) Activities described.---The activities described in this subsection are activities under this Act related to the process for the review of device applications, as defined in section 737(8).

(c) Objectives specified.---The objectives specified in this subsection are the performance goals referred to in section 738A(a)(1) as set forth in letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as published in the Congressional Record.

(d) Internal controls.---The Secretary shall institute appropriate internal controls for appointments under this section.

(e) Sunset.--- The authority to appoint employees under this section shall terminate on the date that is three years after the date of enactment of this section.

* * * *

SEC. __. SUNSET CLAUSE.

The amendments made by this title cease to be effective October 1, ~~2012~~2017, except that section 738A

of the Federal Food, Drug, and Cosmetic Act (regarding annual performance and financial reports) ceases to be effective January 31, ~~2013~~2018.

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SEC. 523, ACCREDITED PERSONS

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(c) Duration. The authority provided by this section terminates October 1, ~~2012~~2017.