

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF
2002

OCTOBER 7, 2002.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mr. TAUZIN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 3580]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3580) to amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Medical Device User Fee and Modernization Act of 2002”.

(b) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—FEES RELATED TO MEDICAL DEVICES

Sec. 101. Findings.
 Sec. 102. Establishment of program.
 Sec. 103. Annual reports.
 Sec. 104. Postmarket surveillance.
 Sec. 105. Consultation.
 Sec. 106. Effective date.
 Sec. 107. Sunset clause.

TITLE II—AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES

Sec. 201. Inspections by accredited persons.
 Sec. 202. Third party review of premarket notification.
 Sec. 203. Designation and regulation of combination products.
 Sec. 204. Report on certain devices.
 Sec. 205. Electronic labeling.
 Sec. 206. Electronic registration.
 Sec. 207. Intended use.
 Sec. 208. Modular review.
 Sec. 209. Pediatric expertise regarding classification-panel review of premarket applications.
 Sec. 210. Internet list of class II devices exempted from requirement of premarket notification.
 Sec. 211. Study by Institute of Medicine of postmarket surveillance regarding pediatric populations.
 Sec. 212. Guidance regarding pediatric devices.
 Sec. 213. Breast implants; study by Comptroller General.
 Sec. 214. Breast implants; research through National Institutes of Health.

TITLE III—ADDITIONAL AMENDMENTS

Sec. 301. Identification of manufacturer of medical devices.
 Sec. 302. Single-use medical devices.

TITLE I—FEES RELATED TO MEDICAL DEVICES

SEC. 101. FINDINGS.

The Congress finds that—

- (1) prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease;
- (2) the public health will be served by furnishing additional funds for the review of devices so that statutorily mandated deadlines may be met; and
- (3) the fees authorized by the amendment made by section 102 will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

SEC. 102. ESTABLISHMENT OF PROGRAM.

(a) **IN GENERAL.**—Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following part:

“PART 3—FEES RELATING TO DEVICES

“SEC. 737. DEFINITIONS.

“For purposes of this subchapter:

“(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; 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 510(o)(3).

“(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 has been approved under section 515(d) or under section 351 of the Public Health Service Act; 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 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 clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.

“(C) The term ‘180-day supplement’ means a supplement to an approved premarket application 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 under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, 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 that requires substantive clinical data.

“(5) 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 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 under section 515 or 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.

“(6) 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.

“(7) 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 April of the preceding fiscal year divided by such Index for April 2002.

“(8) The term ‘affiliate’ means a business entity that has a relationship with a second business entity 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.

“SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

“(a) TYPES OF FEES.—Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002, the Secretary shall assess and collect fees in accordance with this section as follows:

“(1) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE.—

“(A) IN GENERAL.—Except as provided in subparagraph (B) and subsection (d), each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(5) 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 the fee that applies under clause (i).

“(iv) For a 180-day supplement, a fee equal to 21.5 percent of the fee that applies under clause (i), subject to any adjustment under subsection (c)(3).

“(v) For a real-time supplement, a fee equal to 7.2 percent of the fee that applies under clause (i).

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

“(vii) For a premarket notification submission, a fee equal to 1.75 percent of the fee that applies under clause (i), subject to any adjustment under subsection (c)(3).

“(B) EXCEPTIONS.—

“(i) HUMANITARIAN DEVICE EXEMPTION.—A device for which a humanitarian device exemption has been granted is not subject to the fees established in 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 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 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 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, or premarket notification submission except that invoices for applications submitted between October 1, 2002, and the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 under this section shall include all fees payable from October 1, 2002, through September 30, 2003.

“(D) REFUNDS.—

“(i) APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application 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 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.

“(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees under subsection (a) shall be established to generate the following revenue amounts: \$25,125,000 in fiscal year 2003; \$27,255,000 in fiscal year 2004; \$29,785,000 in fiscal year 2005; \$32,615,000 in fiscal year 2006, and \$35,000,000 in fiscal year 2007. If legislation is enacted after the date of the enactment of this Act requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.

“(c) ADJUSTMENTS.—

“(1) INFLATION ADJUSTMENT.—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 greater of—

“(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or

“(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2003 under this subsection.

“(2) WORKLOAD ADJUSTMENT.—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, beginning with fiscal year 2004, be adjusted further each fiscal year to reflect changes in the workload of the Secretary for the process for the review of device 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 premarket applications, investigational new device applications, premarket reports, supplements, and premarket notification submissions submitted to the Secretary.

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), as adjusted for inflation under paragraph (1).

“(3) COMPENSATING ADJUSTMENT.—After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year, if necessary, to reflect the cumulative amount by which collections for previous fiscal years, beginning with fiscal year 2003, fell below the cumulative revenue amounts for such fiscal years specified in subsection (b), adjusted for such fiscal years for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2). Only fees for 180 day supplements and premarket notification submissions shall be increased to generate compensating adjustment revenues.

“(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fees and fee revenues established in subsection (b) if such 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 device 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 user fee balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.

“(5) ANNUAL FEE SETTING.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustment provided under this subsection, except that the fees established for fiscal year 2003 shall be based on a premarket application fee of \$139,000.

“(6) 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.

“(d) SMALL BUSINESS FEE WAIVER AND FEE REDUCTION.—

“(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. 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) of subsection (a)(1)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

“(2) RULES RELATING TO SMALL BUSINESSES.—

“(A) DEFINITION.—

“(i) For purposes of this subsection, the term ‘small business’ means an entity that reported \$10,000,000 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, or parent firms.

“(ii) The Secretary may adjust the \$10,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 13 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.

“(B) EVIDENCE OF QUALIFICATION.—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. 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, which shows an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant shall certify that the information provided is a true and accurate copy of the applicant’s actual tax forms as submitted to the Internal Revenue Service.

“(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(5) may be paid at reduced rates as follows:

“(i) 38 percent of the fee established under subsection (c)(5) for a premarket application, a premarket report, a panel-track supplement, or an efficacy supplement.

“(ii) 44 percent of the fee established under subsection (c)(5) for a 180-day supplement to a medical device application.

“(iii) 25 percent of the fee established under subsection (c)(5) for a real-time supplement to a premarket application.

This subsection may not be construed as authorizing any reduction in the fee established under subsection (c)(5) for a premarket notification submission.

“(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).

“(e) EFFECT OF FAILURE TO PAY FEES.—A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) 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) CONDITIONS.—

“(1) PERFORMANCE GOALS THROUGH FISCAL YEAR 2005; TERMINATION OF PROGRAM AFTER FISCAL YEAR 2005.—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:

“(A)(i) For each of the fiscal years 2003 and 2004, the Secretary is expected to meet all of the goals identified for the fiscal year involved in any letter referred to in section 101(3) of the Medical Device User Fee and Modernization Act of 2002 (referred to in this paragraph as ‘performance goals’) if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than \$205,720,000 multiplied by the adjustment factor applicable to the fiscal year.

“(ii) For each of the fiscal years 2003 and 2004, if the amount so appropriated for the fiscal year involved, excluding the amount of fees appropriated for such fiscal year, is less than the amount that applies under clause (i) for such fiscal year, the following applies:

“(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

“(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2005. A report under the preceding sentence shall be submitted to the Congress not later than July 1 of the fiscal year with which the report is concerned.

“(B)(i) For fiscal year 2005, the Secretary is expected to meet all of the goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

“(I) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

“(II) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

“(III) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.

“(ii) For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:

“(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

“(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Sec-

retary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2006. The report under the preceding sentence shall be submitted to the Congress not later than July 1, 2005.

“(C) For fiscal year 2006, 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 the total of the amounts so appropriated for fiscal years 2003 through 2006, excluding the amount of fees appropriated for such fiscal years, is less than the sum of—

“(i) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2006; and

“(ii) an amount equal to the sum that applies for purposes of subparagraph (B)(i).

“(D) For fiscal year 2007, 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—

“(i) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is less than \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2007; or

“(ii) pursuant to subparagraph (C), fees were not assessed under subsection (a) for fiscal year 2006.

“(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of subparagraph (C) or (D) 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, and premarket notification submissions, and at any time in such fiscal year, notwithstanding the provisions of subsection (a) 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 appropriation Acts. 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 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, 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 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 device 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 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

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

“(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

“(A) \$25,125,000 for fiscal year 2003;

“(B) \$27,255,000 for fiscal year 2004;

“(C) \$29,785,000 for fiscal year 2005;

“(D) \$32,615,000 for fiscal year 2006; and

“(E) \$35,000,000 for fiscal year 2007, as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application fees.

“(4) OFFSET.—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.

“(h) 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.

“(i) WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under subsection (a)(1)(D), a person shall submit to the Secretary a written request for such 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, 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.”.

(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

(1) IN GENERAL.—A person submitting a premarket report to the Secretary of Health and Human Services is exempt from the fee under section 738(a)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section) if—

(A) the premarket report is the first such report submitted to the Secretary by the person; and

(B) before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.

(2) DEFINITIONS.—For purposes of paragraph (1), the terms “device”, “premarket application”, and “premarket report” have the same meanings as apply to such terms for purposes of section 738 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section).

SEC. 103. ANNUAL REPORTS.

Beginning with fiscal year 2003, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report concerning—

(1) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(3) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, not later than 60 days after the end of each fiscal year during which fees are collected under this part; and

(2) 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, not later than 120 days after the end of each fiscal year during which fees are collected under the medical device user-fee program established under the amendment made by section 102.

SEC. 104. POSTMARKET SURVEILLANCE.

(a) ADDITIONAL AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out postmarket surveillance of medical devices, there are authorized to be appropriated to the Food and Drug Administration the following amounts, stated as increases above the amount obligated for such purpose by such Administration for fiscal year 2002:

(1) For fiscal year 2003, an increase of \$3,000,000.

(2) For fiscal year 2004, an increase of \$6,000,000.

(3) For fiscal year 2005 and each subsequent fiscal year, an increase of such sums as may be necessary.

(b) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall conduct a study for the purpose of determining the following with respect to the medical device user-fee program established under the amendment made by section 102:

(A) The impact of such program on the ability of the Food and Drug Administration to conduct postmarket surveillance on medical devices.

(B) The programmatic improvements, if any, needed for adequate postmarket surveillance of medical devices.

(C) The amount of funds needed to conduct adequate postmarket surveillance of medical devices.

(D) The extent to which device companies comply with the postmarket surveillance requirements, including postmarket study commitments.

(E) The recommendations of the Secretary as to whether, and in what amounts, user fees collected under such user-fee program should be dedicated to postmarket surveillance if the program is extended beyond fiscal year 2007.

(2) REPORT.—Not later than January 10, 2007, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that describes the findings of the study under paragraph (1).

SEC. 105. CONSULTATION.

(a) IN GENERAL.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications for fiscal years after fiscal year 2007, and for the reauthorization of sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

(b) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under subsection (a), after negotiations with the regulated industry; shall present such recommendations to the congressional committees specified in such paragraph; shall hold a meeting at which the public may present its views on such recommendations; and shall provide for a period of 30 days for the public to provide written comments on such recommendations.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on the date of the enactment of this Act, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2002, regardless of the date of enactment.

SEC. 107. SUNSET CLAUSE.

The amendments made by this title cease to be effective October 1, 2007, except that section 103 with respect to annual reports ceases to be effective January 31, 2008.

TITLE II—AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES

SEC. 201. INSPECTIONS BY ACCREDITED PERSONS.

(a) IN GENERAL.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following subsection:

“(g)(1) Not later than one year after the date of the enactment of this subsection, the Secretary shall, subject to the provisions of this subsection, accredit persons who are not Federal employees for the purpose of conducting the inspections required in section 510(h), or pursuant to section 510(i), for establishments that manufacture, prepare, propagate, compound, or process class II or class III devices. The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections

“(2) Not later than 180 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited. In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the du-

ties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).

“(3) An accredited person shall, at a minimum, meet the following requirements:

“(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

“(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

“(C) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this Act.

“(D) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

“(i) certify that reported information accurately reflects data reviewed;

“(ii) limit work to that for which competence and capacity are available;

“(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information;

“(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

“(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this Act, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

“(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of accredited persons to conduct inspections under paragraph (1). Such list shall be periodically updated to ensure that the identity of each accredited person is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the withdrawal of accreditation.

“(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of an establishment and the performance of accredited persons.

“(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

“(6)(A) Subject to subparagraphs (B) through (C), a device establishment is eligible for inspections by persons accredited under paragraph (2) if—

“(i) the Secretary classified the results of the most recent inspection of the establishment pursuant to subsection (h) or (i) of section 510 as ‘no action indicated’ or ‘voluntary action indicated’; and

“(ii) with respect to each inspection to be conducted by an accredited person—

“(I) the owner or operator of the establishment submits to the Secretary a notice requesting clearance to use such a person to conduct the inspection, and the Secretary provides such clearance; and

“(II) such notice identifies the accredited person whom the establishment has selected to conduct the inspection, and the Secretary agrees to the selected accredited person.

“(B)(i) The Secretary shall respond to a notice under subparagraph (A) from an establishment not later than 30 days after the Secretary receives the notice. Through such response, the Secretary shall (I) provide clearance under such subparagraph, and agree to the selection of an accredited person, or (II) make a request under clause (ii). If the Secretary fails to respond to the notice within such 30-day period, the establishment is deemed to have such clearance, and to have the agreement of the Secretary for such selection.

“(ii) The request referred to in clause (i)(II) is—

“(I) a request to the establishment involved to submit to the Secretary compliance data in accordance with clause (iii); or

“(II) a request to the establishment, or to the accredited person identified in the notice under subparagraph (A), for information concerning the relationship between the establishment and such accredited person.

The Secretary may make both such requests.

“(iii) The compliance data to be submitted by an establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h), and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other applicable provisions of this Act. Such data shall include complete reports of inspections regarding good manufacturing practice or other quality control audits that, during the preceding two-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

“(iv) Not later than 60 days after receiving compliance data under clause (iii) from an establishment, the Secretary shall provide or deny clearance under subparagraph (A). The Secretary may not deny clearance unless the Secretary provides to the establishment detailed findings that the establishment has failed to demonstrate consistent compliance for purposes of clause (iii). If the Secretary fails to provide such findings to the establishment within such 60-day period, the establishment is deemed to have such clearance.

“(v)(I) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1). Not later than 60 days after receiving the information sought by the request, the Secretary shall agree to, or reject, the selection of such person by the establishment involved. The Secretary may not reject the selection unless the Secretary provides to the establishment the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request. If within such 60-day period the Secretary fails to agree to or reject the selection in accordance with this subclause, the Secretary is deemed to have agreed to the selection.

“(II) If the Secretary rejects the selection of an accredited person by an establishment, the establishment may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A).

“(vi) In the case of an establishment that under clause (iv) is denied clearance under subparagraph (A), or whose selection of an accredited person is rejected under clause (v), the Secretary shall designate a person to review the findings of the Secretary under such clause if, during the 30-day period beginning on the date on which the establishment receives the findings, the establishment requests the review. The review shall commence not later than 30 days after the establishment requests the review, unless the Secretary and the establishment otherwise agree.

“(C)(i) In the case of a device establishment for which the Secretary classified the results of the most recent inspection of the establishment by a person accredited under paragraph (2) as ‘official action indicated’, the establishment is eligible for further inspections by persons accredited under such paragraph if (I) the Secretary issues a written statement to the owner or operator of the establishment that the violations leading to such classification have been resolved, and (II) the Secretary, either upon the Secretary’s own initiative or a petition of the owner or operator of the establishment, notifies the establishment that it has clearance to use an accredited person for the inspections. The Secretary shall respond to such petition within 30 days after the receipt of the petition.

“(ii) If the Secretary denies a petition under clause (i), the establishment involved may, after the expiration of one year after such denial, again petition the Secretary for a determination of eligibility for inspection by persons accredited by the Secretary under paragraph (2). If the Secretary denies such petition, the Secretary shall provide the establishment with a detailed reason for such denial within 60 days after the denial. If, as of the expiration of 48 months after the receipt of the first petition, the establishment has not been inspected by the Secretary in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable, the establishment is eligible for further inspections by accredited persons.

“(7)(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment’s designated representative and discuss each observation. Additionally, such accredited person shall prepare an inspection report (including for

inspections classified as ‘no action indicated’) in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.

“(B) At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected establishment involved, the dates of the inspection, the scope of the inspection, and shall discuss in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this Act, and discuss any recommendations during the inspection or at the inspection’s closing meeting.

“(C) An inspection report under subparagraph (A) shall be sent to the Secretary and the designated representative of the inspected establishment involved at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observations previously provided to the representative of the establishment.

“(D) Any statements or representations made by employees or agents of a device establishment to persons accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18, United States Code.

“(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the facility subject to inspection and the conditions of concern.

“(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

“(9) Nothing in this subsection affects the authority of the Secretary to inspect establishments pursuant to this Act.

“(10)(A) For fiscal year 2005 and subsequent fiscal years, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

“(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the ‘first prior fiscal year’), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

“(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the ‘second prior fiscal year’), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

“(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the ‘compliance budget’), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the ‘inspection budget’).

“(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 515.

“(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a reporting describing the findings made through such determinations.

“(C) For purposes of this paragraph:

“(i) The term ‘base amount’ means the inspection budget determined under subparagraph (B) for fiscal year 2002.

“(ii) The term ‘adjusted base amount’, in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

“(iii) The term ‘adjusted base amount’, with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted based amount applicable to the preceding year increased by 5 percent.

“(11) The authority provided by this subsection terminates on October 1, 2012.

“(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

“(A) the number of inspections conducted by accredited persons and the number of inspections pursuant to subsections (h) and (i) of section 510 conducted by Federal employees;

“(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

“(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

“(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this Act, and whether the number of audits conducted is sufficient to permit these assessments;

“(E) whether this subsection is achieving the goal of ensuring more information about establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to subsection (h) or (i) of section 510;

“(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

“(G) whether the Congress should continue, modify, or terminate the program under this subsection.

“(13) The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.”.

(b) MAINTENANCE OF RECORDS.—Section 704(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(f)) is amended—

(1) in paragraph (1), in the first sentence, by striking “A person accredited” and all that follows through “shall maintain records” and inserting the following: “An accredited person described in paragraph (3) shall maintain records”;

(2) in paragraph (2), by striking “a person accredited under section 523” and inserting “an accredited person described in paragraph (3)”; and

(3) by adding at the end the following paragraph:

“(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

“(A) is accredited under subsection (g); or

“(B) is accredited under section 523.”.

(c) CONFORMING AMENDMENT.—Section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended by inserting after “duly designated by the Secretary” the following: “, or by persons accredited to conduct inspections under section 704(g).”.

SEC. 202. THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m) is amended—

(1) in subsection (c), by striking “The authority” and all that follows and inserting the following: “The authority provided by this section terminates October 1, 2007.”; and

(2) by adding at the end the following subsection:

“(d) REPORT.—Not later than January 10, 2007, the Secretary shall conduct a study based on the experience under the program under this section and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the findings of the study. The objectives of the study shall include determining—

“(1) the number of devices reviewed under this section;

“(2) the number of devices reviewed under this section that were ultimately cleared by the Secretary;

“(3) the number of devices reviewed under this section that were ultimately not cleared by the Secretary;

“(4) the average time period for a review under this section (including the time it takes for the Secretary to review a recommendation of an accredited person under subsection (a) and determine the initial device classification);

“(5) the average time period identified in paragraph (4) compared to the average time period for review of devices solely by the Secretary pursuant to section 510(k);

“(6) if there is a difference in the average time period under paragraph (4) and the average time period under paragraph (5), the reasons for such difference;

“(7) whether the quality of reviews under this section for devices for which no guidance has been issued is qualitatively inferior to reviews by the Secretary for devices for which no guidance has been issued;

“(8) whether the quality of reviews under this section of devices for which no guidance has been issued is qualitatively inferior to reviews under this section of devices for which guidance has been issued;

“(9) whether this section has in any way jeopardized or improved the public health;

“(10) any impact of this section on resources available to the Secretary to review reports under section 510(k); and

“(11) any suggestions for continuation, modification (including expansion of device eligibility), or termination of this section that the Secretary determines to be appropriate.”.

SEC. 203. DESIGNATION AND REGULATION OF COMBINATION PRODUCTS.

Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) in paragraph (1)—

(A) in the first sentence, by striking “shall designate a component of the Food and Drug Administration” and inserting “shall in accordance with this subsection assign an agency center”; and

(B) in each of subparagraphs (A) through (C), by striking “the persons charged” and inserting “the agency center charged”;

(2) by redesignating paragraph (4) as paragraph (5);

(3) by inserting after paragraph (3) the following paragraph:

“(4)(A) Not later than 60 days after the date of the enactment of this paragraph, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the ‘Office’) shall have appropriate scientific and medical expertise, and shall be headed by a director.

“(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

“(C) In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing and coordinating reviews involving more than one agency center.

“(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Nothing in this paragraph shall be construed to limit the postmarket regulatory authority of any agency center.

“(E) In order to ensure the timeliness of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness of the premarket review.

“(F)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the timeliness of the dispute is clearly premature.

“(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

“(G) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be

construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

“(H) Not later than one year after the date of the enactment of this paragraph and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

“(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

“(ii) identifying the number of premarket reviews of such products that involved a consulting agency center; and

“(iii) describing improvements in the consistency of postmarket regulation of combination products.”; and

(4) in paragraph (5) (as redesignated by paragraph (2) of this section)—

(A) by redesignating subparagraphs (A) and (B) as subparagraphs (B) and (C), respectively; and

(B) by inserting before subparagraph (B) the following subparagraph:

“(A) The term ‘agency center’ means a center or alternative organizational component of the Food and Drug Administration.”.

SEC. 204. REPORT ON CERTAIN DEVICES.

Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall report to the appropriate committees of Congress on the timeliness and effectiveness of device premarket reviews by centers other than the Center for Devices and Radiological Health. Such report shall include information on the times required to log in and review original submissions and supplements, times required to review manufacturers’ replies to submissions, and times to approve or clear such devices. Such report shall contain the Secretary’s recommendations on any measures needed to improve performance including, but not limited to, the allocation of additional resources. Such report also shall include the Secretary’s specific recommendation on whether responsibility for regulating such devices should be reassigned to those persons within the Food and Drug Administration who are primarily charged with regulating other types of devices, and whether such a transfer could have a deleterious impact on the public health and on the safety of such devices.

SEC. 205. ELECTRONIC LABELING.

Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following: “Required labeling for prescription devices intended for use in health care facilities may be made available solely by electronic means provided that the labeling complies with all applicable requirements of law and, that the manufacturer affords health care facilities the opportunity to request the labeling in paper form, and after such request, promptly provides the health care facility the requested information without additional cost.”.

SEC. 206. ELECTRONIC REGISTRATION.

Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

“(p) Registrations under subsections (b), (c), (d), and (i) (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.”.

SEC. 207. INTENDED USE.

Section 513(i)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(i)(1)(E)) is amended by striking clause (iv).

SEC. 208. MODULAR REVIEW.

Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

“(3)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review portions of such applications that applicants and the Secretary agree are complete, ready, and appropriate for review.

“(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless issues of safety or effectiveness provide the Secretary cause to review such accepted portion.

“(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall specifically identify, in writing,

the deficiency of such portion and describe in detail the means by which it may be made acceptable, unless the sponsor is no longer pursuing the application.”.

SEC. 209. PEDIATRIC EXPERTISE REGARDING CLASSIFICATION-PANEL REVIEW OF PRE-MARKET APPLICATIONS.

Section 515(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(2)) is amended by adding at the end the following: “If the Secretary determines that there is a reasonable likelihood that the device involved will be used in a pediatric population, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.”.

SEC. 210. INTERNET LIST OF CLASS II DEVICES EXEMPTED FROM REQUIREMENT OF PRE-MARKET NOTIFICATION.

Section 510(m)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)(1)) is amended by adding at the end the following: “The Secretary shall publish such list on the Internet site of the Food and Drug Administration. The list so published shall be updated not later than 30 days after each revision of the list by the Secretary.”.

SEC. 211. STUDY BY INSTITUTE OF MEDICINE OF POSTMARKET SURVEILLANCE REGARDING PEDIATRIC POPULATIONS.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall request the Institute of Medicine to enter into an agreement with the Secretary under which such Institute conducts a study for the purpose of determining whether the system under the Federal Food, Drug, and Cosmetic Act for the postmarket surveillance of medical devices provides adequate safeguards regarding the use of devices in pediatric populations.

(b) **CERTAIN MATTERS.**—The Secretary shall ensure that determinations made in the study under subsection (a) include determinations of—

(1) whether postmarket surveillance studies of implanted medical devices are of long enough duration to evaluate the impact of growth and development for the number of years that the child will have the implant, and whether the studies are adequate to evaluate how children’s active lifestyles may affect the failure rate and longevity of the implant; and

(2) whether the amount of funds allocated for postmarket surveillance by the Food and Drug Administration of medical devices used in pediatric populations is sufficient to provide adequate safeguards for such populations, taking into account the Secretary’s monitoring of commitments made at the time of approval of medical devices, such as phase IV trials, and the Secretary’s monitoring and use of adverse reaction reports, registries, and other postmarket surveillance activities.

(c) **REPORT TO CONGRESS.**—The Secretary shall ensure that, not later than four years after the date of the enactment of this Act, a report describing the findings of the study under subsection (a) is submitted to the Congress. The report shall include any recommendations of the Secretary for administrative or legislative changes to the system of postmarket surveillance referred to in such subsection.

SEC. 212. GUIDANCE REGARDING PEDIATRIC DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following subsection:

“Guidance Regarding Pediatric Devices

“(n) Not later than 270 days after the date of the enactment of the Medical Device User Fee and Modernization Act of 2002, the Secretary shall issue guidance on the following:

“(1) The type of information necessary to provide reasonable assurance of the safety and effectiveness of devices intended for use in pediatric populations.

“(2) Protections for pediatric subjects in clinical investigations of the safety or effectiveness of such devices.”.

SEC. 213. BREAST IMPLANTS; STUDY BY COMPTROLLER GENERAL.

(a) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study to determine the following with respect to breast implants:

(1) The content of information typically provided by health professionals to women who consult with such professionals on the issue of whether to undergo breast implant surgery.

(2) Whether such information is provided by physicians or other health professionals, and whether the information is provided verbally or in writing.

(3) Whether the information provided presents a fair and balanced statement of the risks and benefits of receiving the implants (taking into account the fre-

quency of updates to the information), and if so, at what point in the process of determining whether to undergo surgery is such information provided.

(4) Whether women understand the information that is provided (including full appreciation of the risks), and whether and to what extent the information influences the decision to receive the implants.

(5) The number of adverse events that have been reported, and whether such events have been adequately investigated.

(6) With respect to women who participate as subjects in research being carried out regarding the safety and effectiveness of breast implants:

(A) The content of information provided to the women during the process of obtaining the informed consent of the women to be subjects, and whether such information is appropriately updated.

(B) Whether such process provides written explanations of the criteria for being subjects in the research.

(C) The point at which, in the planning or conduct of the research, the women are provided information regarding the provision of informed consent to be subjects.

(D) Whether, before providing informed consent, the women fully appreciate the risks of being subjects in the research.

(b) REPORT.—The Comptroller General shall submit to the Congress a report describing the findings of the study.

(c) DEFINITION.—For purposes of this section, the term “breast implant” means a breast prosthesis that is implanted to augment or reconstruct the female breast.

SEC. 214. BREAST IMPLANTS; RESEARCH THROUGH NATIONAL INSTITUTES OF HEALTH.

(a) REPORT ON STATUS OF CURRENT RESEARCH.—Not later than 180 days after the date of the enactment of this Act, the Director of the National Institutes of Health shall submit to the Congress a report describing the status of research on breast implants (as defined in section 213(c)) being conducted or supported by such Institutes.

(b) RESEARCH ON LONG-TERM IMPLICATIONS.—Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end of the following section:

“SEC. 498C. BREAST IMPLANT RESEARCH.

“(a) IN GENERAL.—The Director of NIH shall conduct or support prospective or retrospective research to examine the long-term health implications of both saline and silicone breast implants. If scientifically appropriate, such research studies may include the following:

“(1) A multidisciplinary study of women who have received silicone and saline implants and have had an implant for a sufficient amount of time to allow for appropriate comparison as to the long-term health consequences.

“(2) A comparison of women receiving implants for reconstruction after mastectomy to breast cancer patients who have not had reconstruction, including subsets of women with saline implants and women with silicone implants.

“(b) DEFINITION.—For purposes of this section, the term ‘breast implant’ means a breast prosthesis that is implanted to augment or reconstruct the female breast.”.

TITLE III—ADDITIONAL AMENDMENTS

SEC. 301. IDENTIFICATION OF MANUFACTURER OF MEDICAL DEVICES.

(a) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

“(u) If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect 18 months after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date.

SEC. 302. SINGLE-USE MEDICAL DEVICES.

(a) REQUIRED STATEMENTS ON LABELING.—

(1) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act, as amended by section 301 of this Act, is amended by adding at the end the following:

“(v) If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement ‘Reprocessed device for single use. Reprocessed by ____.’ The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) takes effect 15 months after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date.

(b) PREMARKET NOTIFICATION.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by inserting after subsection (n) the following: “(o)(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

“(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within one year after enactment of this subsection, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.

“(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o), adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

“(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

“(D) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

“(2) With respect to critical or semicritical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

“(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

“(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such report has not been submitted to the Secretary.

After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o), adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

“(C) The initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection.

“(D) Section 502(o) applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

“(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semicritical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

“(3) In the case of a reprocessed single-use device that is classified in class III and for which a premarket application is required, the following provisions apply with respect to such reprocessed device in lieu of an application for premarket approval under section 515:

“(A) The device shall not be introduced into interstate commerce or delivered for introduction into interstate commerce unless the person involved has submitted to the Secretary a report in accordance with this paragraph and the Secretary, after reviewing the report, issues an order determining there is a reasonable assurance of the safety and effectiveness for the device.

“(B) The report under subparagraph (A) shall contain the following:

“(i) The device name, including both the trade or proprietary name and the common or usual name.

“(ii) The establishment registration number of the owner or operator submitting the report.

“(iii) Actions taken to comply with performance standards under section 514.

“(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

“(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not a device is safe or effective.

“(vi) A description of the device’s components, ingredients, and properties.

“(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

“(viii) Such samples of the device that the Secretary may reasonably require.

“(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

“(x) A statement that the applicant believes to the best of the applicant’s knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

“(xi) Any additional data and information that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.

“(C) In addition to the information or data required in subparagraph (B), the report under subparagraph (A) shall include the validation data described in paragraph (1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting the report under this paragraph.”.

(c) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(11)(1) The term ‘single-use device’ means a device that is intended for one use, or on a single patient during a single procedure.

“(2)(A) The term ‘reprocessed’, with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

“(B) A single-use device that meets the definition under subparagraph (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term ‘recycled’ rather than the term ‘reprocessed’.

“(3) The term ‘original device’ means a new, unused single-use device.

“(mm)(1) The term ‘critical reprocessed single-use device’ means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

“(2) The term ‘semi-critical reprocessed single-use device’ means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.”.

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 321(b)(2) of Public Law 107–188, is amended by adding at the end the following:

“(gg) The introduction or delivery for introduction into interstate commerce of any device in violation of section 510(o)(3).”.

PURPOSE AND SUMMARY

The purpose of H.R. 3580 is to establish a medical device user fee program at the Food and Drug Administration (FDA) in order to provide FDA with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier point in time, and to ensure that reprocessed medical devices are as safe and effective as original devices.

BACKGROUND AND NEED FOR LEGISLATION

There are more than 10,000 medical device manufacturers in the United States, and these manufacturers submit nearly 5,000 device applications and submissions to the FDA on a yearly basis. While the FDA has done a good job reviewing these applications and submissions, there is recognition that FDA resources are limited, and that without a new infusion of funding, it is likely that review times will increase in the future.

Providing FDA with new resources to review applications and submissions is just one way to ensure expedited review times. Another way to ensure swift approval of safe and effective devices is to enact needed regulatory reforms. The medical device industry is one of the most innovative industries in the United States. The average life cycle for a new medical device frequently lasts less than one year, compared with multi-year life cycles for other FDA-regulated products. It is best for American consumers to receive innovative, safe, and effective medical devices at the earliest point in time, and regulatory reforms will assist in accomplishing this objective.

Further, safe and effective reprocessed medical devices are important to the American health care marketplace because they cost less than original medical devices, thus reducing overall health care costs. However, in certain situations reprocessed medical devices raise questions of functionality and safety and effectiveness that original medical devices may not. Therefore, it is important to enact reforms which take into account the differences between these two types of devices, where they exist.

H.R. 3580 responds to these issues by enacting a medical device user fee program which will provide FDA with more than \$200 million over the five year life of the program. Such new money will

allow FDA to hire more reviewers and improve its infrastructure. The money, to be provided by medical device manufacturers (in the form of application fees) and increased appropriations, will be used by the FDA to meet agreed-upon performance goals. H.R. 3580 further enacts needed regulatory reforms such as third-party inspection and the statutory creation of the Office of Combination Products, both of which will address concerns raised by the medical device industry. Last, this legislation enacts needed medical device reprocessing reforms intended to provide end-users with information about whether the medical devices they use are, or are not, reprocessed, while at the same time providing FDA with more information about whether medical devices can be cleaned, sterilized, and reprocessed without affecting functional performance.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On Wednesday, October 2, 2002, the Committee on Energy and Commerce met in open markup session and favorably ordered reported H.R. 3580, as amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 3580 reported. A motion by Mr. Tauzin to order H.R. 3580 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goals and objectives of this legislation are to establish a medical device user fee program that enables the FDA to better approve safe and effective medical devices; to enact needed regulatory reforms; and to ensure that reprocessed medical devices are safe and effective in all instances.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3580, the Medical Device User Fee and Modernization Act, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee has reviewed this legislation for its budgetary impact and has concluded that it will result in increased discretionary spending of slightly less than \$100 million over a five-year period. This score was developed in close consultation with the Congressional Budget Office (CBO). While CBO has not yet completed its score of this legislation, we believe that their numbers will be comparable to the Committee's estimate.

CONGRESSIONAL BUDGET OFFICE ESTIMATE AND FEDERAL MANDATES STATEMENT

The Congressional Budget Office estimate required pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, and the estimate of Federal mandates required pursuant to section 423 of the Unfunded Mandates Reform Act were requested from the Congressional Budget Office, but were not prepared as of the date of filing of this report. The Congressional Budget Office estimate and accompanying materials will be contained in a supplemental report.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 101. Findings

The medical device industry is growing rapidly. The complexity of medical technology is increasing at an equally rapid pace. Unfortunately, FDA's device review program lacks the resources to keep up with the rapidly growing industry and changing technology. Because prompt approval and clearance of safe and effective medical devices is critical to improving public health, it is the sense of the Committee that adequate funding for the program is essential.

Section 102. Establishment of program

This title gives FDA the authority to collect user fees from manufacturers seeking to market medical devices. In this new program, manufacturers pay fees to FDA in exchange for FDA's agreement

to endeavor to meet device review performance goals that will significantly improve the timeliness, quality, and predictability of the agency's review of devices.

Under this new program, fees will be charged for certain applications, reports, supplements and submissions sent to the Food and Drug Administration for evaluation. Unlike the fees assessed under the Prescription Drug User Fee Act (PDUFA), no annual fees are charged for establishments and products. The fees are based on the relative level of effort required for reviews. The fees for each application category are prescribed in section 738(a) as a percent of the fee for an original premarket approval application (PMA), considered the most resource-intensive type of review. Table 1 below shows the types of applications for which fees will be assessed, the fee as a percent of the fee for a premarket approval application, and the fees that will be assessed for each type of application in FY 2003.

TABLE 1.—APPLICATION FEE TYPES, PERCENT OF PMA FEE, AND FY 2003 AMOUNTS

Type of application	Fee as % of PMA	FY 2003 fee (\$)
Premarket Application (submitted under section 515(c) or section 351 of the Public Health Service Act)	100	139,000
Panel-track Supplements to applications approved under section 515	100	139,000
Efficacy Supplement to an application approved under section 351 of the Public Health Service Act	100	139,000
Premarket Report under section 510(o)(3)	100	139,000
180-day supplement to an approved PMA	¹ 21.5	29,885
Real Time Supplements to applications approved under section 515	7.2	10,008
Premarket Notification Submissions under section 510(k)	¹ 1.75	2,433

¹This is the percentage unless the compensating adjustments is triggered in any year. Then the percentages for 180-day supplements and premarket notification submissions would be higher, since these fees will be increased to generate additional revenues associated with the compensating adjustment.

Fees will be assessed for all applications submitted on or after October 1, 2002. Certain applications are exempted from these fees, including devices for which a humanitarian device exemption has been granted, applications licensed solely for further manufacturing use, noncommercial applications from federal and state government sponsors, premarket notifications reviewed by an accredited third party, as well as devices solely intended for pediatric conditions of use.

Fees can be used by FDA for the “process for the review of device applications.” The “process for the review of device applications” is defined to include a number of activities, including: activities necessary to review applications; the issuance of action letters; preapproval inspections; monitoring of research conducted in connection with reviews; review of devices submitted pursuant to section 351 of the Public Health Service Act; the development of guidance and policy documents to improve the device review process; the development of voluntary test methods and consistent standards; the provision of technical assistance to device manufacturers; device classification activities; evaluation of postmarket studies required as a condition of device approval; and the 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. The Committee believes that FDA should ensure that adequate user fee resources are dedicated to identifying safety

and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, and premarket notification submissions when reviewing information on relevant devices.

Further, the Committee wishes to emphasize the importance of the use of both fees and appropriated dollars to develop the technological expertise available to the FDA for review purposes. The changes in medical technology over the last quarter of a century have been dramatic. The technologies involved in today's medical devices were not even dreamed of 25 years ago. The ability of the Center for Devices and Radiological Health to remain current and expert in these rapidly evolving technologies will certainly be stressed as we move toward devices based on advanced technologies such as nanotechnology and tissue engineering. For this reason, the Committee expects the Center for Devices and Radiological Health to develop a pool of outside technical experts, who would be available on short notice, to provide technical advice on product reviews, pre-approval inspections, and other technical issues for which the Center may need assistance. Such outside expertise is to be funded by a combination of user fees and appropriations and shall be pre-cleared through the appropriate conflict of interest process. The Center's current advisory committee members represent a source for developing such a pool. The Committee intends that this section provides the funds necessary to expand the current advisory committee resource into a preeminent, multi-disciplinary scientific resource the Center can draw on as it sees fit.

The bill uses a revenue model that is based on the latest PDUFA reauthorization, enacted on June 12, 2002—referred to as PDUFA III. The major features of this revenue model are described below.

Statutory Revenue Amounts.—Like PDUFA III, the revenue amounts FDA is expected to collect each year are stated in section 738(b), not the amounts of application fees. The fees will be established to generate \$25.1 million in FY 2003, and reaching \$35 million in FY 2007, plus adjustments. Adjustments are to be made to these statutory amounts for years after FY 2003. Most adjustment provisions follow in subsection 738(c). However, one adjustment contingency is addressed in subsection 738(b). If, after the date of enactment, new legislation should require the funding of additional Federal personnel retirement costs, the fee revenue amounts in this section shall be increased to fund the portion of those costs attributable to the device review process. Each of the other specific adjustment provisions set forth in subsection 738(c) is discussed below.

Inflation Adjustment.—An inflation provision, subsection 738(c)(1), identical to the inflation adjustment provisions in PDUFA III, adjusts statutory revenue levels each year after FY 2003. Fee revenues are adjusted each year by the greater of either the increase in the CPI index for all urban consumers for the most recent year, or for the most recent change in pay for Federal employees stationed in the Washington, DC metropolitan area. These adjustments assure that the personnel resources acquired with additional fee revenue are not diminished over time by inflation.

Workload Adjustment.—A workload adjustment provision, subsection 738(c)(2), increases fee revenue if, over time, there is an increase in aggregate in the major components of FDA's device review work. This parallels the workload adjustment provision in-

cluded in PDUFA III. The components of the device review workload that will be considered in making this measurement are: (1) Premarket applications, whether or not they pay fees; (2) supplements, whether or not they pay fees; (3) investigational new device applications; and (4) premarket notification submissions.

The workload adjuster for each component has as its base the average number of applications of each particular type that FDA received over the five-year period FY 1998 through FY 2002. It requires calculation of a rolling average of submissions for the latest five-year period that ends before the end of each fiscal year beginning on or after October 1, 2002. The percent change in the latest five-year average, compared to the base year, would then be multiplied by the weighting factor for that component. Then all 4 components of the workload adjuster are added together, and the total percentage that results is the workload adjuster that will be used to further adjust the inflation-adjusted statutory revenue levels each year after FY 2003. Use of 5-year rolling averages in this process dampens the impact of revenue fluctuations. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies. Because a revenue target for each year is set in the statute rather than specific fee levels, this adjustment is essential to assure revenues remain in balance with workload. If, over time, the number of applications submitted to FDA for review increases, this will generate additional revenue in proportion to such a workload increase. If there were no workload increase, there would be no increase in fee revenues as a result of this provision.

Compensating Adjustment.—A compensating adjustment provision, subsection 738(c)(3), guarantees stability to the device fee revenues in the absence of more stable annual product and establishment fees that generate two-thirds of PDUFA fee revenues. The compensating adjustment provision will only be invoked if cumulative fee revenues account for less than the statutory revenue levels, adjusted for inflation and workload. If the compensating adjustment becomes necessary in any year, it will impact only fees for the two highest volume application types—180-day supplements and premarket notification submissions. Fees for each of these two types of application would be increased proportionally during the next year by an amount sufficient to make up for this cumulative shortfall in device fee revenue.

Final Year Adjustment.—Subsection 738(c)(4) also allows FDA to make a one-time increase in fees in FY 2007, if necessary, to assure that the agency will have no less than three months of operating reserves on hand at the end of FY 2007 when this legislation will sunset. This will allow the agency to operate for up to 3 months in FY 2008. Further, delaying this payment until FY 2007 minimizes the need for FDA to carry large balances over from year to year, reducing industry outlays until they are necessary to support operations.

Annual Fee Setting.—Subsection 738(c)(5) requires FDA to publish the actual fees for each year in a notice in the Federal Register 60 days before the beginning of the fiscal year. This is the same process used for PDUFA fees. The fee levels will be established to generate the revenue levels set in the statute, plus adjustments in years after FY 2003 as provided in the statute. This annual fee set-

ting may also take into account the most current information available about the volume of each type of application forecast for the coming year. However, since FY 2003 has already begun, the statute sets the fees for FY 2003, based on a fee of \$139,000 for a premarket application fee. All of the other fees for FY 2003 flow from this amount, and are set out in Table 1 above.

The Committee also understands that the device industry is very different from the drug and biologic industries, in that the device industry is largely made up of companies with fewer than 50 employees. Therefore, the Committee strongly believes that the device user fee program should take into account that some smaller companies will not be able to pay the full user fee, due to their lack of revenues. Given that the Committee in no way wants to create governmental barriers to entry into the device marketplace, the user fee program contains a provision to protect small device firms. For purposes of this legislation, a small business is defined as an entity that reported \$10 million or less in "gross receipts or sales" in its most recent Federal income tax return, including the returns of its affiliates, partners, or parent firms. Federal corporate and partnership tax forms all contain a fairly standard line item for reporting the total of "gross receipts or sales." Firms wishing to take advantage of the small business provisions will have to submit certified copies of their most recent Federal income tax filings, including those of their affiliate, partner and parent firms, to verify that they qualify for the small business provisions. Firms that do not submit accurate or complete information in their submissions to qualify for the exemption or reduction will be subject to penalties under 18 U.S.C. 1001.

A fee waiver is granted to a qualifying small business submitting its first premarket application or premarket report. In addition, for subsequent submissions, qualifying small businesses will pay fees at the following reduced rates:

TABLE 2.—REDUCED RATES FOR QUALIFYING SMALL BUSINESSES

Type of submission	Fee as a % of full fee	FY 2003 reduced fee (\$)
Premarket Application, Premarket Report, Panel-track Supplement, or Efficacy Supplement	38	52,820
180-Day Supplement	44	13,149
Real Time Supplement	25	2,502

There is no reduction to the fee for a premarket notification for small firms. The fee is set at a level that all firms, regardless of size, will be able to pay.

Using this \$10 million criterion, and the five-year average number received for each type of submission, FDA estimated that the following numbers of submissions would have been exempt from fees or paid lower fees in each year:

TABLE 3.—ESTIMATED IMPACT OF SMALL BUSINESS CRITERION

Submission type	FY 2000	FY 2001
Original PMA's/BLA's	11 Exempt, 1 Pays Less (18.8%)	11 Exempt, 5 Pay Less (24.0%)
Panel Track Supplements	None pay less (0.0%)	1 Pays Less (9.1%)
180 Day Design Supps.	14 Pay Less (7.4%)	9 Pay Less (4.6%)
Real Time Supplements	9 Pay less (9.5%)	4 Pay Less (4.1%)

In developing this \$10 million criterion for small businesses and applying it to a number of scenarios, it caused the total revenue FDA collected to be less than 13 percent less than it would have been if there had been no waiver and reduced fees for small businesses. Subsection 738(d)(2)(A)(ii) also allows FDA to modify this \$10 million small business criterion if it develops evidence from experience that it results in revenue loss to FDA of 13 percent or more, compared with revenue that would be collected with no waiver or reduced rates for small businesses. To effect a change in the \$10 million level, the data and analysis supporting a change must be published in a notice in the Federal Register.

In order to meet the performance goals associated with device user fees, it is understood that FDA will need substantially increased resources—\$40 million more in FY 2003, increasing to \$50 million more by FY 2007. The fees established in this legislation provide only a portion of the resources needed—\$25.1 million in FY 2003, increasing to \$35 million by FY 2007. In addition to this fee revenue, FDA will need an increase in its base appropriations of \$15 million, and adjustments for inflation, to meet the performance goals.

In FY 2003 the administration request for appropriated budget authority for FDA's devices and radiological health program (which funds the Center for Devices and Radiological Health and related field activities of the Office of Regulatory Affairs), exclusive of funds from fees, is \$190,720,000. This portion of the user fee legislation specifies that FDA must receive appropriated budget authority of \$15 million more than this level, or \$205,720,000, exclusive of user fees, each year for the next five years, and that this base level must also be increased each year for inflation. Further, consequences are established if FDA's appropriated budget authority falls short of this level.

In FY 2003 and FY 2004, if the \$15 million in appropriated funds is built into the base, the Committee expects that FDA will meet all the performance goals specified in the letter referred to in the Act. There is no statutory obligation to meet the goals. Nevertheless, we expect FDA to strive to meet the goals, not only in FY 2003 and FY 2004, but also throughout the existence of this user fee program.

In FY 2003 and FY 2004, if appropriated budget authority for FDA's devices and radiological health program falls short of this level (\$205,720,000 in FY 2003 and the same amount adjusted for inflation in FY 2004), FDA will still collect user fees, and will be expected to meet the performance goals to the extent practicable. It is the Committee's intent that under this language, a slight shortfall in funds will result in FDA meeting the performance goals, or slightly missing the goals. Of course, if the shortfall is great, FDA's ability to meet the performance goals will decline correspondingly.

In FY 2005, the total budget appropriated budget authority for the devices and radiological health program, exclusive of fees, for the fiscal years 2003 through 2005 must equal the sum of the minimum levels set for each of these years. In other words, if there was a shortfall in appropriated budget authority, exclusive of fees, in any year, it must be fully made up by FY 2005. If this benchmark is reached, FDA will be expected to meet the performance

goals. If this benchmark is missed, then FDA will continue to collect user fees in 2005, but it will only be expected to meet the performance goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose.

For each of Fiscal Years 2003, 2004, and 2005, if the additional \$15 million has not been built into the base of the budget, and the FDA has not been made whole by being given a total of 45 million new dollars over this three year period, then the Comptroller General will be required to issue a report to the Congress describing whether and to what extent the Secretary is meeting the performance goals identified for such Fiscal Years. The General Accounting Office will be expected to report: the number of new employees hired to assist the FDA in meeting the performance goals; a detailed utilization analysis of user fee revenues to date; the impact of user fees on review-related activity; the status of systems infrastructure enhancement; actual performance of FDA in meeting the goals; an FTE cost analysis; the use of contract resources for reviews; and recommendations on management, systems, and other changes that could be undertaken to enhance performance to ensure that the goals will be met in FY 2006 and FY 2007.

In FY 2006, the total appropriated budget authority for the devices and radiological health program, exclusive of fees, for the fiscal years 2003 through 2006 must also equal the sum of the minimum levels set for each of these years. In other words, if there was a shortfall in appropriated budget authority, exclusive of fees, in any of the previous three years, it must be fully made up by FY 2006. If this benchmark is missed then the consequences are more severe the program terminates. FDA would no longer be able to collect device user fees, and all associated performance goals would be dissolved.

For FY 2007, FDA's appropriated budget authority for the devices and radiological health program, exclusive of fees, must equal \$205,720,000, adjusted for inflation, and user fees must have been collected in fiscal year 2006, or the program would terminate, fees would not be collected and performance goals would be dissolved.

A failsafe mechanism is provided in the event that the required appropriations are not in place on the first day of each fiscal year. If the required appropriations are subsequently made available, FDA can charge fees for submissions received at any time in the fiscal year, even if the required appropriations were not enacted at the time an application was submitted.

Subsection 738(g)(1) provides standard language that assures that the fees subsequently appropriated under this act are treated as revenue generated and appropriated at the same time, so that they are neutral in their budget impact. FDA is also given the authority to transfer these fees to appropriation accounts for specific fiscal years, in order to pay for operations each year. This language parallels provisions in PDUFA III.

Spending from Appropriations on Device Review.—Subsection 738(g)(2)(A) provides two further limitations, both parallel to limitations in PDUFA III.

The first limitation, subsection 738(g)(2)(A)(i), is that fees may be retained in each fiscal year only up to the amount specified in each year for appropriation acts. FDA may begin collecting fees in any year in which an appropriation for fees for the year, or any portion

of it, has been enacted. However, the appropriation act itself sets the upper limit each year on the amount of fees that may be kept and spent each year. Subsection 738(g)(4) specifies that if, in any year, FDA collects more fees than specified in appropriations, the excess fees collected shall be used to reduce fees that would otherwise be collected in a subsequent fiscal year. Those excess fee revenues would then be used in such subsequent fiscal year.

The second limitation, in subsection 738(g)(2)(A)(ii), dissolves FDA's authority to collect and spend fees in any year that FDA fails to spend on the process for the review of device applications from appropriations as much as it spent on that process from appropriations in FY 2002, adjusted for inflation.

The trigger is based on the amount FDA spends from appropriations on the device review process each year. FDA's accounting system measures spending by organization component. Spending on the device review process, however, is usually only a portion of spending of organization components in CDRH, CBER and ORA. That determination can only be made definitively by merging information from FDA's accounting system, after the close of the fiscal year, with results from time reporting systems that reflect the percent of time each organization component spends on the device review process. This provides the total dollar figure that FDA spent on the device review process. From this total, FDA has to subtract the amount of fee revenue that was spent to determine the amount of spending on the process that came from appropriations. This process does not finally identify exactly how much was spent from appropriations until after the end of the fiscal year.

Like a similar provision in PDUFA III, subsection 738(g)(2)(B) provides FDA a margin of error in its effort to meet this requirement. If FDA's spending is within 5 percent of the amount required by this provision of law, the requirement of this section is considered satisfied. If FDA under-spends by 3 percent or less, there is no penalty. If FDA under-spends by more than 3 percent but not more than 5 percent, FDA will be required to reduce collections in a subsequent year by the amount in excess of 3 percent by which FDA under-spent from appropriations. Spending from appropriations on the device review process each year is expected to be at or very close to the amount specified by this trigger, and may never be more than 5 percent less than the trigger amount. Clearly, over time, as FDA's appropriations increase in the future, as required under subsection 738(f), FDA's spending above this level is expected to increase.

Section 103. Annual reports

The annual reports included in this section replicate the annual reports required by the Prescription Drug User Fee Act.

Section 104. Postmarket surveillance

The Committee understands that the overwhelming majority of medical devices subject to FDA review need only demonstrate substantial equivalence to a predicate device that was previously found by the FDA to demonstrate a reasonable assurance of safety and effectiveness, or the predicate device was on the market prior to the Medical Device Amendments of 1976. Active postmarket surveillance is therefore critical to confirming such an assurance of the

reasonable assurance of safety and effectiveness. The Committee strongly supports the FDA's present postmarket surveillance efforts. Nonetheless, the Committee recognizes that more monies need to be dedicated to this very vital public health and safety function within FDA. The Agency estimates that it spent roughly \$18 million on postmarket surveillance efforts in Fiscal Year 2002. Therefore, this section authorizes an additional \$3 million in Fiscal Year 2003 for this activity, and then another \$3 million increase in Fiscal Year 2004, for these purposes. Further, this section includes a provision requiring the Secretary to conduct a study identifying the impact of the new device user fee program on its vital postmarket surveillance activities, the types of improvements necessary for adequate postmarket surveillance, and other important inquiries. When the Secretary issues this study in January, 2007, the Congress will be in a better position to determine whether user fees should be used extensively for postmarket surveillance activities as they now are in the Prescription Drug User Fee Act. While under the user fee program established by this Act user fees can be used for some postmarket surveillance (see section 737(5) (J) and (K)), such uses are limited.

The Committee believes that the increase in authorized funds should be employed by FDA (1) to do a better job monitoring the long-term, safety, efficacy and reliability of approved medical devices, especially implanted devices; (2) to monitor, document and audit device postmarket studies; (3) to improve adverse event reporting; (4) to facilitate prompt recall of devices that because of unforeseen design flaws, or failure to meet good manufacturing practices, are defective (particularly those whose defects pose a threat to human health); and (5) to better monitor and understand long-term effects of the use of devices in pediatric populations.

Section 105. Consultation

This provision ensures that the Secretary will consult with various stakeholders, both private and public, when developing the next set of performance goals if the medical device user fee act is to be reauthorized. Such consultation should result in performance goals which take into account the concerns of the Congress, academic and scientific experts, health care professionals, patient and consumer advocacy groups, and the regulated industry. Further, if and when the Secretary develops recommendations for the reauthorization of the device user fee program, the Secretary is required to hold a public meeting to solicit input from affected stakeholders.

Section 106. Effective date

This section indicates that the effective date of the device user fee program is October 1, 2002.

Section 107. Sunset

This section indicates the expiration date of device user fee program.

Section 201. Inspections by accredited persons

This section represents a very carefully crafted compromise between Members of the Committee with widely disparate views on

the benefits and risks of permitting third parties, compensated by regulated companies, to perform inspections for the government. As a result of extensive examination of the relevant risks inherent in any imperfect inspection program (whether it be a FDA or third party inspection program), the Committee concludes that the potential improvement in the safety of medical devices outweighs the risk associated with creation of a third party inspection program. One of the critical tools at the FDA's disposal to achieve its goal of protecting the public from unsafe or ineffective medical devices is the authority to conduct inspections of all medical device establishments, foreign or domestic, that market their products in the United States.

There are a number of salient facts not in dispute. Over the last several years the number of medical device firms, domestic and international, has grown dramatically from 9,061 in FY 1997 to 13,701 in FY 2001. The FDA expects this growth to continue, projecting the total number of device firms to exceed 15,000 in FY 2003. The sharp growth of the medical device industry, combined with resource constraints at the FDA, has made it difficult for the FDA to meet its statutory obligation of inspecting each medical device establishment at least once every two years. For this reason it is not surprising to find that the FDA's 2002 Annual Performance Plan "scorecard" rated the "Device Inspection" area as one of those areas at the Agency that is "Not Working Well."

The domestic inspections coverage was only 20 percent in FY 2001 compared to the statutory requirement of 50 percent. This means that the Agency was only inspecting 40% of the number of firms domestically that they are required to inspect under the law. The situation for FDA foreign inspections is even worse. The Agency indicates that the inspection coverage for foreign firms that market their products in the United States was only 11 percent in FY 2001.

It is concerning to the Committee that the Agency does not project improvement in their inspections coverage for the device industry. For FY 2002 and FY 2003 the Agency has targeted domestic inspection coverage to continue at 20 percent and foreign inspection coverage at only 9 percent.

It is also a matter of fact that this poor inspectional record is a function of inadequate resources. Further, the threat of bioterrorism, particularly from abroad, to our food and drug supplies, forces the Committee to conclude that it is highly likely that FDA will not be able to provide the requisite resources or priority to ensuring an adequate level of device inspections, at least for the near future.

While the FDA struggles to meet its statutory mandate of conducting a routine inspection of each domestic medical device firm at least once every two years, some segments of the medical device industry have faced a significant growth in the total number of inspections being required by foreign health agencies and departments. According to information from one large U.S. medical device company, the number of total inspections of their medical device facilities almost doubled from 16 in the period July 1997-June 1998 to 29 in the period July 1999 to June 2000. During this same period the number of FDA inspections for this company declined from nine to six. Other medical device companies have reported a simi-

lar dramatic growth in the number of foreign inspections taking place in their facilities.

Ironically, this proliferation of the total number of medical device inspections is taking place at a time when significant progress is being made to harmonize inspectional requirements around the world. The Global Harmonization Task Force (GHTF) has been working since 1992 to harmonize a wide range of medical device regulatory requirements, with important successes to date. In addition, in 1996 the FDA rewrote its GMP regulation to align it as much as possible with the growing quality systems approach being used by European public health regulatory agencies. Also a widespread system of voluntary quality systems verification and validation such as those of the International Standards Organization (ISO) has developed to provide confidence to original equipment manufacturers, customers, consumers and users of medical devices. As a result of these activities, there has been a significant and substantial international convergence and agreement on the nature of the manufacturing quality system requirements necessary to ensure the production of safe medical devices. Despite this progress, however, the increase in the total number of inspections is causing the FDA and companies alike to look for new ways to streamline systems and avoid duplicative inspections. It has become clear that if each country insists on its own individual medical device inspections then harmonization, while important, is not enough.

Congress has already taken steps to address this situation. In the 1997 FDA Modernization Act (FDAMA) a section is included which provides "[t]he Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States." In addition, Congress mandated in this same provision: "The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections."

Mutual recognition, unlike harmonization, does not require similar or identical regulatory requirements. A mutual recognition arrangement provides that each party is capable of verifying and validating the requirements of the other party, and for that activity to be acceptable in lieu of each party's own activities. In other words, a mutual recognition agreement between the United States and the European Union would permit a properly trained and accredited European entity to inspect a European-based manufacturer which intends to market its product in the United States to FDA standards, and for the FDA to recognize that inspection as though it had conducted it itself.

Such a Mutual Recognition Agreement (MRA) between the United States and the European Union was signed on May 18, 1998. The FDA published a final rule on November 6, 1998 for medical devices and pharmaceuticals under the MRA. The MRA became effective on December 7, 1998. Under this MRA, the FDA approves accredited European third party organizations (referred to

under the MRA as “conformity assessment bodies” (CAB)) to perform quality systems inspections on EU manufacturers that export devices to the United States. Likewise, under the MRA, the EU is approving accredited U.S. third parties to evaluate U.S. manufacturers against EU requirements for devices to be exported to the EU. Earlier this year the FDA notified the EU that the first European third party had been accredited to conduct independent inspections to FDA standards under the MRA. The Committee understands further that the FDA has just accredited a second third party to conduct inspections to FDA standards under the MRA.

Consequently, for the past five years, through the development and implementation of the MRA, the FDA has gained some experience in establishing a third party-based system for conducting quality systems inspections and other regulatory activities. Additionally, the FDA third party review program has given the Agency experience in establishing a third party program, in training and accrediting third parties, in operating in a system where initial actions are conducted by third parties but final action is required by the Agency, and in working through important conflict of interest issues.

The affirmative case for third party inspections rests on the view of the Agency’s experience with third party programs, plus the fact that FDA resources do not allow for an adequate rate of biennial and foreign inspections. Thus, a program specifically aimed at utilizing third party services in the context of medical device quality systems inspections is appropriate.

There are numerous potential advantages to the public in implementing a third party inspections program. Such a program may increase the number of inspections of medical device firms which market their products in the United States and thereby increase the amount of information that the Agency has on the quality systems program at certain specific companies and on the industry as a whole. If the quality of third party inspections is consistently comparable to that of FDA inspections, this should lead to an improvement in the public health and companies’ compliance with existing inspectional requirements. Such a program should also provide the FDA with important new and timely information on more medical device companies than is now possible given the resource constraints at the Agency. Under such a third party inspections system the FDA would retain final say on the status of the company’s quality system at the completion of the third party inspection. In addition, third parties would be obligated to notify the FDA immediately in the event that they find a significant public health risk in the course of an investigation.

With the establishment of a voluntary third party inspection program in the United States, the Committee anticipates that at some time in the future, more and more countries would move towards mutual recognition. The Committee believes that at some point a medical device company that markets its products in the European Union, Canada, the United States, China, Brazil, Mexico and other countries should be able to contract with a single independent third party which has sought and received accreditation from each of these countries to conduct inspections to each of their national standards. Under these circumstances, the third party could perform a single inspection that would cover each nation’s medical de-

vice quality systems requirements. Such a system would ease the threat of the improper use of unnecessary regulatory requirements to stifle legitimate international trade.

In crafting the compromised embodied in section 201, the Committee carefully analyzed the potential risks that an improperly crafted third party inspection program could present. FDA inspections of device manufacturing facilities are the primary means of assuring that postmarket device safety and effectiveness is not jeopardized by poor manufacturing practices. The Committee examined entrusting this responsibility to private parties, compensated by the device manufacturer, and the potential conflicts of interest raised by such arrangements. Further, the Committee examined the risks associated with inspections performed by entities lacking experience or expertise. The Committee addressed the most serious of these legitimate concerns by giving FDA the ability to determine appropriate candidates for participation in the third party program, the ability to disagree with a third party selection based due to conflicts of interest, and by empowering FDA to only accredit third parties with appropriate experience or expertise. And, of course, FDA retains full authority to inspect at will.

No manufacturer seeks to sell defective products, and most are willing to expend the capital necessary to implement meaningful quality control systems. Inherent in any business, however, is the legitimate aim of maximizing profits. The specter of inspection by governmental bodies (in this case the FDA) with the authority to take prompt remedial action with potential consequence to profit ensures that meaningful quality control systems are not compromised in the effort to maximize profits. To ensure that the specter of governmental inspection is maintained, section 201 ensures that FDA must maintain its present level of inspectional resources for biennial, for cause, and international inspections.

The Committee reconciled these disparate views of the third party device inspection question by providing a third party inspection program that is entirely additive to existing FDA efforts to inspect medical device manufacturing facilities for compliance with good manufacturing practices. The cornerstones of the compromise are no diminution of either FDA authority to conduct such inspections, or of the resources that the Agency must devote to such inspections. Under such a third party inspection system FDA would retain final say on the status of a company's quality system at the completion of the third party inspection. In addition, third parties would be obligated to notify FDA immediately in the event they find a significant public health risk in the course of an investigation.

Section 201 establishes a third party inspection program that will permit eligible firms to select, from a list established by FDA, an accredited non-government entity to perform quality system inspections, other than preapproval inspections. FDA determines which persons can qualify to be third party inspectors. A device establishment which had its most recent FDA-inspection characterized as "no action indicated" or "voluntary action indicated" are eligible to use FDA-accredited third parties, after the FDA clears its participation in the program and does not disagree with the establishment's selection of an accredited third party. The purpose of this provision is to increase inspection activity for medical devices

so that the public and firms benefit from regular inspections, and to permit FDA to focus government inspection resources on firms that have greater problems and devices that present higher risks. In addition, the third party inspection program is intended to help qualified firms schedule inspections in a manner that will help them meet the multiple inspection requirements of a global market.

Section 201 describes the minimum requirements a person must meet to qualify to conduct inspections under the program. It establishes stringent conflict of interest standards to ensure that any person qualified to do third party inspections will not have a financial interest in the firm or products being inspected. The provisions of this subsection describe minimum criteria, and the FDA may publish additional criteria for acceptance of third parties including, for example, satisfactory completion of training designed to ensure that the inspections conducted by these third parties are equivalent to the inspections federal employees currently conduct. Once the FDA establishes the criteria it will use to accredit third parties to conduct inspections, the FDA must then promptly respond to accreditation requests by potential third parties. Because the accreditation process will consume FDA resources, in order to allow the process to unfold in an orderly manner this provision limits the number of entities which can be accredited in the first year after the criteria are published to no more than 15 such entities. In addition, FDA is required to audit and monitor the work of accredited third parties and may withdraw accreditation from those that no longer qualify. The third party has the opportunity for an informal hearing prior to withdrawal of its accreditation, but FDA may suspend the accreditation while the matter is being resolved.

Third party inspectors will be expected to conduct inspections that are equivalent to quality system inspections performed by federal employees. Because these accredited persons will be conducting inspections on behalf of FDA, any statement or representations establishment employees make to these accredited persons will be subject to section 1001 of title 18, which provides criminal penalties for making false statements to the government.

The accredited person will also be required to prepare an inspection report for each inspection in a form and manner consistent with reports prepared by federal employees. At a minimum, these reports will identify the persons responsible for GMPs at the establishment, the date and scope of the inspection, the observations identified, and any other information that may be relevant. FDA may develop additional elements that will be part of these reports and may revise the format and content of what will be required as the program gains experience. The accredited party's observations and report will be sent to FDA no later than three weeks following the last day of the inspection. FDA is to be notified immediately any time an accredited person discovers a condition that could cause or contribute to an unreasonable risk to public health.

Compensation for inspection by an accredited third party will be determined by an agreement between the firm and the third party and will be paid by the person who engages the third party. The Congress will receive a report detailing how the third party program has performed, and the program will terminate in ten years unless reauthorized by Congress.

The program is designed to be available to establishments that have been able to demonstrate in the past that they are capable of “consistent compliance” with the quality system regulations. Accordingly, only if FDA has classified the most recent inspection of a device establishment as “no action indicated,” or as “voluntary action indicated,” is that firm eligible to participate in the program. If an establishment’s most recent inspection by FDA was classified as “official action indicated,” that establishment is not eligible to participate in this program. Eligible firms must submit a notice to FDA that (1) requests clearance to participate in the program and (2) identifies the third party the firm intends to employ. FDA can provide clearance and agree to the selection of the identified third party or can ask for additional information. The additional information may relate to the compliance history of the firm or it may relate to the relationship between the firm and the identified third party, or it may relate to both. The statute sets forth deadlines for FDA action on a request or following the receipt of additional information. If FDA fails to meet these deadlines, a request is deemed cleared and/or agreed to. Only those device establishments which have a good history of compliance with good manufacturing practice requirements will be eligible to participate. Further, FDA will be able to deny an establishment’s selection of a third party upon a finding a conflict of interest, such as a financial relationship (other than the third party arrangement) between the device manufacturer and the third party inspector, exists.

Clearance for an establishment to participate in the program remains in the discretion of FDA. Firms wishing to participate must not be subject to a finding of “official action indicated” in its last FDA inspection. Further, upon a request by FDA within 30 days of notification for clearance, the Secretary can require the establishment to demonstrate “consistent compliance” with cGMPs. By “consistent compliance” the Committee understands that the management of the establishment applying for inspections by an accredited third party has put into effect a rigorous system of quality assurance and quality control designed to detect breakdowns in the production, inspection, and other processes vital to the safety and effectiveness of the product and is in full conformance with the requirements under the Act. This does not mean that the production system must be fail-safe. Rather, it means that the system must be able to detect any significant problems, and the management must move quickly to determine the cause, and affect a solution. Demonstration of such “consistent compliance” would be either a history of recent inspections by FDA and/or third parties that resulted in “no action indicated” findings or prompt and effective attention to any findings of “voluntary action indicated.” Usually, such information about “consistent compliance” will be based upon all cGMP or other quality control inspections by FDA and outside parties within the previous two years. Such information may or may not be sufficient to demonstrate “consistent compliance” as the Committee understands the term. This judgment is reserved to FDA.

The Committee instructs FDA to prioritize the focus the program on those qualified firms subject to multiple, duplicative inspections owing to their extensive sales outside of the United States. The

Committee relies upon the judgment of FDA to detect any firm that may attempt to abuse the program.

An establishment that has been denied clearance or whose selection of an accredited person has been rejected may request a review of FDA's findings. The review may be conducted by a designee of FDA who is part of the Food and Drug Administration, such as the FDA's Ombudsman, or by another person within or outside the agency that FDA chooses.

Section 201 also addresses the situation where an establishment that has previously been cleared to participate in the program receives an inspection report from an accredited person that FDA has classified as "official action indicated." In this case, the establishment will continue to be eligible for future third party inspections only if (1) FDA issues a written statement that the violations leading to the classification have been addressed and (2) FDA notifies the establishment, either on FDA's own initiative or in response to a petition from the establishment, that the establishment has clearance to use an identified third party for an inspection. If FDA denies a petition from a firm for further participation in the program following an adverse inspection report by an accredited person, the firm may submit an additional petition one year following the first denial. If FDA does not inspect the establishment within 48 months following the denial of the firm's initial petition, the establishment will become eligible for inspection by accredited persons. The Committee has included this provision because it intends to facilitate responsible inspections of device establishments and seeks to avoid creating incentives for conflicts of interest that might result from negative findings by a third party inspection.

The Committee intends the accredited person inspection program to supplement funds currently dedicated to biennial GMP, international, and for cause inspections of medical device establishments. It is very important to the Committee that the establishment of an accredited person inspection program does not undermine or decrease any of the resources currently being directed to such inspections. In order to avoid the possibility that current inspectional resources will be diminished or diverted to other activities, section 201 provides that the program will remain in effect so long as the amount of monies presently dedicated to biennial, for cause, and international device establishment inspections is maintained. This will be accomplished by having the Comptroller General determine the amount of monies obligated by the Secretary in 2002 for biennial, international and for cause device inspections. This amount will be determined by examining FDA's compliance budget for devices. Once this figure is determined, in order for the third party inspection program to continue this figure must not only be maintained, but must also increase by five percent per year. The Committee understands that a five percent growth rate will allow FDA to maintain its present level of biennial, for cause, and international device establishment inspections. Due to certain budgetary vagaries which at times arise, such as Continuing Resolutions, the maintenance of effort provision allows FDA to miss the base amount in any given year without causing the expiration of the program. However, if the base amount is missed for two consecutive years, this program terminates.

Most importantly, it must be noted that nothing in this section in any way limits FDA's authority to inspect a device manufacturer at any time, regardless of whether the manufacturer has also been inspected by a third party. This program is intended to be entirely additive to FDA's present commitment to inspections.

Section 202. Third party review of premarket notification

Under current law, independent third parties accredited by the Secretary are permitted to review certain devices subject to the premarket notification requirements under Section 510(k). When a device is reviewed by a third party under Section 523 of the Federal Food, Drug, and Cosmetic Act, the Secretary retains the authority to accept or reject the recommendation of the third party. Presently, Section 523 will sunset in 2006.

This section delays the sunset of Section 523 until October 1, 2007. Further, in order to provide better evidence about whether this provision should be extended in 2007, this section requires the Secretary to submit to the Congress a study analyzing whether the program is working to bring devices to the market in a more timely manner, or whether this provision is in any way jeopardizing the public health. Specifically, this section requires the Secretary to recommend to Congress by January, 2007 whether Section 523 should be continued, modified, or terminated.

Section 203. Designation and regulation of combination products

The Committee intends to establish within the Office of the Commissioner of Food and Drugs an Office of Combination Products to promptly assign, and to oversee and coordinate the reviews of combination products. Under this section, the Committee intends for the Office to designate a lead center based upon the product's primary mode of action, as is required under present law.

FDA recently established a Combination Products Program within the Office of the Ombudsman. This Program develops policies, procedures and processes to facilitate the intercenter review process; develops guidance to clarify the regulation of combination products; serves as a focal point to resolve issues arising during premarket review of combination products; and serves as an advocate for combination products. It is the intent of the Committee that these efforts continue under this new Office.

The Office shall consult with the component of the FDA within the Office of the Commissioner responsible for determining whether a product is to be designated (i.e., classified under section 563 of the Act) a combination product. Since the agency's product classification function applies to all FDA-regulated products that may present questions about regulatory jurisdiction, not just combination products, it is the Committee's intent that the product classification function remain intact within an umbrella component of FDA, currently the Office of the Ombudsman, though consultation with the new Office is required in making this determination. Once a combination product is so classified, the new Office shall assume responsibility for its assignment to an agency center. The existing criteria in 503(g)(1) for determining a product's primary mode of action and assigning a product to an agency center with primary jurisdiction shall apply. Also, this provision does not upset the current practice wherein manufacturers are allowed to submit their

products to the Agency Centers they believe should be responsible for the review.

Further, this section ensures that the postmarket regulation of combination products will be consistent and appropriate. By using the word “consistent,” the Committee intends that like products will be treated in a like fashion. If the FDA is not being consistent presently in their postmarket regulation of combination products, this section is not intended to codify the present inconsistency. Nothing in this section is intended to limit current postmarket regulatory authorities. Rather, the Committee intends that combination products be regulated appropriately after marketing under the currently applicable provisions of the law.

A major function of this Office will be ensuring the timeliness of review by coordinating the performance of the reviews in the responsible Agency Centers. The Committee does not intend for the new Office to be micro-managing line reviewers within the different Agency Centers. The bill instead contemplates that, with respect to the timeliness of reviews, the Centers themselves will be responsible to the new Office. The Office will resolve disputes regarding the timeliness of reviews unless the timeliness question is clearly premature. Generally, disputes regarding timeliness are “premature” when the statutory time frame for approval has not yet passed.

Disputes regarding the substance of a premarket review that arise during the review process may be presented to the Commissioner after first being considered by the Center with primary jurisdiction under established scientific dispute resolution procedures. The Commissioner shall consult with the Director of the Office in resolving the dispute. It is the Committee’s intent that this avenue not be available to resolve disputes regarding the outcome (i.e., approval or denial of approval) of a review, as there exist sufficient mechanisms to address such disputes for all products, including those that are combination products.

The Secretary, acting through the Office, and after consulting with stakeholders and agency center directors, shall review each agreement, guidance or practice specific to the assignment of combination products to Centers to determine whether each is consistent with the requirements of new subsection 503(g)(4). The Secretary shall determine whether to continue, modify, revise, or eliminate each such agreement, guidance or practice and shall publish a Notice of Availability in the Federal Register of such modified or revised agreement, guidance or practice. It is the Committee’s intent that the Office shall not be bound by any existing agreement, guidance or agency practice in determining whether to continue, modify, revise or eliminate any such agreement, guidance or practice, or in ensuring the consistent and appropriate postmarket regulation of combination products. Existing agreements, guidances, or practices shall continue in effect until continued, modified, revised, or eliminated.

The Secretary shall report to The Committee within one year of enactment, and annually thereafter, on the activities and impact of the Office. The Committee recognizes that one year may not be sufficient time to realize significant and measurable improvements in some activities related to combination products.

Section 204. Report on certain devices

The Committee is aware of concerns from regulated persons that centers at FDA other than the Center for Devices and Radiological Health review original device submissions and supplements. Comments have been made about the failure to conduct timely and effective reviews. Concerns have also been raised about the risks to the safety of the blood supply if the review of devices critical to assuring blood safety is removed from the Center responsible for the integrated blood safety program. As a result, section 204 requires the Secretary to submit a report to the appropriate committees of Congress analyzing key aspects of the performance of the Centers other than CDRH in conducting premarket device reviews. As part of that report, the bill states that the Secretary is required to include a specific recommendation about whether the review responsibility of devices outside of CDRH should be transferred to persons “who are primarily charged with regulating other types of devices, . . .” This reference is intended to identify CDRH. In other words, if the review of devices, or certain types of devices, by CBER or CDER is inadequate, and the Secretary determines that review by CDRH would provide adequate assurance of safety and effectiveness, the Secretary may recommend a transfer of those device reviews to CDRH, if the transfer will not have a deleterious impact on the public health.

Section 205. Electronic labeling

The Internet and increased computer usage have created a preference in many users for information for use applicable to prescription devices in electronic form. Even casual users of computers have become used to receiving electronic information. The bill conforms FDA practice to the norm by allowing manufacturers to provide health care facilities (such as hospitals, doctors’ offices and clinics) labeling in this alternative medium, so long as the labeling complies with applicable requirements of law. This will better allow manufacturers to provide such facilities with information that is more robust, up-to-date, and user-friendly.

There may be some purchasers of prescription devices, however, that are not computer literate or who lack the necessary equipment to receive electronic information. For these limited cases where a purchaser needs labeling in a more traditional format, this provision allows the purchaser to request such labeling. The Committee intends that manufacturers will respond to such a request promptly and at no cost to the user.

Section 206. Electronic registration

Given the increased reliance on computer usage, this provision requires manufacturers to provide registration information required under section 510 by electronic means, but only upon a finding by the Secretary that electronic receipt of such information is feasible. In assessing the feasibility of electronic registration, the Secretary shall consider whether there are sufficient resources available to FDA to develop and maintain such a system. Once electronic registration is feasible, under this section the Secretary is given the authority to waive the requirement of electronic submission of registration information for manufacturers who cannot reasonably comply with the requirements in this section, and per-

mit them to register through submission to FDA of a hard copy of the required information.

Section 207. Intended use

This provision eliminates the current law sunset on “intended use” for substantial equivalence determinations found within section 513 of the Federal Food, Drug, and Cosmetic Act.

Section 208. Modular review

This provision allows manufacturers to apply for review of portions of their premarket applications, but only when both the Secretary and the applicant agree that such portions, or modules, are complete, ready, and appropriate for review. Under this provision, once a module is reviewed and found acceptable to the Secretary, the Secretary will not be allowed to review the determination again, unless issues of safety or effectiveness cause the Secretary to review such determination.

Section 209. Pediatric expertise regarding classification-panel review of premarket applications

The Committee believes that it is important for advisory committees providing recommendations to the Secretary on devices likely to be used in children to have access to appropriate pediatric expertise. This section requires these advisory committees to either include, or consult with, one or more pediatric experts when the device considered by the advisory committee is reasonably likely to be used in the pediatric population.

Section 210. Internet list of class II devices exempted from requirement of premarket notification

Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), the Secretary was required to publish in the Federal Register a list of each type of class II device exempt from the premarket notification reporting requirements under section 510(k). This section ensures that the list of class II devices exempt from the reporting requirements under section 510(k) is also published on the internet site of the FDA, and that such list be updated not later than 30 days after revisions to the list.

Section 211. Study by Institute of Medicine of postmarket surveillance regarding pediatric populations

This section requires the Secretary to request that the Institute of Medicine contract with the Secretary for the conduct of a study analyzing the adequacy of postmarket surveillance of devices used in, or implanted into, the pediatric population. Of especial importance to the Committee is analysis reviewing the long-term effects, if any, of devices implanted in children. The Secretary is required to ensure that the report is transmitted to the Congress no later than four years after the enactment of this Act.

Section 212. Guidance regarding pediatric devices

This section requires the Secretary to issue guidance about the type of information necessary to meet the reasonable assurance of safety and effectiveness of devices intended for use in the pediatric populations. In no way is the provision intended to lower, change,

or heighten the current law standard for approval of pediatric devices. Instead, this provision is meant to encourage the development of safe and effective devices intended for pediatric populations by having the Secretary specifically and clearly delineate what type of information is necessary to meet the current standard of approval. In developing this guidance, the Committee intends for the Secretary to abide by all current law requirements, including “least burdensome” requirements.

Section 213. Breast implants; study by the Comptroller General

This section requires the General Accounting Office to conduct a study to determine the content of information typically provided to women who consult with health professionals on the issue of whether to undergo breast implant surgery; whether this information is provided in oral or verbal form; whether the information provided is fair and balanced; whether women understand the information that is provided; and adverse event information, among other things.

The Committee believes that it is vital that women considering an implant procedure be provided objective, understandable information about the risks and benefits of implant surgery. Therefore, the Committee strongly encourages the Food and Drug Administration to ensure that women receive such information in a timely fashion, particularly if the procedure is elective. In particular, the agency should consider working with an advisory panel, patients, consumer groups, implant manufacturers, plastic surgeons, and other interested parties to ensure such information is updated correctly, and as soon as possible when new information about adverse events becomes available. The agency should consider writing product guides if it believes it could help communicate fair and balanced information, and if so ensure that such guides are appropriately updated.

The agency should also work with patients, consumer groups, manufacturers, plastic surgeons, and other interested parties to ensure that women enrolling in clinical trials for silicone breast implants are provided with up-to-date, easy to understand informed consent documents, early in the clinical trial enrollment process. The agency should also take appropriate steps to ensure that clinical trial participants receive information on how to report problems about their participation or continued enrollment in a study or a particular clinical trial.

Section 214. Breast implants; research through the National Institutes of Health

The Committee is aware of conflicting research as to the long-term health implications of breast implants. Therefore, the Committee has asked the NIH to report on all of its research in this area. Furthermore, we urge the NIH continue and expand research programs that examine the long-term health implications of breast implants. If scientifically appropriate, such a study should allow for comparisons of women receiving implants for reconstruction after mastectomy to breast cancer patients who have not had reconstruction. The committee believes that it is important for these studies to include women who have had implants for at least eight years, separately analyzing women with saline implants and those with

silicone gel implants. Such a study should include the rate of local complications, which may include capsular contracture, leakage, loss of nipple sensation, problems in breast feeding, deflation and rupture as well as systemic health problems which may include neurological and/or auto-immune irregularities that show possible links to silicone migration, or other leakage or breakage related issues.

The Committee is aware of conflicting research as to the long-term health implications of breast implants. Therefore, the Committee has asked the NIH to report on all of its historical research in this area. Furthermore, we would suggest that the NIH continue and expand research programs that examine the long-term health implications of breast implants. If scientifically appropriate, such a study should allow for comparisons of women receiving implants for reconstruction after mastectomy to breast cancer patients who have not had reconstruction. If appropriate, the agency should also consider comparisons of mastectomy patients with those women receiving implants through elective augmentation procedures, and comparisons with patients who have received other types of plastic surgery. The committee believes that it is important for these studies to include women who have had implants for at least eight years. Such a study might also focus on the rate of local complications, which may include capsular contracture, leakage, loss of nipple sensation, problems in breast feeding, deflation and rupture as well as systemic health problems which may include neurological and/or auto-immune irregularities that show possible links to silicone migration, or other leakage or breakage related issues.

Section 301. Identification of manufacturer of medical devices

Title III makes changes to the regulatory scheme for single use devices that are reprocessed. A single use device is a device that is intended for use by the end user on only one patient during a single procedure. A device has been reprocessed when the original device has been used on a patient and then subject to additional processing and manufacturing so that it can be used again (one time) on a patient.

The changes being effected by Title III reflect a balancing of competing concerns. The Committee recognizes that there are cost savings associated with using devices that have been reprocessed. Therefore, we want to ensure access to safe and effective reprocessed devices. FDA's current regulatory scheme creates certain barriers for those in the business of reprocessing devices. We want to eliminate those barriers in a way that does not undercut the FDA's ability to protect the public health. The Committee also recognizes that the reprocessing of a single-use device may raise issues that are not addressed and need not be addressed when the device is originally manufactured. The Committee wants to ensure that devices that undergo reprocessing continue to be safe for use on patients and continue to work as intended. We want to ensure that FDA has adequate tools to do this.

Section 301 requires all devices (or permanent attachments thereto) prominently and conspicuously to bear the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol that identifies such manufacturer. It permits FDA to waive the requirements if it is not fea-

sible or would compromise the provision of reasonable assurance of the safety or effectiveness of the device. For example, if a manufacturer believes that the medical device is too small or too fragile to bear the name or attachment, the manufacturer may petition the agency to waive this requirement. Further, the Secretary should consider waiving this requirement when compliance with the requirement would heighten the clearance/approval burden for the manufacturer. Such a situation exists where compliance would obligate the manufacturer to conduct additional biocompatibility testing in order to obtain clearance/approval. The Committee intends for FDA to post on its website or publish in the Federal Register any waivers it grants to provide the information to similarly situated manufacturers. This section applies to all devices, not just reprocessed single use devices.

Section 302. Single-use medical devices

Section 302 includes a requirement that all of the labeling of reprocessed single-use devices bear a statement indicating that the device has been reprocessed and who has done the reprocessing. This new requirement, combined with the new requirement in Section 301, is important for several reasons. Both requirements let the end user know which company is responsible for manufacturing or reprocessing the device. Section 302 allows users of reprocessed devices to know that they are using a reprocessed device as well as who has done such reprocessing. This disclosure is important not only to ensure that the user has all relevant information about the device, but also to help ensure that any reports about the device, particularly those related to problems with the device, will accurately identify the manufacturer and whether the device was reprocessed. The Committee understands that FDA has not been able to compile information regarding adverse events associated with reprocessed devices and whether this is a problem, in part, because reports may not be identifying certain devices as reprocessed.

Section 302 also gives FDA authority to identify (by publishing a list in the Federal Register), reprocessed single-use devices for which it determines that validation data regarding cleaning and sterilization, and functional performance are needed to ensure that the device will remain substantially equivalent to its predicate after the maximum number of times the device is reprocessed as intended by the reprocessor. FDA can also require such information for a device not included on the list if it is for a device or type of device for which FDA has not previously received a 510(k).

The type of validation data that is necessary for clearance will vary. In some cases FDA may be able to rely primarily on a sound scientific rationale that the reprocessing does not adversely affect device integrity or function. In other cases it will be necessary for the manufacturer to provide test data demonstrating that the reprocessed device continues to meet its specifications. The Committee intends that the Secretary have flexibility in determining the type of validation data required under Section 510(o)(1)(A), and that the Secretary only require the type or types of validation data that are necessary to protect the public health. In determining the type or types of data to be submitted for FDA's review, the Secretary should be mindful of FDAMA, which obligates FDA to impose the least burdensome requirements on companies seeking pre-

market clearance/approval for their devices. Additionally, the Committee recognizes there is a difference between validation and verification. The former involves a level of rigor and statistical probability that a device or a process will consistently perform as intended; the latter demonstrates through testing or observation that a specific requirement has been fulfilled.

Section 302 also gives FDA the authority to terminate an exemption from the requirement to submit a 510(k) for a critical or semi-critical reprocessed single use device if FDA determines that such termination is needed to provide a reasonable assurance of safety and effectiveness. The Committee is providing this authority in recognition of the fact that although a single use device as originally manufactured may be of sufficiently low risk to warrant an exemption from the requirement to submit a 510(k), reprocessing may, in certain circumstances, raise issues (e.g., related to appropriate cleaning and/or sterilization, and functional performance) to warrant review by FDA. The definitions for critical and semi-critical devices are adopted from the criteria established by E.H. Spaulding (Proceedings of International Conference on Nosocomial Infections, 1970. American Hospital Association, Chicago 1971; 254–274).

In order to permit reproprocessors to submit validation data for single use devices listed by the Secretary, the Committee included in the legislation a grace period in which the Secretary would not take an enforcement action against the reproprocessor or a listed device until certain events occurred, if the reproprocessor timely submitted validation data. The Committee believes that the Secretary shall take action promptly if the Secretary finds that the data shows a reprocessed single use device is not substantially equivalent to its predicate device. Certainly if a party fails to submit data to the Secretary according to the timeframes in this legislation, the Secretary should issue an order determining the single use reprocessed device is not substantially equivalent to its predicate, thus resulting in its removal from commercial distribution.

Finally, section 302 creates a new type of application for class III reprocessed single use devices that previously would have required submission of a PMA. New section 510(o)(3) requires the manufacturer of such devices to submit a report in accordance with the paragraph. The device cannot be marketed unless after reviewing such report, the Secretary issues an order determining that there is a reasonable assurance of safety and effectiveness for the device. The information required to be submitted in such report tracks the information required to be submitted in a PMA, except that the manufacturer need not supply certain information about the manufacture and operation of the original device. It is the inability to provide this information (because it is available only from the original equipment manufacturer) that has made it difficult for reprocessing manufacturers to get PMA approval. The only way for reprocessing manufacturers to obtain this information is to get a right of reference from the original equipment manufacturers (OEMs) and the OEM's have been unwilling to provide it. FDA still is able to require all, or some, of the other information needed to establish a reasonable assurance of safety and effectiveness that would have been required in a PMA, including clinical data. The Committee intends that the new process for approval of premarket reports allows FDA the flexibility to decide precisely what specific

data requirements for a particular Class III reprocessed single use device are appropriate, depending on the specific safety and/or effectiveness issues presented by the device under review. However, the Committee intends that the standard for approval of a pre-market report be identical to the standard for a PMA approval under section 515: a reasonable assurance of safety and effectiveness. Nothing in this section is to be construed as lowering this standard. Section 302 also provides that the report must include validation data that are appropriate for evaluating these devices. Because section 302 is creating a new type of application, it also adds a new prohibited act to ensure that FDA has adequate enforcement authority.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * *

(1)(1) *The term “single-use device” means a device that is intended for one use, or on a single patient during a single procedure.*

(2)(A) *The term “reprocessed”, with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.*

(B) *A single-use device that meets the definition under subparagraph (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term “recycled” rather than the term “reprocessed”.*

(3) *The term “original device” means a new, unused single-use device.*

(mm)(1) *The term “critical reprocessed single-use device” means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.*

(2) *The term “semi-critical reprocessed single-use device” means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.*

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * *

(gg) *The introduction or delivery for introduction into interstate commerce of any device in violation of section 510(o)(3).*

* * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) * * *

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. *Required labeling for prescription devices intended for use in health care facilities may be made available solely by electronic means provided that the labeling complies with all applicable requirements of law and, that the manufacturer affords health care facilities the opportunity to request the labeling in paper form, and after such request, promptly provides the health care facility the requested information without additional cost.*

* * * * *

(u) *If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device.*

(v) *If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by ____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.*

EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND
BIOLOGICAL PRODUCTS

SEC. 503. (a) * * *

* * * * *

(g)(1) The Secretary **【shall designate a component of the Food and Drug Administration】** *shall in accordance with this subsection assign an agency center* to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), **【the persons charged】** *the agency center charged* with premarket review of drugs shall have primary jurisdiction,

(B) a device, **【the persons charged】** *the agency center charged* with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, **【the persons charged】** *the agency center charged* with premarket review of biological products shall have primary jurisdiction.

* * * * *

(4)(A) *Not later than 60 days after the date of the enactment of this paragraph, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the “Office”) shall have appropriate scientific and medical expertise, and shall be headed by a director.*

(B) *In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.*

(C) *In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing and coordinating reviews involving more than one agency center.*

(D) *In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Nothing in this paragraph shall be construed to limit the postmarket regulatory authority of any agency center.*

(E) *In order to ensure the timeliness of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness of the premarket review.*

(F)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the timeliness of the dispute is clearly premature.

(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(G) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(H) Not later than one year after the date of the enactment of this paragraph and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

(ii) identifying the number of premarket reviews of such products that involved a consulting agency center; and

(iii) describing improvements in the consistency of postmarket regulation of combination products.

[(4)] (5) As used in this subsection:

(A) The term “agency center” means a center or alternative organizational component of the Food and Drug Administration.

[(A)] (B) The term “biological product” has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

[(B)] (C) The term “market clearance” includes—

(i) * * *

* * * * *

REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES

SEC. 510. (a) * * *

* * * * *

(h) Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 and every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated

by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

* * * * *

(m)(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register. *The Secretary shall publish such list on the Internet site of the Food and Drug Administration. The list so published shall be updated not later than 30 days after each revision of the list by the Secretary.*

* * * * *

(o)(1) *With respect to reprocessed single-use devices for which reports are required under subsection (k):*

(A) *The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within one year after enactment of this subsection, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.*

(B) *In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o), adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii)*

the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

(2) With respect to critical or semicritical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o), adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) The initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection.

(D) Section 502(o) applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semicritical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(3) In the case of a reprocessed single-use device that is classified in class III and for which a premarket application is required, the following provisions apply with respect to such reprocessed device in lieu of an application for premarket approval under section 515:

(A) The device shall not be introduced into interstate commerce or delivered for introduction into interstate commerce unless the person involved has submitted to the Secretary a report in accordance with this paragraph and the Secretary, after reviewing the report, issues an order determining there is a reasonable assurance of the safety and effectiveness for the device.

(B) The report under subparagraph (A) shall contain the following:

(i) The device name, including both the trade or proprietary name and the common or usual name.

(ii) The establishment registration number of the owner or operator submitting the report.

(iii) Actions taken to comply with performance standards under section 514.

(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not a device is safe or effective.

(vi) A description of the device's components, ingredients, and properties.

(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

(viii) Such samples of the device that the Secretary may reasonably require.

(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

(x) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

(xi) Any additional data and information that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.

(C) In addition to the information or data required in subparagraph (B), the report under subparagraph (A) shall include the validation data described in paragraph (1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting the report under this paragraph.

(p) Registrations under subsections (b), (c), (d), and (i) (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

* * * * *

CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. (a) * * *

* * * * *

Substantial Equivalence

(i)(1)(A) * * *

* * * * *

(E)(i) * * *

* * * * *

[(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.]

* * * * *

PREMARKET APPROVAL

General Requirement

SEC. 515. (a) * * *

* * * * *

Application for Premarket Approval

(c)(1) * * *

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) * * *

* * * * *

refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. *If the Secretary determines that there is a reasonable likelihood that the device involved will be used in a pediatric population, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.*

(3)(A) *Prior to the submission of an application under this subsection, the Secretary shall accept and review portions of such applications that applicants and the Secretary agree are complete, ready, and appropriate for review.*

(B) *Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless issues of safety or effectiveness provide the Secretary cause to review such accepted portion.*

(C) *Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall specifically identify, in writing, the deficiency of such portion and describe in detail the means by which it may be made acceptable, unless the sponsor is no longer pursuing the application.*

* * * * *

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

SEC. 520. (a) * * *

* * * * *

Guidance Regarding Pediatric Devices

(n) *Not later than 270 days after the date of the enactment of the Medical Device User Fee and Modernization Act of 2002, the Secretary shall issue guidance on the following:*

(1) *The type of information necessary to provide reasonable assurance of the safety and effectiveness of devices intended for use in pediatric populations.*

(2) *Protections for pediatric subjects in clinical investigations of the safety or effectiveness of such devices.*

* * * * *

SEC. 523. ACCREDITED PERSONS.

(a) * * *

* * * * *

(c) DURATION.—[The authority provided by this section terminates—

[(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k), or

[(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection,

whichever occurs first.] *The authority provided by this section terminates October 1, 2007.*

(d) REPORT.—*Not later than January 10, 2007, the Secretary shall conduct a study based on the experience under the program under this section and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the findings of the study. The objectives of the study shall include determining—*

- (1) *the number of devices reviewed under this section;*
- (2) *the number of devices reviewed under this section that were ultimately cleared by the Secretary;*
- (3) *the number of devices reviewed under this section that were ultimately not cleared by the Secretary;*
- (4) *the average time period for a review under this section (including the time it takes for the Secretary to review a recommendation of an accredited person under subsection (a) and determine the initial device classification);*
- (5) *the average time period identified in paragraph (4) compared to the average time period for review of devices solely by the Secretary pursuant to section 510(k);*
- (6) *if there is a difference in the average time period under paragraph (4) and the average time period under paragraph (5), the reasons for such difference;*
- (7) *whether the quality of reviews under this section for devices for which no guidance has been issued is qualitatively inferior to reviews by the Secretary for devices for which no guidance has been issued;*
- (8) *whether the quality of reviews under this section of devices for which no guidance has been issued is qualitatively inferior to reviews under this section of devices for which guidance has been issued;*
- (9) *whether this section has in any way jeopardized or improved the public health;*
- (10) *any impact of this section on resources available to the Secretary to review reports under section 510(k); and*
- (11) *any suggestions for continuation, modification (including expansion of device eligibility), or termination of this section that the Secretary determines to be appropriate.*

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

* * * * *

FACTORY INSPECTION

SEC. 704. (a) * * *

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(f)(1) **【A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records】** *An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.*

(2) Within 15 days after the receipt of a written request from the Secretary to [a person accredited under section 523] *an accredited person described in paragraph (3)* for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) *For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—*

(A) is accredited under subsection (g); or

(B) is accredited under section 523.

(g)(1) Not later than one year after the date of the enactment of this subsection, the Secretary shall, subject to the provisions of this subsection, accredit persons who are not Federal employees for the purpose of conducting the inspections required in section 510(h), or pursuant to section 510(i), for establishments that manufacture, prepare, propagate, compound, or process class II or class III devices. The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections

(2) Not later than 180 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited. In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(C) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this Act.

(D) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this Act, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of accredited persons to conduct inspections under paragraph (1). Such list shall be periodically updated to ensure that the identity of each accredited person is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the withdrawal of accreditation.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of an establishment and the performance of accredited persons.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) through (C), a device establishment is eligible for inspections by persons accredited under paragraph (2) if—

(i) the Secretary classified the results of the most recent inspection of the establishment pursuant to subsection (h) or (i) of section 510 as “no action indicated” or “voluntary action indicated”; and

(ii) with respect to each inspection to be conducted by an accredited person—

(I) the owner or operator of the establishment submits to the Secretary a notice requesting clearance to use such a person to conduct the inspection, and the Secretary provides such clearance; and

(II) such notice identifies the accredited person whom the establishment has selected to conduct the inspection, and the Secretary agrees to the selected accredited person.

(B)(i) The Secretary shall respond to a notice under subparagraph (A) from an establishment not later than 30 days after the Secretary receives the notice. Through such response, the Secretary shall (I) provide clearance under such subparagraph, and agree to the selection of an accredited person, or (II) make a request under clause (ii).

If the Secretary fails to respond to the notice within such 30-day period, the establishment is deemed to have such clearance, and to have the agreement of the Secretary for such selection.

(ii) The request referred to in clause (i)(II) is—

(I) a request to the establishment involved to submit to the Secretary compliance data in accordance with clause (iii); or

(II) a request to the establishment, or to the accredited person identified in the notice under subparagraph (A), for information concerning the relationship between the establishment and such accredited person.

The Secretary may make both such requests.

(iii) The compliance data to be submitted by an establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h), and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other applicable provisions of this Act. Such data shall include complete reports of inspections regarding good manufacturing practice or other quality control audits that, during the preceding two-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(iv) Not later than 60 days after receiving compliance data under clause (iii) from an establishment, the Secretary shall provide or deny clearance under subparagraph (A). The Secretary may not deny clearance unless the Secretary provides to the establishment detailed findings that the establishment has failed to demonstrate consistent compliance for purposes of clause (iii). If the Secretary fails to provide such findings to the establishment within such 60-day period, the establishment is deemed to have such clearance.

(v)(I) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1). Not later than 60 days after receiving the information sought by the request, the Secretary shall agree to, or reject, the selection of such person by the establishment involved. The Secretary may not reject the selection unless the Secretary provides to the establishment the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request. If within such 60-day period the Secretary fails to agree to or reject the selection in accordance with this subclause, the Secretary is deemed to have agreed to the selection.

(II) If the Secretary rejects the selection of an accredited person by an establishment, the establishment may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A).

(vi) *In the case of an establishment that under clause (iv) is denied clearance under subparagraph (A), or whose selection of an accredited person is rejected under clause (v), the Secretary shall designate a person to review the findings of the Secretary under such clause if, during the 30-day period beginning on the date on which the establishment receives the findings, the establishment requests the review. The review shall commence not later than 30 days after the establishment requests the review, unless the Secretary and the establishment otherwise agree.*

(C)(i) *In the case of a device establishment for which the Secretary classified the results of the most recent inspection of the establishment by a person accredited under paragraph (2) as “official action indicated”, the establishment is eligible for further inspections by persons accredited under such paragraph if (I) the Secretary issues a written statement to the owner or operator of the establishment that the violations leading to such classification have been resolved, and (II) the Secretary, either upon the Secretary’s own initiative or a petition of the owner or operator of the establishment, notifies the establishment that it has clearance to use an accredited person for the inspections. The Secretary shall respond to such petition within 30 days after the receipt of the petition.*

(ii) *If the Secretary denies a petition under clause (i), the establishment involved may, after the expiration of one year after such denial, again petition the Secretary for a determination of eligibility for inspection by persons accredited by the Secretary under paragraph (2). If the Secretary denies such petition, the Secretary shall provide the establishment with a detailed reason for such denial within 60 days after the denial. If, as of the expiration of 48 months after the receipt of the first petition, the establishment has not been inspected by the Secretary in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable, the establishment is eligible for further inspections by accredited persons.*

(7)(A) *Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment’s designated representative and discuss each observation. Additionally, such accredited person shall prepare an inspection report (including for inspections classified as “no action indicated”) in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.*

(B) *At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected establishment involved, the dates of the inspection, the scope of the inspection, and shall discuss in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this Act, and discuss any recommendations during the inspection or at the inspection’s closing meeting.*

(C) *An inspection report under subparagraph (A) shall be sent to the Secretary and the designated representative of the inspected establishment involved at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection*

observations previously provided to the representative of the establishment.

(D) Any statements or representations made by employees or agents of a device establishment to persons accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18, United States Code.

(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the facility subject to inspection and the conditions of concern.

(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(9) Nothing in this subsection affects the authority of the Secretary to inspect establishments pursuant to this Act.

(10)(A) For fiscal year 2005 and subsequent fiscal years, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the “first prior fiscal year”), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the “second prior fiscal year”), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the “compliance budget”), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the “inspection budget”).

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 515.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a reporting describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term “base amount” means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term “adjusted base amount”, in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term “adjusted base amount”, with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted based amount applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on October 1, 2012.

(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons and the number of inspections pursuant to subsections (h) and (i) of section 510 conducted by Federal employees;

(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this Act, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to subsection (h) or (i) of section 510;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

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SUBCHAPTER C—FEES

* * * * *

PART 3—FEES RELATING TO DEVICES

SEC. 737. DEFINITIONS.

For purposes of this subchapter:

(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; 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 510(o)(3).

(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 has been approved under section 515(d) or under section 351 of the Public Health Service Act; 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 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 clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term “180-day supplement” means a supplement to an approved premarket application 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 under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, 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 that requires substantive clinical data.

(5) 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 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 under section 515 or 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.

(6) 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.

(7) 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 April of the preceding fiscal year divided by such Index for April 2002.

(8) The term “affiliate” means a business entity that has a relationship with a second business entity 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.

SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) **TYPES OF FEES.**—Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) **PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE.**—

(A) **IN GENERAL.**—Except as provided in subparagraph

(B) and subsection (d), each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(5) 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 the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 21.5 percent of the fee that applies under clause (i), subject to any adjustment under subsection (c)(3).

(v) For a real-time supplement, a fee equal to 7.2 percent of the fee that applies under clause (i).

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

(vii) For a premarket notification submission, a fee equal to 1.75 percent of the fee that applies under clause (i), subject to any adjustment under subsection (c)(3).

(B) **EXCEPTIONS.**—

(i) **HUMANITARIAN DEVICE EXEMPTION.**—A device for which a humanitarian device exemption has been granted is not subject to the fees established in 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 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 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 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, or premarket notification submission except that invoices for applications submitted between October 1, 2002, and the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 under this section shall include all fees payable from October 1, 2002, through September 30, 2003.

(D) *REFUNDS.*—

(i) *APPLICATION REFUSED FOR FILING.*—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application 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 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.

(b) *FEE REVENUE AMOUNTS.*—Except as provided in subsections (c), (d), (f), and (g), the fees under subsection (a) shall be established to generate the following revenue amounts: \$25,125,000 in fiscal

year 2003; \$27,255,000 in fiscal year 2004; \$29,785,000 in fiscal year 2005; \$32,615,000 in fiscal year 2006, and \$35,000,000 in fiscal year 2007. If legislation is enacted after the date of the enactment of this Act requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—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 greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2003 under this subsection.

(2) WORKLOAD ADJUSTMENT.—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, beginning with fiscal year 2004, be adjusted further each fiscal year to reflect changes in the workload of the Secretary for the process for the review of device 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 premarket applications, investigational new device applications, premarket reports, supplements, and premarket notification submissions submitted to the Secretary. 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), as adjusted for inflation under paragraph (1).

(3) COMPENSATING ADJUSTMENT.—After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year, if necessary, to reflect the cumulative amount by which collections for previous fiscal years, beginning with fiscal year 2003, fell below the cumulative revenue amounts for such fiscal years

specified in subsection (b), adjusted for such fiscal years for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2). Only fees for 180 day supplements and premarket notification submissions shall be increased to generate compensating adjustment revenues.

(4) *FINAL YEAR ADJUSTMENT.*—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fees and fee revenues established in subsection (b) if such 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 device 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 user fee balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.

(5) *ANNUAL FEE SETTING.*—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustment provided under this subsection, except that the fees established for fiscal year 2003 shall be based on a premarket application fee of \$139,000.

(6) *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.

(d) *SMALL BUSINESS FEE WAIVER AND FEE REDUCTION.*—

(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. 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) of subsection (a)(1)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) *RULES RELATING TO SMALL BUSINESSES.*—

(A) *DEFINITION.*—

(i) For purposes of this subsection, the term “small business” means an entity that reported \$10,000,000 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, or parent firms.

(ii) The Secretary may adjust the \$10,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 13 percent or more than would occur without small busi-

ness exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.

(B) *EVIDENCE OF QUALIFICATION.*—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. 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, which shows an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant shall certify that the information provided is a true and accurate copy of the applicant's actual tax forms as submitted to the Internal Revenue Service.

(C) *REDUCED FEES.*—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(5) may be paid at reduced rates as follows:

(i) 38 percent of the fee established under subsection (c)(5) for a premarket application, a premarket report, a panel-track supplement, or an efficacy supplement.

(ii) 44 percent of the fee established under subsection (c)(5) for a 180-day supplement to a medical device application.

(iii) 25 percent of the fee established under subsection (c)(5) for a real-time supplement to a premarket application.

This subsection may not be construed as authorizing any reduction in the fee established under subsection (c)(5) for a premarket notification submission.

(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).

(e) *EFFECT OF FAILURE TO PAY FEES.*—A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) 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) *CONDITIONS.*—

(1) *PERFORMANCE GOALS THROUGH FISCAL YEAR 2005; TERMINATION OF PROGRAM AFTER FISCAL YEAR 2005.*—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:

(A)(i) For each of the fiscal years 2003 and 2004, the Secretary is expected to meet all of the goals identified for the fiscal year involved in any letter referred to in section 101(3) of the Medical Device User Fee and Modernization Act of 2002 (referred to in this paragraph as “performance goals”) if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal

year, is equal to or greater than \$205,720,000 multiplied by the adjustment factor applicable to the fiscal year.

(ii) For each of the fiscal years 2003 and 2004, if the amount so appropriated for the fiscal year involved, excluding the amount of fees appropriated for such fiscal year, is less than the amount that applies under clause (i) for such fiscal year, the following applies:

(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2005. A report under the preceding sentence shall be submitted to the Congress not later than July 1 of the fiscal year with which the report is concerned.

(B)(i) For fiscal year 2005, the Secretary is expected to meet all of the goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

(I) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

(II) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

(III) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.

(ii) For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:

(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2006. The report under the preceding sentence shall be submitted to the Congress not later than July 1, 2005.

(C) For fiscal year 2006, 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 the total of the amounts so appropriated for fiscal years 2003 through 2006, excluding the amount of

fees appropriated for such fiscal years, is less than the sum of—

(i) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2006; and

(ii) an amount equal to the sum that applies for purposes of subparagraph (B)(i).

(D) For fiscal year 2007, 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—

(i) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is less than \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2007; or

(ii) pursuant to subparagraph (C), fees were not assessed under subsection (a) for fiscal year 2006.

(2) *AUTHORITY.*—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of subparagraph (C) or (D) 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, and premarket notification submissions, and at any time in such fiscal year, notwithstanding the provisions of subsection (a) 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 appropriation Acts. 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 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, 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 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 device 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 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

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

(3) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated for fees under this section—

(A) \$25,125,000 for fiscal year 2003;

(B) \$27,255,000 for fiscal year 2004;

(C) \$29,785,000 for fiscal year 2005;

(D) \$32,615,000 for fiscal year 2006; and

(E) \$35,000,000 for fiscal year 2007,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application fees.

(4) **OFFSET.**—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.

(h) **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.

(i) **WRITTEN REQUESTS FOR REFUNDS.**—To qualify for consideration for a refund under subsection (a)(1)(D), a person shall submit to the Secretary a written request for such 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, 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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SECTION 498C OF THE PUBLIC HEALTH SERVICE ACT

SEC. 498C. BREAST IMPLANT RESEARCH.

(a) **IN GENERAL.**—The Director of NIH shall conduct or support prospective or retrospective research to examine the long-term health implications of both saline and silicone breast implants. If scientifically appropriate, such research studies may include the following:

(1) A multidisciplinary study of women who have received silicone and saline implants and have had an implant for a suffi-

cient amount of time to allow for appropriate comparison as to the long-term health consequences.

(2) A comparison of women receiving implants for reconstruction after mastectomy to breast cancer patients who have not had reconstruction, including subsets of women with saline implants and women with silicone implants.

(b) DEFINITION.—For purposes of this section, the term “breast implant” means a breast prosthesis that is implanted to augment or reconstruct the female breast.

