

107TH CONGRESS
2^D SESSION

H. R. 3580

AN ACT

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
 3 “Medical Device User Fee and Modernization Act of
 4 2002”.

5 (b) TABLE OF CONTENTS.—The table of contents for
 6 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.

1 **TITLE I—FEES RELATED TO**
2 **MEDICAL DEVICES**

3 **SEC. 101. FINDINGS.**

4 The Congress finds that—

5 (1) prompt approval and clearance of safe and
6 effective devices is critical to the improvement of the
7 public health so that patients may enjoy the benefits
8 of devices to diagnose, treat, and prevent disease;

9 (2) the public health will be served by fur-
10 nishing additional funds for the review of devices so
11 that statutorily mandated deadlines may be met; and

12 (3) the fees authorized by the amendment made
13 by section 102 will be dedicated to meeting the goals
14 identified in the letters from the Secretary of Health
15 and Human Services to the Committee on Energy
16 and Commerce of the House of Representatives and
17 the Committee on Health, Education, Labor, and
18 Pensions of the Senate.

19 **SEC. 102. ESTABLISHMENT OF PROGRAM.**

20 (a) **IN GENERAL.**—Subchapter C of chapter VII of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 379F et seq.) is amended by adding at the end the fol-
23 lowing part:

1 **“PART 3—FEES RELATING TO DEVICES**

2 **“SEC. 737. DEFINITIONS.**

3 “For purposes of this subchapter:

4 “(1) The term ‘premarket application’ means—

5 “(A) an application for approval of a de-
6 vice submitted under section 515(e) or section
7 351 of the Public Health Service Act; or

8 “(B) a product development protocol de-
9 scribed in section 515(f).

10 Such term does not include a supplement, a pre-
11 market report, or a premarket notification submis-
12 sion.

13 “(2) The term ‘premarket report’ means a re-
14 port submitted under section 510(o)(3).

15 “(3) The term ‘premarket notification submis-
16 sion’ means a report submitted under section
17 510(k).

18 “(4)(A) The term ‘supplement’, with respect to
19 a panel-track supplement, a 180-day supplement, a
20 real-time supplement, or an efficacy supplement,
21 means a request to the Secretary to approve a
22 change in a device for which—

23 “(i) an application has been approved
24 under section 515(d) or under section 351 of
25 the Public Health Service Act; or

1 “(ii) a notice of completion has become ef-
2 fective under section 515(f).

3 “(B) The term ‘panel-track supplement’ means
4 a supplement to an approved premarket application
5 under section 515 that requests a significant change
6 in design or performance of the device, or a new in-
7 dication for use of the device, and for which clinical
8 data are generally necessary to provide a reasonable
9 assurance of safety and effectiveness.

10 “(C) The term ‘180-day supplement’ means a
11 supplement to an approved premarket application
12 under section 515 that is not a panel-track supple-
13 ment and requests a significant change in compo-
14 nents, materials, design, specification, software,
15 color additives, or labeling.

16 “(D) The term ‘real-time supplement’ means a
17 supplement to an approved premarket application
18 under section 515 that requests a minor change to
19 the device, such as a minor change to the design of
20 the device, software, manufacturing, sterilization, or
21 labeling, and for which the applicant has requested
22 and the agency has granted a meeting or similar
23 forum to jointly review and determine the status of
24 the supplement.

1 “(E) The term ‘efficacy supplement’ means a
2 supplement to an approved premarket application
3 under section 351 of the Public Health Service Act
4 that requires substantive clinical data.

5 “(5) The term ‘process for the review of device
6 applications’ means the following activities of the
7 Secretary with respect to the review of premarket
8 applications, premarket reports, supplements, and
9 premarket notification submissions:

10 “(A) The activities necessary for the re-
11 view of premarket applications, premarket re-
12 ports, supplements, and premarket notification
13 submissions.

14 “(B) The issuance of action letters that
15 allow the marketing of devices or which set
16 forth in detail the specific deficiencies in such
17 applications, reports, supplements, or submis-
18 sions and, where appropriate, the actions nec-
19 essary to place them in condition for approval.

20 “(C) The inspection of manufacturing es-
21 tablishments and other facilities undertaken as
22 part of the Secretary’s review of pending pre-
23 market applications, premarket reports, and
24 supplements.

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

4 “(E) Review of device applications subject
5 to section 351 of the Public Health Service Act
6 for an investigational new drug application
7 under section 505(i) or for an investigational
8 device exemption under section 520(g) and ac-
9 tivities conducted in anticipation of the submis-
10 sion of such applications under section 505(i)
11 or 520(g).

12 “(F) The development of guidance, policy
13 documents, or regulations to improve the proc-
14 ess for the review of premarket applications,
15 premarket reports, supplements, and premarket
16 notification submissions.

17 “(G) The development of voluntary test
18 methods, consensus standards, or mandatory
19 performance standards under section 514 in
20 connection with the review of such applications,
21 reports, supplements, or submissions and re-
22 lated activities.

23 “(H) The provision of technical assistance
24 to device manufacturers in connection with the

1 submission of such applications, reports, supple-
2 ments, or submissions.

3 “(I) Any activity undertaken under section
4 513 or 515(i) in connection with the initial clas-
5 sification or reclassification of a device or under
6 section 515(b) in connection with any require-
7 ment for approval of a device.

8 “(J) Evaluation of postmarket studies re-
9 quired as a condition of an approval of a pre-
10 market application under section 515 or section
11 351 of the Public Health Service Act.

12 “(K) Compiling, developing, and reviewing
13 information on relevant devices to identify safe-
14 ty and effectiveness issues for devices subject to
15 premarket applications, premarket reports, sup-
16 plements, or premarket notification submis-
17 sions.

18 “(6) The term ‘costs of resources allocated for
19 the process for the review of device applications’
20 means the expenses incurred in connection with the
21 process for the review of device applications for—

22 “(A) officers and employees of the Food
23 and Drug Administration, contractors of the
24 Food and Drug Administration, advisory com-
25 mittees, and costs related to such officers, em-

1 employees, and committees and to contracts with
2 such contractors;

3 “(B) management of information, and the
4 acquisition, maintenance, and repair of com-
5 puter resources;

6 “(C) leasing, maintenance, renovation, and
7 repair of facilities and acquisition, maintenance,
8 and repair of fixtures, furniture, scientific
9 equipment, and other necessary materials and
10 supplies; and

11 “(D) collecting fees and accounting for re-
12 sources allocated for the review of premarket
13 applications, premarket reports, supplements,
14 and submissions.

15 “(7) The term ‘adjustment factor’ applicable to
16 a fiscal year is the Consumer Price Index for all
17 urban consumers (all items; United States city aver-
18 age) for April of the preceding fiscal year divided by
19 such Index for April 2002.

20 “(8) The term ‘affiliate’ means a business enti-
21 ty that has a relationship with a second business en-
22 tity if, directly or indirectly—

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

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

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

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

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

10 “(A) IN GENERAL.—Except as provided in
11 subparagraph (B) and subsection (d), each per-
12 son who submits any of the following, on or
13 after October 1, 2002, shall be subject to a fee
14 established under subsection (c)(5) for the fis-
15 cal year involved in accordance with the fol-
16 lowing:

17 “(i) A premarket application.

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

21 “(iii) For a panel track supplement, a
22 fee equal to the fee that applies under
23 clause (i).

24 “(iv) For a 180-day supplement, a fee
25 equal to 21.5 percent of the fee that ap-

1 plies under clause (i), subject to any ad-
2 justment under subsection (c)(3).

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

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

9 “(vii) For a premarket notification
10 submission, a fee equal to 1.75 percent of
11 the fee that applies under clause (i), sub-
12 ject to any adjustment under subsection
13 (c)(3).

14 “(B) EXCEPTIONS.—

15 “(i) HUMANITARIAN DEVICE EXEMP-
16 TION.—A device for which a humanitarian
17 device exemption has been granted is not
18 subject to the fees established in subpara-
19 graph (A).

20 “(ii) FURTHER MANUFACTURING
21 USE.—No fee shall be required under sub-
22 paragraph (A) for the submission of a pre-
23 market application under section 351 of
24 the Public Health Service Act for a prod-

1 uct licensed for further manufacturing use
2 only.

3 “(iii) STATE OR FEDERAL GOVERN-
4 MENT SPONSORS.—No fee shall be re-
5 quired under subparagraph (A) for a pre-
6 market application, premarket report, sup-
7 plement, or premarket notification submis-
8 sion submitted by a State or Federal Gov-
9 ernment entity unless the device involved is
10 to be distributed commercially.

11 “(iv) PREMARKET NOTIFICATIONS BY
12 THIRD PARTIES.—No fee shall be required
13 under subparagraph (A) for a premarket
14 notification submission reviewed by an ac-
15 credited person pursuant to section 523.

16 “(v) PEDIATRIC CONDITIONS OF
17 USE.—

18 “(I) IN GENERAL.—No fee shall
19 be required under subparagraph (A)
20 for a premarket application or pre-
21 market notification submission if the
22 proposed conditions of use for the de-
23 vice involved are solely for a pediatric
24 population. No fee shall be required
25 under such subparagraph for a sup-

1 supplement if the sole purpose of the sup-
2 plement is to propose conditions of
3 use for a pediatric population.

4 “(II) SUBSEQUENT PROPOSAL OF
5 ADULT CONDITIONS OF USE.—In the
6 case of a person who submits a pre-
7 market application for which, under
8 subclause (I), a fee under subpara-
9 graph (A) is not required, any supple-
10 ment to such application that pro-
11 poses conditions of use for any adult
12 population is subject to the fee that
13 applies under such subparagraph for a
14 premarket application.

15 “(C) PAYMENT.—The fee required by sub-
16 paragraph (A) shall be due upon submission of
17 the premarket application, premarket report,
18 supplement, or premarket notification submis-
19 sion except that invoices for applications sub-
20 mitted between October 1, 2002, and the date
21 of the enactment of the Medical Device User
22 Fee and Modernization Act of 2002 shall be
23 payable on October 30, 2002. Applicants sub-
24 mitting portions of applications pursuant to
25 section 515(e)(3) shall pay such fees upon sub-

1 mission of the first portion of such applications.
2 The fees credited to fiscal year 2003 under this
3 section shall include all fees payable from Octo-
4 ber 1, 2002, through September 30, 2003.

5 “(D) REFUNDS.—

6 “(i) APPLICATION REFUSED FOR FIL-
7 ING.—The Secretary shall refund 75 per-
8 cent of the fee paid under subparagraph
9 (A) for any application or supplement that
10 is refused for filing.

11 “(ii) APPLICATION WITHDRAWN BE-
12 FORE FILING.—The Secretary shall refund
13 75 percent of the fee paid under subpara-
14 graph (A) for any application or supple-
15 ment that is withdrawn prior to the filing
16 decision of the Secretary.

17 “(iii) APPLICATION WITHDRAWN BE-
18 FORE FIRST ACTION.—After receipt of a
19 request for a refund of the fee paid under
20 subparagraph (A) for a premarket applica-
21 tion, premarket report, or supplement that
22 is withdrawn after filing but before a first
23 action, the Secretary may return some or
24 all of the fee. The amount of refund, if
25 any, shall be based on the level of effort al-

1 ready expended on the review of such ap-
2 plication, report, or supplement. The Sec-
3 retary shall have sole discretion to refund
4 a fee or portion of the fee under this sub-
5 paragraph. A determination by the Sec-
6 retary concerning a refund under this
7 paragraph shall not be reviewable.

8 “(b) FEE REVENUE AMOUNTS.—Except as provided
9 in subsections (c), (d), (f), and (g), the fees under sub-
10 section (a) shall be established to generate the following
11 revenue amounts: \$25,125,000 in fiscal year 2003;
12 \$27,255,000 in fiscal year 2004; \$29,785,000 in fiscal
13 year 2005; \$32,615,000 in fiscal year 2006, and
14 \$35,000,000 in fiscal year 2007. If legislation is enacted
15 after the date of the enactment of this Act requiring the
16 Secretary to fund additional costs of the retirement of
17 Federal personnel, fee revenue amounts under this sub-
18 section shall be increased in each year by the amount nec-
19 essary to fully fund the portion of such additional costs
20 that are attributable to the process for the review of device
21 applications.

22 “(c) ADJUSTMENTS.—

23 “(1) INFLATION ADJUSTMENT.—The revenues
24 established in subsection (b) shall be adjusted by the

1 Secretary by notice, published in the Federal Reg-
2 ister, for a fiscal year to reflect the greater of—

3 “(A) the total percentage change that oc-
4 curred in the Consumer Price Index for all
5 urban consumers (all items; U.S. city average)
6 for the 12 month period ending June 30 pre-
7 ceding the fiscal year for which fees are being
8 established, or

9 “(B) the total percentage change for the
10 previous fiscal year in basic pay under the Gen-
11 eral Schedule in accordance with section 5332
12 of title 5, United States Code, as adjusted by
13 any locality-based comparability payment pur-
14 suant to section 5304 of such title for Federal
15 employees stationed in the District of Columbia.

16 The adjustment made each fiscal year by this sub-
17 section shall be added on a compounded basis to the
18 sum of all adjustments made each fiscal year after
19 fiscal year 2003 under this subsection.

20 “(2) WORKLOAD ADJUSTMENT.—After the fee
21 revenues established in subsection (b) are adjusted
22 for a fiscal year for inflation in accordance with
23 paragraph (1), the fee revenues shall, beginning with
24 fiscal year 2004, be adjusted further each fiscal year
25 to reflect changes in the workload of the Secretary

1 for the process for the review of device applications.

2 With respect to such adjustment:

3 “(A) The adjustment shall be determined
4 by the Secretary based on a weighted average
5 of the change in the total number of premarket
6 applications, investigational new device applica-
7 tions, premarket reports, supplements, and pre-
8 market notification submissions submitted to
9 the Secretary. The Secretary shall publish in
10 the Federal Register the fee revenues and fees
11 resulting from the adjustment and the sup-
12 porting methodologies.

13 “(B) Under no circumstances shall the ad-
14 justment result in fee revenues for a fiscal year
15 that are less than the fee revenues for the fiscal
16 year established in subsection (b), as adjusted
17 for inflation under paragraph (1).

18 “(3) COMPENSATING ADJUSTMENT.—After the
19 fee revenues established in subsection (b) are ad-
20 justed for a fiscal year for inflation in accordance
21 with paragraph (1), and for workload in accordance
22 with paragraph (2), the fee revenues shall, beginning
23 with fiscal year 2004, be adjusted further each fiscal
24 year, if necessary, to reflect the cumulative amount
25 by which collections for previous fiscal years, begin-

1 ning with fiscal year 2003, fell below the cumulative
2 revenue amounts for such fiscal years specified in
3 subsection (b), adjusted for such fiscal years for in-
4 flation in accordance with paragraph (1), and for
5 workload in accordance with paragraph (2). Only
6 fees for 180 day supplements and premarket notifi-
7 cation submissions shall be increased to generate
8 compensating adjustment revenues.

9 “(4) FINAL YEAR ADJUSTMENT.—For fiscal
10 year 2007, the Secretary may, in addition to adjust-
11 ments under paragraphs (1) and (2), further in-
12 crease the fees and fee revenues established in sub-
13 section (b) if such adjustment is necessary to pro-
14 vide for not more than three months of operating re-
15 serves of carryover user fees for the process for the
16 review of device applications for the first three
17 months of fiscal year 2008. If such an adjustment
18 is necessary, the rationale for the amount of the in-
19 crease shall be contained in the annual notice estab-
20 lishing fee revenues and fees for fiscal year 2007. If
21 the Secretary has carryover user fee balances for
22 such process in excess of three months of such oper-
23 ating reserves, the adjustment under this paragraph
24 shall not be made.

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

10 “(6) LIMIT.—The total amount of fees charged,
11 as adjusted under this subsection, for a fiscal year
12 may not exceed the total costs for such fiscal year
13 for the resources allocated for the process for the re-
14 view of device applications.

15 “(d) SMALL BUSINESS FEE WAIVER AND FEE RE-
16 DUCTION.—

17 “(1) IN GENERAL.—The Secretary shall grant a
18 waiver of the fee required under subsection (a) for
19 one premarket application, or one premarket report,
20 where the Secretary finds that the applicant involved
21 is a small business submitting its first premarket
22 application to the Secretary, or its first premarket
23 report, respectively, for review. In addition, for sub-
24 sequent premarket applications, premarket reports,
25 and supplements where the Secretary finds that the

1 applicant involved is a small business, the fees speci-
2 fied in clauses (i) through (vi) of subsection
3 (a)(1)(A) may be paid at a reduced rate in accord-
4 ance with paragraph (2)(C).

5 “(2) RULES RELATING TO SMALL BUSI-
6 NESSES.—

7 “(A) DEFINITION.—

8 “(i) For purposes of this subsection,
9 the term ‘small business’ means an entity
10 that reported \$10,000,000 or less of gross
11 receipts or sales in its most recent Federal
12 income tax return for a taxable year, in-
13 cluding such returns of all of its affiliates,
14 partners, or parent firms.

15 “(ii) The Secretary may adjust the
16 \$10,000,000 threshold established in
17 clause (i) if the Secretary has evidence
18 from actual experience that this threshold
19 results in a reduction in revenues from
20 premarket applications, premarket reports,
21 and supplements that is 13 percent or
22 more than would occur without small busi-
23 ness exemptions and lower fee rates. To
24 adjust this threshold, the Secretary shall
25 publish a notice in the Federal Register

1 setting out the rationale for the adjust-
2 ment, and the new threshold.

3 “(B) EVIDENCE OF QUALIFICATION.—An
4 applicant shall pay the higher fees established
5 by the Secretary each year unless the applicant
6 submits evidence that it qualifies for a waiver
7 of the fee or the lower fee rate. The applicant
8 shall support its claim that it meets the defini-
9 tion under subparagraph (A) by submission of
10 a copy of its most recent Federal income tax re-
11 turn for a taxable year, which shows an amount
12 of gross sales or receipts that is less than the
13 maximum established in subparagraph (A). The
14 applicant shall certify that the information pro-
15 vided is a true and accurate copy of the appli-
16 cant’s actual tax forms as submitted to the In-
17 ternal Revenue Service.

18 “(C) REDUCED FEES.—Where the Sec-
19 retary finds that the applicant involved meets
20 the definition under subparagraph (A), the fees
21 established under subsection (c)(5) may be paid
22 at reduced rates as follows:

23 “(i) 38 percent of the fee established
24 under subsection (c)(5) for a premarket
25 application, a premarket report, a panel-

1 track supplement, or an efficacy supple-
2 ment.

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

6 “(iii) 25 percent of the fee established
7 under subsection (c)(5) for a real-time sup-
8 plement to a premarket application.

9 This subsection may not be construed as au-
10 thorizing any reduction in the fee established
11 under subsection (c)(5) for a premarket notifi-
12 cation submission.

13 “(D) REQUEST FOR FEE WAIVER OR RE-
14 DUCTION.—An applicant seeking a fee waiver
15 or reduction under this subsection shall submit
16 supporting information to the Secretary at least
17 60 days before the fee is required pursuant to
18 subsection (a).

19 “(e) EFFECT OF FAILURE TO PAY FEES.—A pre-
20 market application, premarket report, supplement, or pre-
21 market notification submission submitted by a person sub-
22 ject to fees under subsection (a) shall be considered incom-
23 plete and shall not be accepted for filing by the Secretary
24 until all fees owed by such person have been paid.

25 “(f) CONDITIONS.—

1 “(1) PERFORMANCE GOALS THROUGH FISCAL
2 YEAR 2005; TERMINATION OF PROGRAM AFTER FIS-
3 CAL YEAR 2005.—With respect to the amount that,
4 under the salaries and expenses account of the Food
5 and Drug Administration, is appropriated for a fis-
6 cal year for devices and radiological products:

7 “(A)(i) For each of the fiscal years 2003
8 and 2004, the Secretary is expected to meet all
9 of the goals identified for the fiscal year in-
10 volved in any letter referred to in section
11 101(3) of the Medical Device User Fee and
12 Modernization Act of 2002 (referred to in this
13 paragraph as ‘performance goals’) if the
14 amount so appropriated for such fiscal year, ex-
15 cluding the amount of fees appropriated for
16 such fiscal year, is equal to or greater than
17 \$205,720,000 multiplied by the adjustment fac-
18 tor applicable to the fiscal year.

19 “(ii) For each of the fiscal years 2003 and
20 2004, if the amount so appropriated for the fis-
21 cal year involved, excluding the amount of fees
22 appropriated for such fiscal year, is less than
23 the amount that applies under clause (i) for
24 such fiscal year, the following applies:

1 “(I) The Secretary is expected to meet
2 such goals to the extent practicable, taking
3 into account the amounts that are avail-
4 able to the Secretary for such purpose,
5 whether from fees under subsection (a) or
6 otherwise.

7 “(II) The Comptroller General of the
8 United States shall submit to the Congress
9 a report describing whether and to what
10 extent the Secretary is meeting the per-
11 formance goals identified for such fiscal
12 year, and whether the Secretary will be
13 able to meet all performance goals identi-
14 fied for fiscal year 2005. A report under
15 the preceding sentence shall be submitted
16 to the Congress not later than July 1 of
17 the fiscal year with which the report is
18 concerned.

19 “(B)(i) For fiscal year 2005, the Secretary
20 is expected to meet all of the goals identified for
21 the fiscal year if the total of the amounts so ap-
22 propriated for fiscal years 2003 through 2005,
23 excluding the amount of fees appropriated for
24 such fiscal years, is equal to or greater than the
25 sum of—

1 “(I) \$205,720,000 multiplied by the
2 adjustment factor applicable to fiscal year
3 2003;

4 “(II) \$205,720,000 multiplied by the
5 adjustment factor applicable to fiscal year
6 2004; and

7 “(III) \$205,720,000 multiplied by the
8 adjustment factor applicable to fiscal year
9 2005.

10 “(ii) For fiscal year 2005, if the total of
11 the amounts so appropriated for fiscal years
12 2003 through 2005, excluding the amount of
13 fees appropriated for such fiscal years, is less
14 than the sum that applies under clause (i) for
15 fiscal year 2005, the following applies:

16 “(I) The Secretary is expected to meet
17 such goals to the extent practicable, taking
18 into account the amounts that are avail-
19 able to the Secretary for such purpose,
20 whether from fees under subsection (a) or
21 otherwise.

22 “(II) The Comptroller General of the
23 United States shall submit to the Congress
24 a report describing whether and to what
25 extent the Secretary is meeting the per-

1 performance goals identified for such fiscal
2 year, and whether the Secretary will be
3 able to meet all performance goals identi-
4 fied for fiscal year 2006. The report under
5 the preceding sentence shall be submitted
6 to the Congress not later than July 1,
7 2005.

8 “(C) For fiscal year 2006, fees may not be
9 assessed under subsection (a) for the fiscal
10 year, and the Secretary is not expected to meet
11 any performance goals identified for the fiscal
12 year, if the total of the amounts so appro-
13 priated for fiscal years 2003 through 2006, ex-
14 cluding the amount of fees appropriated for
15 such fiscal years, is less than the sum of—

16 “(i) \$205,720,000 multiplied by the
17 adjustment factor applicable to fiscal year
18 2006; and

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

22 “(D) For fiscal year 2007, fees may not be
23 assessed under subsection (a) for the fiscal
24 year, and the Secretary is not expected to meet

1 any performance goals identified for the fiscal
2 year, if—

3 “(i) the amount so appropriated for
4 the fiscal year, excluding the amount of
5 fees appropriated for the fiscal year, is less
6 than \$205,720,000 multiplied by the ad-
7 justment factor applicable to fiscal year
8 2007; or

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

12 “(2) AUTHORITY.—If the Secretary does not
13 assess fees under subsection (a) during any portion
14 of a fiscal year because of subparagraph (C) or (D)
15 of paragraph (1) and if at a later date in such fiscal
16 year the Secretary may assess such fees, the Sec-
17 retary may assess and collect such fees, without any
18 modification in the rate for premarket applications,
19 supplements, premarket reports, and premarket no-
20 tification submissions, and at any time in such fiscal
21 year, notwithstanding the provisions of subsection
22 (a) relating to the date fees are to be paid.

23 “(g) CREDITING AND AVAILABILITY OF FEES.—

24 “(1) IN GENERAL.—Fees authorized under sub-
25 section (a) shall be collected and available for obliga-

1 tion only to the extent and in the amount provided
2 in advance in appropriation Acts. Such fees are au-
3 thorized to be appropriated to remain available until
4 expended. Such sums as may be necessary may be
5 transferred from the Food and Drug Administration
6 salaries and expenses appropriation account without
7 fiscal year limitation to such appropriation account
8 for salaries and expenses with such fiscal year limi-
9 tation. The sums transferred shall be available solely
10 for the process for the review of device applications.

11 “(2) COLLECTIONS AND APPROPRIATION
12 ACTS.—

13 “(A) IN GENERAL.—The fees authorized
14 by this section—

15 “(i) shall be retained in each fiscal
16 year in an amount not to exceed the
17 amount specified in appropriation Acts, or
18 otherwise made available for obligation, for
19 such fiscal year, and

20 “(ii) shall only be collected and avail-
21 able to defray increases in the costs of the
22 resources allocated for the process for the
23 review of device applications (including in-
24 creases in such costs for an additional
25 number of full-time equivalent positions in

1 the Department of Health and Human
2 Services to be engaged in such process)
3 over such costs, excluding costs paid from
4 fees collected under this section, for fiscal
5 year 2002 multiplied by the adjustment
6 factor.

7 “(B) COMPLIANCE.—The Secretary shall
8 be considered to have met the requirements of
9 subparagraph (A)(ii) in any fiscal year if the
10 costs funded by appropriations and allocated for
11 the process for the review of device
12 applications—

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

16 “(ii)(I) are more than 3 percent below
17 the level specified in subparagraph (A)(ii),
18 and fees assessed for a subsequent fiscal
19 year are decreased by the amount in excess
20 of 3 percent by which such costs fell below
21 the level specified in such subparagraph;
22 and

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

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—

2 There are authorized to be appropriated for fees
3 under this section—

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

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

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

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

8 and

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

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

13 “(4) OFFSET.—Any amount of fees collected
14 for a fiscal year under this section that exceeds the
15 amount of fees specified in appropriation Acts for
16 such fiscal year shall be credited to the appropria-
17 tion account of the Food and Drug Administration
18 as provided in paragraph (1), and shall be sub-
19 tracted from the amount of fees that would other-
20 wise be authorized to be collected under this section
21 pursuant to appropriation Acts for a subsequent fis-
22 cal year.

23 “(h) COLLECTION OF UNPAID FEES.—In any case
24 where the Secretary does not receive payment of a fee as-
25 sessed under subsection (a) within 30 days after it is due,

1 such fee shall be treated as a claim of the United States
2 Government subject to subchapter II of chapter 37 of title
3 31, United States Code.

4 “(i) WRITTEN REQUESTS FOR REFUNDS.—To qual-
5 ify for consideration for a refund under subsection
6 (a)(1)(D), a person shall submit to the Secretary a written
7 request for such refund not later than 180 days after such
8 fee is due.

9 “(j) CONSTRUCTION.—This section may not be con-
10 strued to require that the number of full-time equivalent
11 positions in the Department of Health and Human Serv-
12 ices, for officers, employees, and advisory committees not
13 engaged in the process of the review of device applications,
14 be reduced to offset the number of officers, employees, and
15 advisory committees so engaged.”.

16 (b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-
17 MITTING PREMARKET REPORTS.—

18 (1) IN GENERAL.—A person submitting a pre-
19 market report to the Secretary of Health and
20 Human Services is exempt from the fee under sec-
21 tion 738(a)(1)(A)(ii) of the Federal Food, Drug, and
22 Cosmetic Act (as added by subsection (a) of this sec-
23 tion) if—

1 (A) the premarket report is the first such
2 report submitted to the Secretary by the per-
3 son; and

4 (B) before October 1, 2002, the person
5 submitted a premarket application to the Sec-
6 retary for the same device as the device for
7 which the person is submitting the premarket
8 report.

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

15 **SEC. 103. ANNUAL REPORTS.**

16 Beginning with fiscal year 2003, the Secretary shall
17 prepare and submit to the Committee on Energy and
18 Commerce of the House of Representatives and the Com-
19 mittee on Health, Education, Labor and Pensions of the
20 Senate a report concerning—

21 (1) the progress of the Food and Drug Admin-
22 istration in achieving the goals identified in the let-
23 ters described in section 101(3) during such fiscal
24 year and the future plans of the Food and Drug Ad-
25 ministration for meeting the goals, not later than 60

1 days after the end of each fiscal year during which
2 fees are collected under this part; and

3 (2) the implementation of the authority for
4 such fees during such fiscal year, and the use, by
5 the Food and Drug Administration, of the fees col-
6 lected during such fiscal year, not later than 120
7 days after the end of each fiscal year during which
8 fees are collected under the medical device user-fee
9 program established under the amendment made by
10 section 102.

11 **SEC. 104. POSTMARKET SURVEILLANCE.**

12 (a) **ADDITIONAL AUTHORIZATION OF APPROPRIA-**
13 **TIONS.**—For the purpose of carrying out postmarket sur-
14 veillance of medical devices, there are authorized to be ap-
15 propriated to the Food and Drug Administration the fol-
16 lowing amounts, stated as increases above the amount ob-
17 ligated for such purpose by such Administration for fiscal
18 year 2002:

19 (1) For fiscal year 2003, an increase of
20 \$3,000,000.

21 (2) For fiscal year 2004, an increase of
22 \$6,000,000.

23 (3) For fiscal year 2005 and each subsequent
24 fiscal year, an increase of such sums as may be nec-
25 essary.

1 (b) STUDY.—

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

8 (A) The impact of such program on the
9 ability of the Food and Drug Administration to
10 conduct postmarket surveillance on medical de-
11 vices.

12 (B) The programmatic improvements, if
13 any, needed for adequate postmarket surveil-
14 lance of medical devices.

15 (C) The amount of funds needed to con-
16 duct adequate postmarket surveillance of med-
17 ical devices.

18 (D) The extent to which device companies
19 comply with the postmarket surveillance re-
20 quirements, including postmarket study com-
21 mitments.

22 (E) The recommendations of the Secretary
23 as to whether, and in what amounts, user fees
24 collected under such user-fee program should be

1 dedicated to postmarket surveillance if the pro-
2 gram is extended beyond fiscal year 2007.

3 (2) REPORT.—Not later than January 10,
4 2007, the Secretary shall submit to the Committee
5 on Energy and Commerce of the House of Rep-
6 resentatives, and the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate, a report
8 that describes the findings of the study under para-
9 graph (1).

10 **SEC. 105. CONSULTATION.**

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

24 (b) RECOMMENDATIONS.—The Secretary shall pub-
25 lish in the Federal Register recommendations under sub-

1 section (a), after negotiations with the regulated industry;
2 shall present such recommendations to the congressional
3 committees specified in such paragraph; shall hold a meet-
4 ing at which the public may present its views on such rec-
5 ommendations; and shall provide for a period of 30 days
6 for the public to provide written comments on such rec-
7 ommendations.

8 **SEC. 106. EFFECTIVE DATE.**

9 The amendments made by this title shall take effect
10 on the date of the enactment of this Act, except that fees
11 shall be assessed for all premarket applications, premarket
12 reports, supplements, and premarket notification submis-
13 sions received on or after October 1, 2002, regardless of
14 the date of enactment.

15 **SEC. 107. SUNSET CLAUSE.**

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

19 **TITLE II—AMENDMENTS RE-**
20 **GARDING REGULATION OF**
21 **MEDICAL DEVICES**

22 **SEC. 201. INSPECTIONS BY ACCREDITED PERSONS.**

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

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

12 “(2) Not later than 180 days after the date of enact-
13 ment of this subsection, the Secretary shall publish in the
14 Federal Register criteria to accredit or deny accreditation
15 to persons who request to perform the duties specified in
16 paragraph (1). Thereafter, the Secretary shall inform
17 those requesting accreditation, within 60 days after the
18 receipt of such request, whether the request for accredita-
19 tion is adequate for review, and the Secretary shall
20 promptly act on the request for accreditation. Any result-
21 ing accreditation shall state that such person is accredited
22 to conduct inspections at establishments identified in
23 paragraph (1). The accreditation of such person shall
24 specify the particular activities under this subsection for
25 which such person is accredited. In the first year following

1 the publication in the Federal Register of criteria to ac-
2 credit or deny accreditation to persons who request to per-
3 form the duties specified in paragraph (1), the Secretary
4 shall accredit no more than 15 persons who request to per-
5 form duties specified in paragraph (1).

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

8 “(A) Such person shall be an independent orga-
9 nization which is not owned or controlled by a man-
10 ufacturer, supplier, or vendor of articles regulated
11 under this Act and which has no organizational, ma-
12 terial, or financial affiliation (including a consult-
13 ative affiliation) with such a manufacturer, supplier,
14 or vendor.

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

18 “(C) Such person shall not engage in the de-
19 sign, manufacture, promotion, or sale of articles reg-
20 ulated under this Act.

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

1 “(i) certify that reported information accu-
2 rately reflects data reviewed;

3 “(ii) limit work to that for which com-
4 petence and capacity are available;

5 “(iii) treat information received, records,
6 reports, and recommendations as confidential
7 commercial or financial information or trade se-
8 cret information;

9 “(iv) promptly respond and attempt to re-
10 solve complaints regarding its activities for
11 which it is accredited; and

12 “(v) protect against the use, in carrying
13 out paragraph (1), of any officer or employee of
14 the accredited person who has a financial con-
15 flict of interest regarding any product regulated
16 under this Act, and annually make available to
17 the public disclosures of the extent to which the
18 accredited person, and the officers and employ-
19 ees of the person, have maintained compliance
20 with requirements under this clause relating to
21 financial conflicts of interest.

22 “(4) The Secretary shall publish on the Internet site
23 of the Food and Drug Administration a list of accredited
24 persons to conduct inspections under paragraph (1). Such
25 list shall be periodically updated to ensure that the iden-

1 tity of each accredited person is known to the public. The
2 updating of such list shall be no later than one month
3 after the accreditation of a person under this subsection
4 or the withdrawal of accreditation.

5 “(5)(A) To ensure that persons accredited under this
6 subsection continue to meet the standards of accredita-
7 tion, the Secretary shall audit the performance of such
8 persons on a periodic basis through the review of inspec-
9 tion reports and inspections by persons designated by the
10 Secretary to evaluate the compliance status of an estab-
11 lishment and the performance of accredited persons.

12 “(B) The Secretary may withdraw accreditation of
13 any person accredited under paragraph (2), after pro-
14 viding notice and an opportunity for an informal hearing,
15 when such person is substantially not in compliance with
16 the standards of accreditation or poses a threat to public
17 health or fails to act in a manner that is consistent with
18 the purposes of this subsection. The Secretary may sus-
19 pend the accreditation of such person during the pendency
20 of the process under the preceding sentence.

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

24 “(i) the Secretary classified the results of the
25 most recent inspection of the establishment pursuant

1 to subsection (h) or (i) of section 510 as ‘no action
2 indicated’ or ‘voluntary action indicated’; and

3 “(ii) with respect to each inspection to be con-
4 ducted by an accredited person—

5 “(I) the owner or operator of the establish-
6 ment submits to the Secretary a notice request-
7 ing clearance to use such a person to conduct
8 the inspection, and the Secretary provides such
9 clearance; and

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

14 “(B)(i) The Secretary shall respond to a notice under
15 subparagraph (A) from an establishment not later than
16 30 days after the Secretary receives the notice. Through
17 such response, the Secretary shall (I) provide clearance
18 under such subparagraph, and agree to the selection of
19 an accredited person, or (II) make a request under clause
20 (ii). If the Secretary fails to respond to the notice within
21 such 30-day period, the establishment is deemed to have
22 such clearance, and to have the agreement of the Sec-
23 retary for such selection.

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

1 “(I) a request to the establishment involved to
2 submit to the Secretary compliance data in accord-
3 ance with clause (iii); or

4 “(II) a request to the establishment, or to the
5 accredited person identified in the notice under sub-
6 paragraph (A), for information concerning the rela-
7 tionship between the establishment and such accred-
8 ited person.

9 The Secretary may make both such requests.

10 “(iii) The compliance data to be submitted by an es-
11 tablishment under clause (ii) are data describing whether
12 the quality controls of the establishment have been suffi-
13 cient for ensuring consistent compliance with current good
14 manufacturing practice within the meaning of section
15 501(h), and data otherwise describing whether the estab-
16 lishment has consistently been in compliance with sections
17 501 and 502 and other applicable provisions of this Act.
18 Such data shall include complete reports of inspections re-
19 garding good manufacturing practice or other quality con-
20 trol audits that, during the preceding two-year period,
21 were conducted at the establishment by persons other than
22 the owner or operator of the establishment, together with
23 all other data the Secretary deems necessary. Data under
24 the preceding sentence shall demonstrate to the Secretary
25 whether the establishment has facilitated consistent com-

1 pliance by promptly correcting any compliance problems
2 identified in such inspections.

3 “(iv) Not later than 60 days after receiving compli-
4 ance data under clause (iii) from an establishment, the
5 Secretary shall provide or deny clearance under subpara-
6 graph (A). The Secretary may not deny clearance unless
7 the Secretary provides to the establishment detailed find-
8 ings that the establishment has failed to demonstrate con-
9 sistent compliance for purposes of clause (iii). If the Sec-
10 retary fails to provide such findings to the establishment
11 within such 60-day period, the establishment is deemed
12 to have such clearance.

13 “(v)(I) A request to an accredited person under
14 clause (ii)(II) may not seek any information that is not
15 required to be maintained by such person in records under
16 subsection (f)(1). Not later than 60 days after receiving
17 the information sought by the request, the Secretary shall
18 agree to, or reject, the selection of such person by the es-
19 tablishment involved. The Secretary may not reject the se-
20 lection unless the Secretary provides to the establishment
21 the reasons for such rejection. Reasons for the rejection
22 may include that the establishment or the accredited per-
23 son, as the case may be, has failed to fully respond to
24 the request. If within such 60-day period the Secretary
25 fails to agree to or reject the selection in accordance with

1 this subclause, the Secretary is deemed to have agreed to
2 the selection.

3 “(II) If the Secretary rejects the selection of an ac-
4 credited person by an establishment, the establishment
5 may make an additional selection of an accredited person
6 by submitting to the Secretary a notice that identifies the
7 additional selection. Clauses (i) and (ii), and subclause (I)
8 of this clause, apply to the selection of an accredited per-
9 son through a notice under the preceding sentence in the
10 same manner and to the same extent as such provisions
11 apply to a selection of an accredited person through a no-
12 tice under subparagraph (A).

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

24 “(C)(i) In the case of a device establishment for
25 which the Secretary classified the results of the most re-

1 cent inspection of the establishment by a person accredited
2 under paragraph (2) as ‘official action indicated’, the es-
3 tablishment is eligible for further inspections by persons
4 accredited under such paragraph if (I) the Secretary
5 issues a written statement to the owner or operator of the
6 establishment that the violations leading to such classifica-
7 tion have been resolved, and (II) the Secretary, either
8 upon the Secretary’s own initiative or a petition of the
9 owner or operator of the establishment, notifies the estab-
10 lishment that it has clearance to use an accredited person
11 for the inspections. The Secretary shall respond to such
12 petition within 30 days after the receipt of the petition.

13 “(ii) If the Secretary denies a petition under clause
14 (i), the establishment involved may, after the expiration
15 of one year after such denial, again petition the Secretary
16 for a determination of eligibility for inspection by persons
17 accredited by the Secretary under paragraph (2). If the
18 Secretary denies such petition, the Secretary shall provide
19 the establishment with a detailed reason for such denial
20 within 60 days after the denial. If, as of the expiration
21 of 48 months after the receipt of the first petition, the
22 establishment has not been inspected by the Secretary in
23 accordance with section 510(h), or has not during such
24 period been inspected pursuant to section 510(i), as appli-

1 cable, the establishment is eligible for further inspections
2 by accredited persons.

3 “(7)(A) Persons accredited under paragraph (2) to
4 conduct inspections shall record in writing their inspection
5 observations and shall present the observations to the de-
6 vice establishment’s designated representative and discuss
7 each observation. Additionally, such accredited person
8 shall prepare an inspection report (including for inspec-
9 tions classified as ‘no action indicated’) in a form and
10 manner consistent with such reports prepared by employ-
11 ees and officials designated by the Secretary to conduct
12 inspections.

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

22 “(C) An inspection report under subparagraph (A)
23 shall be sent to the Secretary and the designated rep-
24 resentative of the inspected establishment involved at the
25 same time, but under no circumstances later than three

1 weeks after the last day of the inspection. The report to
2 the Secretary shall be accompanied by all written inspec-
3 tion observations previously provided to the representative
4 of the establishment.

5 “(D) Any statements or representations made by em-
6 ployees or agents of a device establishment to persons ac-
7 credited under paragraph (2) to conduct inspections shall
8 be subject to section 1001 of title 18, United States Code.

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

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

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

23 “(10)(A) For fiscal year 2005 and subsequent fiscal
24 years, no device establishment may be inspected during

1 the fiscal year involved by a person accredited under para-
2 graph (2) if—

3 “(i) of the amounts appropriated for salaries
4 and expenses of the Food and Drug Administration
5 for the preceding fiscal year (referred to in this sub-
6 paragraph as the ‘first prior fiscal year’), the
7 amount obligated by the Secretary for inspections of
8 device establishments by the Secretary was less than
9 the adjusted base amount applicable to such first
10 prior fiscal year; and

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

19 “(B)(i) Subject to clause (ii), the Comptroller Gen-
20 eral of the United States shall determine the amount that
21 was obligated by the Secretary for fiscal year 2002 for
22 compliance activities of the Food and Drug Administra-
23 tion with respect to devices (referred to in this subpara-
24 graph as the ‘compliance budget’), and of such amount,
25 the amount that was obligated for inspections by the Sec-

1 retary of device establishments (referred to in this sub-
2 paragraph as the ‘inspection budget’).

3 “(ii) For purposes of determinations under clause (i),
4 the Comptroller General shall not include in the compli-
5 ance budget or the inspection budget any amounts obli-
6 gated for inspections of device establishments conducted
7 as part of the process of reviewing applications under sec-
8 tion 515.

9 “(iii) Not later than March 31, 2003, the Comptroller
10 General shall complete the determinations required in this
11 subparagraph and submit to the Secretary and the Con-
12 gress a reporting describing the findings made through
13 such determinations.

14 “(C) For purposes of this paragraph:

15 “(i) The term ‘base amount’ means the inspec-
16 tion budget determined under subparagraph (B) for
17 fiscal year 2002.

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

22 “(iii) The term ‘adjusted base amount’, with re-
23 spect to applicability to fiscal year 2004 or any sub-
24 sequent fiscal year, means the adjusted based

1 amount applicable to the preceding year increased by
2 5 percent.

3 “(11) The authority provided by this subsection ter-
4 minates on October 1, 2012.

5 “(12) No later than four years after the enactment
6 of this subsection the Comptroller General shall report to
7 the Committee on Energy and Commerce of the House
8 of Representatives and the Committee on Health, Edu-
9 cation, Labor and Pensions of the Senate—

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

14 “(B) the number of persons who sought accred-
15 itation under this subsection, as well as the number
16 of persons who were accredited under this sub-
17 section;

18 “(C) the reasons why persons who sought ac-
19 creditation, but were denied accreditation, were de-
20 nied;

21 “(D) the number of audits conducted by the
22 Secretary of accredited persons, the quality of in-
23 spections conducted by accredited persons, whether
24 accredited persons are meeting their obligations

1 under this Act, and whether the number of audits
2 conducted is sufficient to permit these assessments;

3 “(E) whether this subsection is achieving the
4 goal of ensuring more information about establish-
5 ment compliance is being presented to the Secretary,
6 and whether that information is of a quality con-
7 sistent with information obtained by the Secretary
8 pursuant to subsection (h) or (i) of section 510;

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

13 “(G) whether the Congress should continue,
14 modify, or terminate the program under this sub-
15 section.

16 “(13) The Secretary shall include in the annual re-
17 port required under section 903(g) the names of all ac-
18 credited persons and the particular activities under this
19 subsection for which each such person is accredited and
20 the name of each accredited person whose accreditation
21 has been withdrawn during the year.”.

22 (b) MAINTENANCE OF RECORDS.—Section 704(f) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 374(f)) is amended—

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

6 (2) in paragraph (2), by striking “a person ac-
7 credited under section 523” and inserting “an ac-
8 credited person described in paragraph (3)”; and

9 (3) by adding at the end the following para-
10 graph:

11 “(3) For purposes of paragraphs (1) and (2), an ac-
12 credited person described in this paragraph is a person
13 who—

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

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

16 (c) CONFORMING AMENDMENT.—Section 510(h) of
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 360(h)) is amended by inserting after “duly designated
19 by the Secretary” the following: “, or by persons accred-
20 ited to conduct inspections under section 704(g),”.

21 **SEC. 202. THIRD PARTY REVIEW OF PREMARKET NOTIFICA-**
22 **TION.**

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

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

5 (2) by adding at the end the following sub-
6 section:

7 “(d) REPORT.—Not later than January 10, 2007, the
8 Secretary shall conduct a study based on the experience
9 under the program under this section and submit to the
10 Committee on Energy and Commerce of the House of
11 Representatives, and the Committee on Health, Edu-
12 cation, Labor, and Pensions of the Senate, a report de-
13 scribing the findings of the study. The objectives of the
14 study shall include determining—

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

17 “(2) the number of devices reviewed under this
18 section that were ultimately cleared by the Sec-
19 retary;

20 “(3) the number of devices reviewed under this
21 section that were ultimately not cleared by the Sec-
22 retary;

23 “(4) the average time period for a review under
24 this section (including the time it takes for the Sec-
25 retary to review a recommendation of an accredited

1 person under subsection (a) and determine the ini-
2 tial device classification);

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

7 “(6) if there is a difference in the average time
8 period under paragraph (4) and the average time pe-
9 riod under paragraph (5), the reasons for such dif-
10 ference;

11 “(7) whether the quality of reviews under this
12 section for devices for which no guidance has been
13 issued is qualitatively inferior to reviews by the Sec-
14 retary for devices for which no guidance has been
15 issued;

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

21 “(9) whether this section has in any way jeop-
22 ardized or improved the public health;

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

1 “(11) any suggestions for continuation, modi-
2 fication (including expansion of device eligibility), or
3 termination of this section that the Secretary deter-
4 mines to be appropriate.”.

5 **SEC. 203. DESIGNATION AND REGULATION OF COMBINA-**
6 **TION PRODUCTS.**

7 Section 503(g) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 353(g)) is amended—

9 (1) in paragraph (1) -

10 (A) in the first sentence, by striking “shall
11 designate a component of the Food and Drug
12 Administration” and inserting “shall in accord-
13 ance with this subsection assign an agency cen-
14 ter”; and

15 (B) in each of subparagraphs (A) through
16 (C), by striking “the persons charged” and in-
17 serting “the agency center charged”;

18 (2) by redesignating paragraph (4) as para-
19 graph (5);

20 (3) by inserting after paragraph (3) the fol-
21 lowing paragraph:

22 “(4)(A) Not later than 60 days after the date of the
23 enactment of this paragraph, the Secretary shall establish
24 within the Office of the Commissioner of Food and Drugs
25 an office to ensure the prompt assignment of combination

1 products to agency centers, the timely premarket review
2 of such products, and consistent and appropriate
3 postmarket regulation of like products subject to the same
4 statutory requirements to the extent permitted by law. Ad-
5 ditionally, the office shall, in determining whether a prod-
6 uct is to be designated a combination product, consult with
7 the component within the Office of the Commissioner of
8 Food and Drugs that is responsible for such determina-
9 tions. Such office (referred to in this paragraph as the
10 ‘Office’) shall have appropriate scientific and medical ex-
11 pertise, and shall be headed by a director.

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

16 “(C) In carrying out this subsection, the Office shall
17 ensure timely and effective premarket reviews by over-
18 seeing and coordinating reviews involving more than one
19 agency center.

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

1 “(E) In order to ensure the timeliness of the pre-
2 market review of a combination product, the agency center
3 with primary jurisdiction for the product, and the con-
4 sulting agency center, shall be responsible to the Office
5 with respect to the timeliness of the premarket review.

6 “(F)(i) Any dispute regarding the timeliness of the
7 premarket review of a combination product may be pre-
8 sented to the Office for resolution, unless the timeliness
9 of the dispute is clearly premature.

10 “(ii) During the review process, any dispute regard-
11 ing the substance of the premarket review may be pre-
12 sented to the Commissioner of Food and Drugs after first
13 being considered by the agency center with primary juris-
14 diction of the premarket review, under the scientific dis-
15 pute resolution procedures for such center. The Commis-
16 sioner of Food and Drugs shall consult with the Director
17 of the Office in resolving the substantive dispute.

18 “(G) The Secretary, acting through the Office, shall
19 review each agreement, guidance, or practice of the Sec-
20 retary that is specific to the assignment of combination
21 products to agency centers and shall determine whether
22 the agreement, guidance, or practice is consistent with the
23 requirements of this subsection. In carrying out such re-
24 view, the Secretary shall consult with stakeholders and the
25 directors of the agency centers. After such consultation,

1 the Secretary shall determine whether to continue in ef-
2 fect, modify, revise, or eliminate such agreement, guid-
3 ance, or practice, and shall publish in the Federal Register
4 a notice of the availability of such modified or revised
5 agreement, guidance or practice. Nothing in this para-
6 graph shall be construed as preventing the Secretary from
7 following each agreement, guidance, or practice until con-
8 tinued, modified, revised, or eliminated.

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

14 “(i) describing the numbers and types of com-
15 bination products under review and the timeliness in
16 days of such assignments, reviews, and dispute reso-
17 lutions;

18 “(ii) identifying the number of premarket re-
19 views of such products that involved a consulting
20 agency center; and

21 “(iii) describing improvements in the consist-
22 ency of postmarket regulation of combination prod-
23 ucts.”; and

24 (4) in paragraph (5) (as redesignated by para-
25 graph (2) of this section)—

1 (A) by redesignating subparagraphs (A)
2 and (B) as subparagraphs (B) and (C), respec-
3 tively; and

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

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

9 **SEC. 204. REPORT ON CERTAIN DEVICES.**

10 Not later than one year after the date of enactment
11 of this Act, the Secretary of Health and Human Services
12 shall report to the appropriate committees of Congress on
13 the timeliness and effectiveness of device premarket re-
14 views by centers other than the Center for Devices and
15 Radiological Health. Such report shall include information
16 on the times required to log in and review original submis-
17 sions and supplements, times required to review manufac-
18 turers’ replies to submissions, and times to approve or
19 clear such devices. Such report shall contain the Sec-
20 retary’s recommendations on any measures needed to im-
21 prove performance including, but not limited to, the alloca-
22 tion of additional resources. Such report also shall include
23 the Secretary’s specific recommendation on whether re-
24 sponsibility for regulating such devices should be reas-
25 signed to those persons within the Food and Drug Admin-

1 istration who are primarily charged with regulating other
2 types of devices, and whether such a transfer could have
3 a deleterious impact on the public health and on the safety
4 of such devices.

5 **SEC. 205. ELECTRONIC LABELING.**

6 Section 502(f) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 352(f)) is amended by adding at the
8 end the following: “Required labeling for prescription de-
9 vices intended for use in health care facilities may be made
10 available solely by electronic means provided that the la-
11 beling complies with all applicable requirements of law
12 and, that the manufacturer affords health care facilities
13 the opportunity to request the labeling in paper form, and
14 after such request, promptly provides the health care facil-
15 ity the requested information without additional cost.”.

16 **SEC. 206. ELECTRONIC REGISTRATION.**

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

20 “(p) Registrations under subsections (b), (c), (d), and
21 (i) (including the submission of updated information) shall
22 be submitted to the Secretary by electronic means, upon
23 a finding by the Secretary that the electronic receipt of
24 such registrations is feasible, unless the Secretary grants
25 a request for waiver of such requirement because use of

1 electronic means is not reasonable for the person request-
2 ing such waiver.”.

3 **SEC. 207. INTENDED USE.**

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

7 **SEC. 208. MODULAR REVIEW.**

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

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

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

22 “(C) Whenever the Secretary determines that a por-
23 tion of a submission under subparagraph (A) is unaccept-
24 able, the Secretary shall specifically identify, in writing,
25 the deficiency of such portion and describe in detail the

1 means by which it may be made acceptable, unless the
2 sponsor is no longer pursuing the application.”.

3 **SEC. 209. PEDIATRIC EXPERTISE REGARDING CLASSIFICA-**
4 **TION-PANEL REVIEW OF PREMARKET APPLI-**
5 **CATIONS.**

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

13 **SEC. 210. INTERNET LIST OF CLASS II DEVICES EXEMPTED**
14 **FROM REQUIREMENT OF PREMARKET NOTI-**
15 **FICATION.**

16 Section 510(m)(1) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 360(m)(1)) is amended by add-
18 ing at the end the following: “The Secretary shall publish
19 such list on the Internet site of the Food and Drug Ad-
20 ministration. The list so published shall be updated not
21 later than 30 days after each revision of the list by the
22 Secretary.”.

1 **SEC. 211. STUDY BY INSTITUTE OF MEDICINE OF**
2 **POSTMARKET SURVEILLANCE REGARDING**
3 **PEDIATRIC POPULATIONS.**

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

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

16 (1) whether postmarket surveillance studies of
17 implanted medical devices are of long enough dura-
18 tion to evaluate the impact of growth and develop-
19 ment for the number of years that the child will
20 have the implant, and whether the studies are ade-
21 quate to evaluate how children’s active lifestyles may
22 affect the failure rate and longevity of the implant;
23 and

24 (2) whether the amount of funds allocated for
25 postmarket surveillance by the Food and Drug Ad-
26 ministration of medical devices used in pediatric

1 populations is sufficient to provide adequate safe-
2 guards for such populations, taking into account the
3 Secretary's monitoring of commitments made at the
4 time of approval of medical devices, such as phase
5 IV trials, and the Secretary's monitoring and use of
6 adverse reaction reports, registries, and other
7 postmarket surveillance activities.

8 (c) REPORT TO CONGRESS.—The Secretary shall en-
9 sure that, not later than four years after the date of the
10 enactment of this Act, a report describing the findings of
11 the study under subsection (a) is submitted to the Con-
12 gress. The report shall include any recommendations of
13 the Secretary for administrative or legislative changes to
14 the system of postmarket surveillance referred to in such
15 subsection.

16 **SEC. 212. GUIDANCE REGARDING PEDIATRIC DEVICES.**

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

20 “Guidance Regarding Pediatric Devices

21 “(n) Not later than 270 days after the date of the
22 enactment of the Medical Device User Fee and Moderniza-
23 tion Act of 2002, the Secretary shall issue guidance on
24 the following:

1 whether to undergo surgery is such information pro-
2 vided.

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

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

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

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

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

21 (C) The point at which, in the planning or
22 conduct of the research, the women are pro-
23 vided information regarding the provision of in-
24 formed consent to be subjects.

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

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

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

10 **SEC. 214. BREAST IMPLANTS; RESEARCH THROUGH NA-**
11 **TIONAL INSTITUTES OF HEALTH.**

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

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

23 **“SEC. 498C. BREAST IMPLANT RESEARCH.**

24 “(a) IN GENERAL.—The Director of NIH shall con-
25 duct or support prospective or retrospective research to

1 examine the long-term health implications of both saline
2 and silicone breast implants. If scientifically appropriate,
3 such research studies may include the following:

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

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

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

17 **TITLE III—ADDITIONAL**
18 **AMENDMENTS**

19 **SEC. 301. IDENTIFICATION OF MANUFACTURER OF MED-**
20 **ICAL DEVICES.**

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

24 “(u) If it is a device, unless it, or an attachment
25 thereto, prominently and conspicuously bears the name of

1 the manufacturer of the device, a generally recognized ab-
2 breviation of such name, or a unique and generally recog-
3 nized symbol identifying such manufacturer, except that
4 the Secretary may waive any requirement under this para-
5 graph for the device if the Secretary determines that com-
6 pliance with the requirement is not feasible for the device
7 or would compromise the provision of reasonable assur-
8 ance of the safety or effectiveness of the device.”.

9 (b) **EFFECTIVE DATE.**—The amendment made by
10 subsection (a) takes effect 18 months after the date of
11 the enactment of this Act, and only applies to devices in-
12 troduced or delivered for introduction into interstate com-
13 merce after such effective date.

14 **SEC. 302. SINGLE-USE MEDICAL DEVICES.**

15 (a) **REQUIRED STATEMENTS ON LABELING.**—

16 (1) **IN GENERAL.**—Section 502 of the Federal
17 Food, Drug, and Cosmetic Act, as amended by sec-
18 tion 301 of this Act, is amended by adding at the
19 end the following:

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

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

6 (b) PREMARKET NOTIFICATION.—Section 510 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360)
8 is amended by inserting after subsection (n) the following:

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

11 “(A) The Secretary shall identify such devices
12 or types of devices for which reports under such sub-
13 section must, in order to ensure that the device is
14 substantially equivalent to a predicate device, include
15 validation data, the types of which shall be specified
16 by the Secretary, regarding cleaning and steriliza-
17 tion, and functional performance demonstrating that
18 the single-use device will remain substantially equiv-
19 alent to its predicate device after the maximum
20 number of times the device is reprocessed as in-
21 tended by the person submitting the premarket noti-
22 fication. Within one year after enactment of this
23 subsection, the Secretary shall publish in the Fed-
24 eral Register a list of the types so identified, and
25 shall revise the list as appropriate. Reports under

1 subsection (k) for devices or types of devices within
2 a type included on the list are, upon publication of
3 the list, required to include such validation data.

4 “(B) In the case of each report under sub-
5 section (k) that was submitted to the Secretary be-
6 fore the publication of the initial list under subpara-
7 graph (A), or any revision thereof, and was for a de-
8 vice or type of device included on such list, the per-
9 son who submitted the report under subsection (k)
10 shall submit validation data as described in subpara-
11 graph (A) to the Secretary not later than nine
12 months after the publication of the list. During such
13 nine-month period, the Secretary may not take any
14 action under this Act against such device solely on
15 the basis that the validation data for the device have
16 not been submitted to the Secretary. After the sub-
17 mission of the validation data to the Secretary, the
18 Secretary may not determine that the device is mis-
19 branded under section 502(o), adulterated under
20 section 501(f)(1)(B), or take action against the de-
21 vice under section 301(p) for failure to provide any
22 information required by subsection (k) until (i) the
23 review is terminated by withdrawal of the submis-
24 sion of the report under subsection (k); (ii) the Sec-
25 retary finds the data to be acceptable and issues a

1 letter; or (iii) the Secretary determines that the de-
2 vice is not substantially equivalent to a predicate de-
3 vice. Upon a determination that a device is not sub-
4 stantially equivalent to a predicate device, or if such
5 submission is withdrawn, the device can no longer be
6 legally marketed.

7 “(C) In the case of a report under subsection
8 (k) for a device identified under subparagraph (A)
9 that is of a type for which the Secretary has not
10 previously received a report under such subsection,
11 the Secretary may, in advance of revising the list
12 under subparagraph (A) to include such type, re-
13 quire that the report include the validation data
14 specified in subparagraph (A).

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

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

22 “(A) The Secretary shall identify such devices
23 or types of devices for which such exemptions should
24 be terminated in order to provide a reasonable as-
25 surance of the safety and effectiveness of the de-

1 vices. The Secretary shall publish in the Federal
2 Register a list of the devices or types of devices so
3 identified, and shall revise the list as appropriate.
4 The exemption for each device or type included on
5 the list is terminated upon the publication of the
6 list. For each report under subsection (k) submitted
7 pursuant to this subparagraph the Secretary shall
8 require the validation data described in paragraph
9 (1)(A).

10 “(B) For each device or type of device included
11 on the list under subparagraph (A), a report under
12 subsection (k) shall be submitted to the Secretary
13 not later than 15 months after the publication of the
14 initial list, or a revision of the list, whichever termi-
15 nates the exemption for the device. During such 15-
16 month period, the Secretary may not take any action
17 under this Act against such device solely on the
18 basis that such report has not been submitted to the
19 Secretary. After the submission of the report to the
20 Secretary the Secretary may not determine that the
21 device is misbranded under section 502(o), adulter-
22 ated under section 501(f)(1)(B), or take action
23 against the device under section 301(p) for failure to
24 provide any information required by subsection (k)
25 until (i) the review is terminated by withdrawal of

1 the submission; (ii) the Secretary determines by
2 order that the device is substantially equivalent to a
3 predicate device; or (iii) the Secretary determines by
4 order that the device is not substantially equivalent
5 to a predicate device. Upon a determination that a
6 device is not substantially equivalent to a predicate
7 device, the device can no longer be legally marketed.

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

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

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

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

1 “(A) The device shall not be introduced into
2 interstate commerce or delivered for introduction
3 into interstate commerce unless the person involved
4 has submitted to the Secretary a report in accord-
5 ance with this paragraph and the Secretary, after
6 reviewing the report, issues an order determining
7 there is a reasonable assurance of the safety and ef-
8 fectiveness for the device.

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

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

14 “(ii) The establishment registration num-
15 ber of the owner or operator submitting the re-
16 port.

17 “(iii) Actions taken to comply with per-
18 formance standards under section 514.

19 “(iv) Proposed labels, labeling, and adver-
20 tising sufficient to describe the device, its in-
21 tended use, and directions for use.

22 “(v) Full reports of all information, pub-
23 lished or known to or which should be reason-
24 ably known to the applicant, concerning inves-

1 tigitations which have been made to show wheth-
2 er or not a device is safe or effective.

3 “(vi) A description of the device’s compo-
4 nents, ingredients, and properties.

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

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

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

13 “(x) A statement that the applicant be-
14 lieves to the best of the applicant’s knowledge
15 that all data and information submitted to the
16 Secretary are truthful and accurate and that no
17 material fact has been omitted in the report.

18 “(xi) Any additional data and information
19 that the Secretary determines is necessary to
20 determine whether there is reasonable assur-
21 ance of safety and effectiveness for the repro-
22 cessed device.

23 “(C) In addition to the information or data re-
24 quired in subparagraph (B), the report under sub-
25 paragraph (A) shall include the validation data de-

1 scribed in paragraph (1)(A) that demonstrates that
2 the reasonable assurance of the safety or effective-
3 ness of the device will remain after the maximum
4 number of times the device is reprocessed as in-
5 tended by the person submitting the report under
6 this paragraph.”.

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

10 “(1)(1) The term ‘single-use device’ means a device
11 that is intended for one use, or on a single patient during
12 a single procedure.

13 “(2)(A) The term ‘reprocessed’, with respect to a sin-
14 gle-use device, means an original device that has pre-
15 viously been used on a patient and has been subjected to
16 additional processing and manufacturing for the purpose
17 of an additional single use on a patient. The subsequent
18 processing and manufacture of a reprocessed single-use
19 device shall result in a device that is reprocessed within
20 the meaning of this definition.

21 “(B) A single-use device that meets the definition
22 under subparagraph (A) shall be considered a reprocessed
23 device without regard to any description of the device used
24 by the manufacturer of the device or other persons, includ-

1 ing a description that uses the term ‘recycled’ rather than
2 the term ‘reprocessed’.

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

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

9 “(2) The term ‘semi-critical reprocessed single-use
10 device’ means a reprocessed single-use device that is in-
11 tended to contact intact mucous membranes and not pene-
12 trate normally sterile areas of the body.”.

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

17 “(gg) The introduction or delivery for introduction
18 into interstate commerce of any device in violation of sec-
19 tion 510(o)(3).”.

Passed the House of Representatives October 9,
2002.

Attest:

Clerk.

107TH CONGRESS
2D SESSION

H. R. 3580

AN ACT

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