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H. R. 3580

[Report No. 107–728]

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 20, 2001

Mr. GREENWOOD (for himself, Ms. ESHOO, Mr. UPTON, Mr. PALLONE, Mr. DEUTSCH, Mr. TOWNS, Mr. BRYANT, and Mr. BARTON of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

OCTOBER 7, 2002

Additional sponsors: Mr. PICKERING, Mr. ENGEL, Mr. LUTHER, Mr. RAMSTAD, Mr. RUSH, Mr. EHRLICH, Mr. WYNN, Mr. BURR of North Carolina, Mrs. ROUKEMA, Mr. PITTS, Mr. WHITFIELD, Mr. NORWOOD, Mrs. JOHNSON of Connecticut, Mr. HALL of Texas, Mr. FORD, and Mr. KENNEDY of Minnesota

OCTOBER 7, 2002

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on December 20, 2001]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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:

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 Moderniza-

tion 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 supple-

ment 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 Sec-

retary. 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 tax-

able 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 fis-

cal 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, sup-

plements, 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 as-

sessed 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 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 sub-

paragraph (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 con-

sistent 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 Sec-

retary" 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 PREMARKET 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 PREMARKET 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 dura-

tion 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 frequency 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 sub-

mitted 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 de-

termine 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:

"(ll)(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).".

Union Calendar No. 455

107TH CONGRESS
2D SESSION

H. R. 3580

[Report No. 107–728]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

OCTOBER 7, 2002

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed