

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5651

---

## 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. Debarment of accredited persons.
- Sec. 204. Designation and regulation of combination products.
- Sec. 205. Report on certain devices.
- Sec. 206. Electronic labeling.
- Sec. 207. Electronic registration.
- Sec. 208. Intended use.
- Sec. 209. Modular review.
- Sec. 210. Pediatric expertise regarding classification-panel review of premarket applications.
- Sec. 211. Internet list of class II devices exempted from requirement of premarket notification.
- Sec. 212. Study by Institute of Medicine of postmarket surveillance regarding pediatric populations.
- Sec. 213. Guidance regarding pediatric devices.
- Sec. 214. Breast implants; study by Comptroller General.
- Sec. 215. 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.
- Sec. 303. MedWatch.

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 making  
10                  additional funds available for the purpose of aug-  
11                  menting the resources of the Food and Drug Admin-  
12                  istration that are devoted to the process for the re-  
13                  view of devices and the assurance of device safety  
14                  and effectiveness so that statutorily mandated dead-  
15                  lines may be met; and

16                  (3) the fees authorized by this title will be dedi-  
17                  cated to meeting the goals identified in the letters  
18                  from the Secretary of Health and Human Services  
19                  to the Committee on Energy and Commerce of the  
20                  House of Representatives and the Committee on  
21                  Health, Education, Labor, and Pensions of the Sen-  
22                  ate, as set forth in the Congressional Record.

23   **SEC. 102. ESTABLISHMENT OF PROGRAM.**

24           (a) IN GENERAL.—Subchapter C of chapter VII of  
25   the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 379F et seq.) is amended by adding at the end the fol-  
2 lowing part:

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

4 **“SEC. 737. DEFINITIONS.**

5 “For purposes of this subchapter:

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

7 “(A) an application for approval of a de-  
8 vice submitted under section 515(c) or section  
9 351 of the Public Health Service Act; or

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

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

15 “(2) The term ‘premarket report’ means a re-  
16 port submitted under section 515(c)(2).

17 “(3) The term ‘premarket notification submis-  
18 sion’ means a report submitted under section  
19 510(k).

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

1           “(i) an application or report has been ap-  
2           proved under section 515(d), or an application  
3           has been approved under section 351 of the  
4           Public Health Service Act; or

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

7           “(B) The term ‘panel-track supplement’ means  
8           a supplement to an approved premarket application  
9           or premarket report under section 515 that requests  
10          a significant change in design or performance of the  
11          device, or a new indication for use of the device, and  
12          for which clinical data are generally necessary to  
13          provide a reasonable assurance of safety and effec-  
14          tiveness.

15          “(C) The term ‘180-day supplement’ means a  
16          supplement to an approved premarket application or  
17          premarket report under section 515 that is not a  
18          panel-track supplement and requests a significant  
19          change in components, materials, design, specifica-  
20          tion, software, color additives, or labeling.

21          “(D) The term ‘real-time supplement’ means a  
22          supplement to an approved premarket application or  
23          premarket report under section 515 that requests a  
24          minor change to the device, such as a minor change  
25          to the design of the device, software, manufacturing,

1 sterilization, or labeling, and for which the applicant  
2 has requested and the agency has granted a meeting  
3 or similar forum to jointly review and determine the  
4 status of the supplement.

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

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

14 “(A) The activities necessary for the re-  
15 view of premarket applications, premarket re-  
16 ports, supplements, and premarket notification  
17 submissions.

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

24 “(C) The inspection of manufacturing es-  
25 tablishments and other facilities undertaken as

1 part of the Secretary’s review of pending pre-  
2 market applications, premarket reports, and  
3 supplements.

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

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

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

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

1           “(H) The provision of technical assistance  
2 to device manufacturers in connection with the  
3 submission of such applications, reports, supple-  
4 ments, or submissions.

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

10           “(J) Evaluation of postmarket studies re-  
11 quired as a condition of an approval of a pre-  
12 market application under section 515 or section  
13 351 of the Public Health Service Act.

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

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

24           “(A) officers and employees of the Food  
25 and Drug Administration, contractors of the

1 Food and Drug Administration, advisory com-  
2 mittees, and costs related to such officers, em-  
3 ployees, and committees and to contracts with  
4 such contractors;

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

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

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

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

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

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

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

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

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

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

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

20           “(i) A premarket application.

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

1           “(iii) For a panel track supplement, a  
2 fee equal to the fee that applies under  
3 clause (i).

4           “(iv) For a 180-day supplement, a fee  
5 equal to 21.5 percent of the fee that ap-  
6 plies under clause (i), subject to any ad-  
7 justment under subsection (c)(3).

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

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

14           “(vii) For a premarket notification  
15 submission, a fee equal to 1.42 percent of  
16 the fee that applies under clause (i), sub-  
17 ject to any adjustment under subsection  
18 (c)(3) and any adjustment under sub-  
19 section (e)(2)(C)(ii).

20           “(B) EXCEPTIONS.—

21           “(i) HUMANITARIAN DEVICE EXEMP-  
22 TION.—An application under section  
23 520(m) is not subject to any fee under  
24 subparagraph (A).

1           “(ii) FURTHER MANUFACTURING  
2 USE.—No fee shall be required under sub-  
3 paragraph (A) for the submission of a pre-  
4 market application under section 351 of  
5 the Public Health Service Act for a prod-  
6 uct licensed for further manufacturing use  
7 only.

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

16           “(iv) PREMARKET NOTIFICATIONS BY  
17 THIRD PARTIES.—No fee shall be required  
18 under subparagraph (A) for a premarket  
19 notification submission reviewed by an ac-  
20 credited person pursuant to section 523.

21           “(v) PEDIATRIC CONDITIONS OF  
22 USE.—

23                   “(I) IN GENERAL.—No fee shall  
24 be required under subparagraph (A)  
25 for a premarket application, pre-

1 market report, or premarket notifica-  
2 tion submission if the proposed condi-  
3 tions of use for the device involved are  
4 solely for a pediatric population. No  
5 fee shall be required under such sub-  
6 paragraph for a supplement if the sole  
7 purpose of the supplement is to pro-  
8 pose conditions of use for a pediatric  
9 population.

10 “(II) SUBSEQUENT PROPOSAL OF  
11 ADULT CONDITIONS OF USE.—In the  
12 case of a person who submits a pre-  
13 market application or premarket re-  
14 port for which, under subclause (I), a  
15 fee under subparagraph (A) is not re-  
16 quired, any supplement to such appli-  
17 cation that proposes conditions of use  
18 for any adult population is subject to  
19 the fee that applies under such sub-  
20 paragraph for a premarket applica-  
21 tion.

22 “(C) PAYMENT.—The fee required by sub-  
23 paragraph (A) shall be due upon submission of  
24 the premarket application, premarket report,  
25 supplement, or premarket notification submis-

1           sion except that invoices for applications sub-  
2           mitted between October 1, 2002, and the date  
3           of the enactment of the Medical Device User  
4           Fee and Modernization Act of 2002 shall be  
5           payable on October 30, 2002. Applicants sub-  
6           mitting portions of applications pursuant to  
7           section 515(c)(3) shall pay such fees upon sub-  
8           mission of the first portion of such applications.  
9           The fees credited to fiscal year 2003 under this  
10          section shall include all fees payable from Octo-  
11          ber 1, 2002, through September 30, 2003.

12           “(D) REFUNDS.—

13                   “(i) APPLICATION REFUSED FOR FIL-  
14                   ING.—The Secretary shall refund 75 per-  
15                   cent of the fee paid under subparagraph  
16                   (A) for any application or supplement that  
17                   is refused for filing.

18                   “(ii) APPLICATION WITHDRAWN BE-  
19                   FORE FILING.—The Secretary shall refund  
20                   75 percent of the fee paid under subpara-  
21                   graph (A) for any application or supple-  
22                   ment that is withdrawn prior to the filing  
23                   decision of the Secretary.

24                   “(iii) APPLICATION WITHDRAWN BE-  
25                   FORE FIRST ACTION.—After receipt of a

1 request for a refund of the fee paid under  
2 subparagraph (A) for a premarket applica-  
3 tion, premarket report, or supplement that  
4 is withdrawn after filing but before a first  
5 action, the Secretary may return some or  
6 all of the fee. The amount of refund, if  
7 any, shall be based on the level of effort al-  
8 ready expended on the review of such ap-  
9 plication, report, or supplement. The Sec-  
10 retary shall have sole discretion to refund  
11 a fee or portion of the fee under this sub-  
12 paragraph. A determination by the Sec-  
13 retary concerning a refund under this  
14 paragraph shall not be reviewable.

15 “(b) FEE REVENUE AMOUNTS.—Except as provided  
16 in subsections (c), (d), (e), (g), and (h), the fees under  
17 subsection (a) shall be established to generate the fol-  
18 lowing revenue amounts: \$25,125,000 in fiscal year 2003;  
19 \$27,255,000 in fiscal year 2004; \$29,785,000 in fiscal  
20 year 2005; \$32,615,000 in fiscal year 2006, and  
21 \$35,000,000 in fiscal year 2007. If legislation is enacted  
22 after the date of the enactment of the Medical Device User  
23 Fee and Modernization Act of 2002 requiring the Sec-  
24 retary to fund additional costs of the retirement of Federal  
25 personnel, fee revenue amounts under this subsection shall

1 be increased in each year by the amount necessary to fully  
2 fund the portion of such additional costs that are attrib-  
3 utable to the process for the review of device applications.

4 “(c) ADJUSTMENTS.—

5 “(1) INFLATION ADJUSTMENT.—The revenues  
6 established in subsection (b) shall be adjusted by the  
7 Secretary by notice, published in the Federal Reg-  
8 ister, for a fiscal year to reflect the greater of—

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

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

22 The adjustment made each fiscal year by this sub-  
23 section shall be added on a compounded basis to the  
24 sum of all adjustments made each fiscal year after  
25 fiscal year 2003 under this subsection.

1           “(2) WORKLOAD ADJUSTMENT.—After the fee  
2 revenues established in subsection (b) are adjusted  
3 for a fiscal year for inflation in accordance with  
4 paragraph (1), the fee revenues shall, beginning with  
5 fiscal year 2004, be adjusted further each fiscal year  
6 to reflect changes in the workload of the Secretary  
7 for the process for the review of device applications.  
8 With respect to such adjustment:

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

19           “(B) Under no circumstances shall the ad-  
20 justment result in fee revenues for a fiscal year  
21 that are less than the fee revenues for the fiscal  
22 year established in subsection (b), as adjusted  
23 for inflation under paragraph (1).

24           “(3) COMPENSATING ADJUSTMENT.—After the  
25 fee revenues established in subsection (b) are ad-

1       justed for a fiscal year for inflation in accordance  
2       with paragraph (1), and for workload in accordance  
3       with paragraph (2), the fee revenues shall, beginning  
4       with fiscal year 2004, be adjusted further each fiscal  
5       year, if necessary, to reflect the cumulative amount  
6       by which collections for previous fiscal years, begin-  
7       ning with fiscal year 2003, fell below the cumulative  
8       revenue amounts for such fiscal years specified in  
9       subsection (b), adjusted for such fiscal years for in-  
10      flation in accordance with paragraph (1), and for  
11      workload in accordance with paragraph (2).

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

1       ating reserves, the adjustment under this paragraph  
2       shall not be made.

3               “(5) ANNUAL FEE SETTING.—The Secretary  
4       shall, 60 days before the start of each fiscal year  
5       after September 30, 2002, establish, for the next fis-  
6       cal year, and publish in the Federal Register, fees  
7       under subsection (a), based on the revenue amounts  
8       established under subsection (b) and the adjustment  
9       provided under this subsection and subsection  
10      (e)(2)(C)(ii), except that the fees established for fis-  
11      cal year 2003 shall be based on a premarket applica-  
12      tion fee of \$154,000.

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

18              “(d) SMALL BUSINESSES; FEE WAIVER AND FEE  
19      REDUCTION REGARDING PREMARKET APPROVAL  
20      FEES.—

21              “(1) IN GENERAL.—The Secretary shall grant a  
22      waiver of the fee required under subsection (a) for  
23      one premarket application, or one premarket report,  
24      where the Secretary finds that the applicant involved  
25      is a small business submitting its first premarket

1 application to the Secretary, or its first premarket  
2 report, respectively, for review. In addition, for sub-  
3 sequent premarket applications, premarket reports,  
4 and supplements where the Secretary finds that the  
5 applicant involved is a small business, the fees speci-  
6 fied in clauses (i) through (vi) of subsection  
7 (a)(1)(A) may be paid at a reduced rate in accord-  
8 ance with paragraph (2)(C).

9 “(2) RULES RELATING TO PREMARKET AP-  
10 PROVAL FEES.—

11 “(A) DEFINITION.—

12 “(i) IN GENERAL.—For purposes of  
13 this subsection, the term ‘small business’  
14 means an entity that reported \$30,000,000  
15 or less of gross receipts or sales in its most  
16 recent Federal income tax return for a tax-  
17 able year, including such returns of all of  
18 its affiliates, partners, and parent firms.

19 “(ii) ADJUSTMENT.—The Secretary  
20 may adjust the \$30,000,000 threshold es-  
21 tablished in clause (i) if the Secretary has  
22 evidence from actual experience that this  
23 threshold results in a reduction in revenues  
24 from premarket applications, premarket re-  
25 ports, and supplements that is 16 percent

1 or more than would occur without small  
2 business exemptions and lower fee rates.  
3 To adjust this threshold, the Secretary  
4 shall publish a notice in the Federal Reg-  
5 ister setting out the rationale for the ad-  
6 justment, and the new threshold.

7 “(B) EVIDENCE OF QUALIFICATION.—An  
8 applicant shall pay the higher fees established  
9 by the Secretary each year unless the applicant  
10 submits evidence that it qualifies for a waiver  
11 of the fee or the lower fee rate. The applicant  
12 shall support its claim that it meets the defini-  
13 tion under subparagraph (A) by submission of  
14 a copy of its most recent Federal income tax re-  
15 turn for a taxable year, and a copy of such re-  
16 turns of its affiliates, partners, and parent  
17 firms, which show an amount of gross sales or  
18 receipts that is less than the maximum estab-  
19 lished in subparagraph (A). The applicant, and  
20 each of such affiliates, partners, and parent  
21 firms, shall certify that the information pro-  
22 vided is a true and accurate copy of the actual  
23 tax forms they submitted to the Internal Rev-  
24 enue Service. If no tax forms are submitted for  
25 affiliates, partners, or parent firms, the appli-

1           cant shall certify that the applicant has no af-  
2           filiates, partners, or parent firms, respectively.

3           “(C) REDUCED FEES.—Where the Sec-  
4           retary finds that the applicant involved meets  
5           the definition under subparagraph (A), the fees  
6           established under subsection (c)(5) may be paid  
7           at a reduced rate of 38 percent of the fee estab-  
8           lished under such subsection for a premarket  
9           application, a premarket report, or a supple-  
10          ment.

11          “(D) REQUEST FOR FEE WAIVER OR RE-  
12          DUCTION.—An applicant seeking a fee waiver  
13          or reduction under this subsection shall submit  
14          supporting information to the Secretary at least  
15          60 days before the fee is required pursuant to  
16          subsection (a). The decision of the Secretary re-  
17          garding whether an entity qualifies for such a  
18          waiver or reduction is not reviewable.

19          “(e) SMALL BUSINESSES; FEE REDUCTION REGARD-  
20          ING PREMARKET NOTIFICATION SUBMISSIONS.—

21                 “(1) IN GENERAL.—Where the Secretary finds  
22                 that the applicant involved is a small business, the  
23                 fee specified in subsection (a)(1)(A)(vii) may be paid  
24                 at a reduced rate in accordance with paragraph  
25                 (2)(C).

1           “(2) RULES RELATING TO PREMARKET NOTIFI-  
2           CATION SUBMISSIONS.—

3           “(A) DEFINITION.—For purposes of this  
4           subsection, the term ‘small business’ means an  
5           entity that reported \$30,000,000 or less of  
6           gross receipts or sales in its most recent Fed-  
7           eral income tax return for a taxable year, in-  
8           cluding such returns of all of its affiliates, part-  
9           ners, and parent firms.

10           “(B) EVIDENCE OF QUALIFICATION.—An  
11           applicant shall pay the higher fees established  
12           by the Secretary each year unless the applicant  
13           submits evidence that it qualifies for the lower  
14           fee rate. The applicant shall support its claim  
15           that it meets the definition under subparagraph  
16           (A) by submission of a copy of its most recent  
17           Federal income tax return for a taxable year,  
18           and a copy of such returns of its affiliates,  
19           partners, and parent firms. which show an  
20           amount of gross sales or receipts that is less  
21           than the maximum established in subparagraph  
22           (A). The applicant, and each of such affiliates,  
23           partners, and parent firms, shall certify that  
24           the information provided is a true and accurate  
25           copy of the actual tax forms they submitted to

1 the Internal Revenue Service. If no tax forms  
2 are submitted for affiliates, partners, or parent  
3 firms, the applicant shall certify that the appli-  
4 cant has no affiliates, partners, or parent firms,  
5 respectively.

6 “(C) REDUCED FEES.—

7 “(i) IN GENERAL.—Where the Sec-  
8 retary finds that the applicant involved  
9 meets the definition under subparagraph  
10 (A), the fee for a premarket notification  
11 submission may be paid at 80 percent of  
12 the fee that applies under subsection  
13 (a)(1)(A)(vii), as adjusted under clause (ii)  
14 and as established under subsection (c)(5).

15 “(ii) ADJUSTMENT PER FEE REVENUE  
16 AMOUNT.—For fiscal year 2004 and each  
17 subsequent fiscal year, the Secretary, in  
18 setting the revenue amount under sub-  
19 section (c)(5) for premarket notification  
20 submissions, shall determine the revenue  
21 amount that would apply if all such sub-  
22 missions for the fiscal year involved paid a  
23 fee equal to 1.42 percent of the amount  
24 that applies under subsection (a)(1)(A)(i)  
25 for premarket applications, and shall ad-

1           just the fee under subsection (a)(1)(A)(vii)  
2           for premarket notification submissions  
3           such that the reduced fees collected under  
4           clause (i) of this subparagraph, when  
5           added to fees for such submissions that are  
6           not paid at the reduced rate, will equal  
7           such revenue amount for the fiscal year.

8           “(D) REQUEST FOR REDUCTION.—An ap-  
9           plicant seeking a fee reduction under this sub-  
10          section shall submit supporting information to  
11          the Secretary at least 60 days before the fee is  
12          required pursuant to subsection (a). The deci-  
13          sion of the Secretary regarding whether an enti-  
14          ty qualifies for such a reduction is not review-  
15          able.

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

22          “(g) CONDITIONS.—

23                 “(1) PERFORMANCE GOALS THROUGH FISCAL  
24                 YEAR 2005; TERMINATION OF PROGRAM AFTER FIS-  
25                 CAL YEAR 2005.—With respect to the amount that,

1 under the salaries and expenses account of the Food  
2 and Drug Administration, is appropriated for a fis-  
3 cal year for devices and radiological products:

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

16 “(ii) For each of the fiscal years 2003 and  
17 2004, if the amount so appropriated for the fis-  
18 cal year involved, excluding the amount of fees  
19 appropriated for such fiscal year, is less than  
20 the amount that applies under clause (i) for  
21 such fiscal year, the following applies:

22 “(I) The Secretary is expected to meet  
23 such goals to the extent practicable, taking  
24 into account the amounts that are avail-  
25 able to the Secretary for such purpose,

1           whether from fees under subsection (a) or  
2           otherwise.

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

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

22                  “(I) \$205,720,000 multiplied by the  
23                  adjustment factor applicable to fiscal year  
24                  2003;

1           “(II) \$205,720,000 multiplied by the  
2           adjustment factor applicable to fiscal year  
3           2004; and

4           “(III) \$205,720,000 multiplied by the  
5           adjustment factor applicable to fiscal year  
6           2005.

7           “(ii) For fiscal year 2005, if the total of  
8           the amounts so appropriated for fiscal years  
9           2003 through 2005, excluding the amount of  
10          fees appropriated for such fiscal years, is less  
11          than the sum that applies under clause (i) for  
12          fiscal year 2005, the following applies:

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

19           “(II) The Comptroller General of the  
20           United States shall submit to the Congress  
21           a report describing whether and to what  
22           extent the Secretary is meeting the per-  
23           formance goals identified for such fiscal  
24           year, and whether the Secretary will be  
25           able to meet all performance goals identi-

1           fied for fiscal year 2006. The report under  
2           the preceding sentence shall be submitted  
3           to the Congress not later than July 1,  
4           2005.

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

13                   “(i) \$205,720,000 multiplied by the  
14                   adjustment factor applicable to fiscal year  
15                   2006; and

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

19          “(D) For fiscal year 2007, fees may not be  
20          assessed under subsection (a) for the fiscal  
21          year, and the Secretary is not expected to meet  
22          any performance goals identified for the fiscal  
23          year, if—

24                   “(i) the amount so appropriated for  
25                   the fiscal year, excluding the amount of

1 fees appropriated for the fiscal year, is less  
2 than \$205,720,000 multiplied by the ad-  
3 justment factor applicable to fiscal year  
4 2007; or

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

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

19 “(h) CREDITING AND AVAILABILITY OF FEES.—

20 “(1) IN GENERAL.—Fees authorized under sub-  
21 section (a) shall be collected and available for obliga-  
22 tion only to the extent and in the amount provided  
23 in advance in appropriation Acts. Such fees are au-  
24 thorized to be appropriated to remain available until  
25 expended. Such sums as may be necessary may be

1 transferred from the Food and Drug Administration  
2 salaries and expenses appropriation account without  
3 fiscal year limitation to such appropriation account  
4 for salaries and expenses with such fiscal year limi-  
5 tation. The sums transferred shall be available solely  
6 for the process for the review of device applications.

7 “(2) COLLECTIONS AND APPROPRIATION  
8 ACTS.—

9 “(A) IN GENERAL.—The fees authorized  
10 by this section—

11 “(i) shall be retained in each fiscal  
12 year in an amount not to exceed the  
13 amount specified in appropriation Acts, or  
14 otherwise made available for obligation, for  
15 such fiscal year, and

16 “(ii) shall only be collected and avail-  
17 able to defray increases in the costs of the  
18 resources allocated for the process for the  
19 review of device applications (including in-  
20 creases in such costs for an additional  
21 number of full-time equivalent positions in  
22 the Department of Health and Human  
23 Services to be engaged in such process)  
24 over such costs, excluding costs paid from  
25 fees collected under this section, for fiscal

1           year 2002 multiplied by the adjustment  
2           factor.

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

9                   “(i) are not more than 3 percent  
10                  below the level specified in subparagraph  
11                  (A)(ii); or

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

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

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

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

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

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

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

4 and

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

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

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

19 “(i) COLLECTION OF UNPAID FEES.—In any case  
20 where the Secretary does not receive payment of a fee as-  
21 sessed under subsection (a) within 30 days after it is due,  
22 such fee shall be treated as a claim of the United States  
23 Government subject to subchapter II of chapter 37 of title  
24 31, United States Code.

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

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

13       (b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-  
14 MITTING PREMARKET REPORTS.—

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

21           (A) the premarket report is the first such  
22 report submitted to the Secretary by the per-  
23 son; and

24           (B) before October 1, 2002, the person  
25 submitted a premarket application to the Sec-

1           retary for the same device as the device for  
2           which the person is submitting the premarket  
3           report.

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

10 **SEC. 103. ANNUAL REPORTS.**

11           Beginning with fiscal year 2003, the Secretary shall  
12           prepare and submit to the Committee on Energy and  
13           Commerce of the House of Representatives and the Com-  
14           mittee on Health, Education, Labor and Pensions of the  
15           Senate a report concerning—

16           (1) the progress of the Food and Drug Admin-  
17           istration in achieving the goals identified in the let-  
18           ters described in section 101(3) during such fiscal  
19           year and the future plans of the Food and Drug Ad-  
20           ministration for meeting the goals, not later than 60  
21           days after the end of each fiscal year during which  
22           fees are collected under this part; and

23           (2) the implementation of the authority for  
24           such fees during such fiscal year, and the use, by  
25           the Food and Drug Administration, of the fees col-

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

6 **SEC. 104. POSTMARKET SURVEILLANCE.**

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

14 (1) For fiscal year 2003, an increase of  
15 \$3,000,000.

16 (2) For fiscal year 2004, an increase of  
17 \$6,000,000.

18 (3) For fiscal year 2005 and each subsequent  
19 fiscal year, an increase of such sums as may be nec-  
20 essary.

21 (b) **STUDY.**—

22 (1) **IN GENERAL.**—The Secretary of Health and  
23 Human Services (referred to in this section as the  
24 “Secretary”) shall conduct a study for the purpose  
25 of determining the following with respect to the

1 medical device user-fee program established under  
2 the amendment made by section 102:

3 (A) The impact of such program on the  
4 ability of the Food and Drug Administration to  
5 conduct postmarket surveillance on medical de-  
6 vices.

7 (B) The programmatic improvements, if  
8 any, needed for adequate postmarket surveil-  
9 lance of medical devices.

10 (C) The amount of funds needed to con-  
11 duct adequate postmarket surveillance of med-  
12 ical devices.

13 (D) The extent to which device companies  
14 comply with the postmarket surveillance re-  
15 quirements, including postmarket study com-  
16 mitments.

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

22 (2) REPORT.—Not later than January 10,  
23 2007, the Secretary shall submit to the Committee  
24 on Energy and Commerce of the House of Rep-  
25 resentatives, and the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate, a report  
2 that describes the findings of the study under para-  
3 graph (1).

4 **SEC. 105. CONSULTATION.**

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

18 (b) RECOMMENDATIONS.—The Secretary shall pub-  
19 lish in the Federal Register recommendations under sub-  
20 section (a), after negotiations with the regulated industry;  
21 shall present such recommendations to the congressional  
22 committees specified in such paragraph; shall hold a meet-  
23 ing at which the public may present its views on such rec-  
24 ommendations; and shall provide for a period of 30 days

1 for the public to provide written comments on such rec-  
2 ommendations.

3 **SEC. 106. EFFECTIVE DATE.**

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

10 **SEC. 107. SUNSET CLAUSE.**

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

14 **TITLE II—AMENDMENTS RE-**  
15 **GARDING REGULATION OF**  
16 **MEDICAL DEVICES**

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

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

21 “(g)(1) Not later than one year after the date of the  
22 enactment of this subsection, the Secretary shall, subject  
23 to the provisions of this subsection, accredit persons for  
24 the purpose of conducting inspections of establishments  
25 that manufacture, prepare, propagate, compound, or proc-

1 ess class II or class III devices that are required in section  
2 510(h), or inspections of such establishments required to  
3 register pursuant to section 510(i). The owner or operator  
4 of such an establishment that is eligible under paragraph  
5 (6) may, from the list published under paragraph (4), se-  
6 lect an accredited person to conduct such inspections.

7       “(2) Not later than 180 days after the date of enact-  
8 ment of this subsection, the Secretary shall publish in the  
9 Federal Register criteria to accredit or deny accreditation  
10 to persons who request to perform the duties specified in  
11 paragraph (1). Thereafter, the Secretary shall inform  
12 those requesting accreditation, within 60 days after the  
13 receipt of such request, whether the request for accredita-  
14 tion is adequate for review, and the Secretary shall  
15 promptly act on the request for accreditation. Any result-  
16 ing accreditation shall state that such person is accredited  
17 to conduct inspections at device establishments identified  
18 in paragraph (1). The accreditation of such person shall  
19 specify the particular activities under this subsection for  
20 which such person is accredited. In the first year following  
21 the publication in the Federal Register of criteria to ac-  
22 credit or deny accreditation to persons who request to per-  
23 form the duties specified in paragraph (1), the Secretary  
24 shall accredit no more than 15 persons who request to per-  
25 form duties specified in paragraph (1).

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

3           “(A) Such person may not be an employee of  
4 the Federal Government.

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

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

15           “(D) Such person shall not engage in the de-  
16 sign, manufacture, promotion, or sale of articles reg-  
17 ulated under this Act.

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

23                   “(i) certify that reported information accu-  
24 rately reflects data reviewed, inspection obser-  
25 vations made, other matters that relate to or

1 may influence compliance with this Act, and  
2 recommendations made during an inspection or  
3 at an inspection's closing meeting;

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

6 “(iii) treat information received, records,  
7 reports, and recommendations as confidential  
8 commercial or financial information or trade se-  
9 cret information, except such information may  
10 be made available to the Secretary;

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

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

24 “(4) The Secretary shall publish on the Internet site  
25 of the Food and Drug Administration a list of persons

1 who are accredited under paragraph (2). Such list shall  
2 be updated to ensure that the identity of each accredited  
3 person, and the particular activities for which the person  
4 is accredited, is known to the public. The updating of such  
5 list shall be no later than one month after the accredita-  
6 tion of a person under this subsection or the suspension  
7 or withdrawal of accreditation, or the modification of the  
8 particular activities for which the person is accredited.

9       “(5)(A) To ensure that persons accredited under this  
10 subsection continue to meet the standards of accredita-  
11 tion, the Secretary shall (i) audit the performance of such  
12 persons on a periodic basis through the review of inspec-  
13 tion reports and inspections by persons designated by the  
14 Secretary to evaluate the compliance status of a device es-  
15 tablishment and the performance of accredited persons,  
16 and (ii) take such additional measures as the Secretary  
17 determines to be appropriate.

18       “(B) The Secretary may withdraw accreditation of  
19 any person accredited under paragraph (2), after pro-  
20 viding notice and an opportunity for an informal hearing,  
21 when such person is substantially not in compliance with  
22 the standards of accreditation, or poses a threat to public  
23 health or fails to act in a manner that is consistent with  
24 the purposes of this subsection. The Secretary may sus-

1 pend the accreditation of such person during the pendency  
2 of the process under the preceding sentence.

3 “(6)(A) Subject to subparagraphs (B) and (C), a de-  
4 vice establishment is eligible for inspections by persons ac-  
5 credited under paragraph (2) if the following conditions  
6 are met:

7 “(i) The Secretary classified the results of the  
8 most recent inspection of the establishment pursuant  
9 to subsection (h) or (i) of section 510 as ‘no action  
10 indicated’ or ‘voluntary action indicated’.

11 “(ii) With respect to each inspection to be con-  
12 ducted by an accredited person—

13 “(I) the owner or operator of the establish-  
14 ment submits to the Secretary a notice request-  
15 ing clearance to use such a person to conduct  
16 the inspection, and the Secretary provides such  
17 clearance; and

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

22 “(iii) With respect to the devices that are man-  
23 ufactured, prepared, propagated, compounded, or  
24 processed by the establishment, at least one of such

1 devices is marketed in the United States, and the  
2 following additional conditions are met:

3 “(I) At least one of such devices is mar-  
4 keted, or is intended to be marketed, in one or  
5 more foreign countries, one of which countries  
6 certifies, accredits, or otherwise recognizes the  
7 person accredited under paragraph (2) and  
8 identified under subclause (II) of this clause.

9 “(II) The owner or operator of the estab-  
10 lishment submits to the Secretary a statement  
11 that the law of a country in which such a device  
12 is marketed, or is intended to be marketed, rec-  
13 ognizes an inspection of the establishment by  
14 the Secretary, and not later than 30 days after  
15 receiving such statement, the Secretary informs  
16 the owner or operator of the establishment that  
17 the owner or operator may submit a notice re-  
18 questing clearance under clause (ii).

19 “(iv)(I) In the case of an inspection to be con-  
20 ducted pursuant to 510(h), persons accredited under  
21 paragraph (2) did not conduct the two immediately  
22 preceding inspections of the establishment, except  
23 that the establishment may petition the Secretary  
24 for a waiver of such condition. Such a waiver may  
25 be granted only if the petition states a commercial

1 reason for the waiver; the Secretary determines that  
2 the public health would be served by granting the  
3 waiver; and the Secretary has conducted an inspec-  
4 tion of the establishment during the four-year period  
5 preceding the date on which the notice under clause  
6 (ii) is submitted to the Secretary. Such a waiver is  
7 deemed to be granted only if the petition states a  
8 commercial reason for the waiver; the Secretary has  
9 not determined that the public health would be  
10 served by granting the waiver; and the owner or op-  
11 erator of the device establishment has requested in  
12 writing, not later than 18 months following the most  
13 recent inspection of such establishment by a person  
14 accredited under paragraph (2), that the Secretary  
15 inspect the establishment and the Secretary has not  
16 conducted an inspection within 30 months after the  
17 most recent inspection. With respect to such a waiv-  
18 er that is granted or deemed to be granted, no addi-  
19 tional such waiver may be granted until after the  
20 Secretary has conducted an inspection of the estab-  
21 lishment.

22 “(II) In the case of an inspection to be con-  
23 ducted pursuant to 510(i), the Secretary periodically  
24 conducts inspections of the establishment.

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

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

12               “(I) a request to the device establishment in-  
13 volved to submit to the Secretary compliance data in  
14 accordance with clause (iii); or

15               “(II) a request to the establishment, or to the  
16 accredited person identified in the notice under sub-  
17 paragraph (A), for information concerning the rela-  
18 tionship between the establishment and such accred-  
19 ited person, including information about the number  
20 of inspections of the establishment, or other estab-  
21 lishments owned or operated by the owner or oper-  
22 ator of the establishment, that have been conducted  
23 by the accredited person.

24 The Secretary may make both such requests.

1       “(iii) The compliance data to be submitted by a de-  
2 vice establishment under clause (ii) are data describing  
3 whether the quality controls of the establishment have  
4 been sufficient for ensuring consistent compliance with  
5 current good manufacturing practice within the meaning  
6 of section 501(h), and data otherwise describing whether  
7 the establishment has consistently been in compliance with  
8 sections 501 and 502 and other applicable provisions of  
9 this Act. Such data shall include complete reports of in-  
10 spections regarding good manufacturing practice or other  
11 quality control audits that, during the preceding two-year  
12 period, were conducted at the establishment by persons  
13 other than the owner or operator of the establishment, to-  
14 gether with all other compliance data the Secretary deems  
15 necessary. Data under the preceding sentence shall dem-  
16 onstrate to the Secretary whether the establishment has  
17 facilitated consistent compliance by promptly correcting  
18 any compliance problems identified in such inspections.

19       “(iv) Not later than 60 days after receiving compli-  
20 ance data under clause (iii) from a device establishment,  
21 the Secretary shall provide or deny clearance under sub-  
22 paragraph (A). The Secretary may deny clearance if the  
23 Secretary determines that the establishment has failed to  
24 demonstrate consistent compliance for purposes of clause  
25 (iii). The Secretary shall provide to the establishment a

1 statement of such reasons for such determination. If the  
2 Secretary fails to provide such statement to the establish-  
3 ment within such 60-day period, the establishment is  
4 deemed to have such clearance.

5       “(v)(I) A request to an accredited person under  
6 clause (ii)(II) may not seek any information that is not  
7 required to be maintained by such person in records under  
8 subsection (f)(1). Not later than 60 days after receiving  
9 the information sought by the request, the Secretary shall  
10 agree to, or reject, the selection of such person by the de-  
11 vice establishment involved. The Secretary may reject the  
12 selection if the Secretary provides to the establishment a  
13 statement of the reasons for such rejection. Reasons for  
14 the rejection may include that the establishment or the  
15 accredited person, as the case may be, has failed to fully  
16 respond to the request, or that the Secretary has concerns  
17 regarding the relationship between the establishment and  
18 such accredited person. If within such 60-day period the  
19 Secretary fails to agree to or reject the selection in accord-  
20 ance with this subclause, the Secretary is deemed to have  
21 agreed to the selection.

22       “(II) If the Secretary rejects the selection of an ac-  
23 credited person by a device establishment, the establish-  
24 ment may make an additional selection of an accredited  
25 person by submitting to the Secretary a notice that identi-

1 fies the additional selection. Clauses (i) and (ii), and sub-  
2 clause (I) of this clause, apply to the selection of an ac-  
3 credited person through a notice under the preceding sen-  
4 tence in the same manner and to the same extent as such  
5 provisions apply to a selection of an accredited person  
6 through a notice under subparagraph (A).

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

18       “(C)(i) In the case of a device establishment for  
19 which the Secretary classified the results of the most re-  
20 cent inspection of the establishment by a person accredited  
21 under paragraph (2) as ‘official action indicated’, the es-  
22 tablishment, if otherwise eligible under subparagraph (A),  
23 is eligible for further inspections by persons accredited  
24 under such paragraph if (I) the Secretary issues a written  
25 statement to the owner or operator of the establishment

1 that the violations leading to such classification have been  
2 resolved, and (II) the Secretary, either upon the Sec-  
3 retary's own initiative or a petition of the owner or oper-  
4 ator of the establishment, notifies the establishment that  
5 it has clearance to use an accredited person for the inspec-  
6 tions. The Secretary shall respond to such petition within  
7 30 days after the receipt of the petition.

8       “(ii) If the Secretary denies a petition under clause  
9 (i), the device establishment involved may, after the expi-  
10 ration of one year after such denial, again petition the Sec-  
11 retary for a determination of eligibility for inspection by  
12 persons accredited by the Secretary under paragraph (2).  
13 If the Secretary denies such petition, the Secretary shall  
14 provide the establishment with such reasons for such de-  
15 nial within 60 days after the denial. If, as of the expiration  
16 of 48 months after the receipt of the first petition, the  
17 establishment has not been inspected by the Secretary in  
18 accordance with section 510(h), or has not during such  
19 period been inspected pursuant to section 510(i), as appli-  
20 cable, the establishment is eligible for further inspections  
21 by accredited persons.

22       “(7)(A) Persons accredited under paragraph (2) to  
23 conduct inspections shall record in writing their inspection  
24 observations and shall present the observations to the de-  
25 vice establishment's designated representative and de-

1 scribe each observation. Additionally, such accredited per-  
2 son shall prepare an inspection report (including for in-  
3 spections classified as ‘no action indicated’) in a form and  
4 manner consistent with such reports prepared by employ-  
5 ees and officials designated by the Secretary to conduct  
6 inspections.

7 “(B) At a minimum, an inspection report under sub-  
8 paragraph (A) shall identify the persons responsible for  
9 good manufacturing practice compliance at the inspected  
10 device establishment, the dates of the inspection, the scope  
11 of the inspection, and shall describe in detail each observa-  
12 tion identified by the accredited person, identify other  
13 matters that relate to or may influence compliance with  
14 this Act, and describe any recommendations during the  
15 inspection or at the inspection’s closing meeting.

16 “(C) An inspection report under subparagraph (A)  
17 shall be sent to the Secretary and to the designated rep-  
18 resentative of the inspected device establishment at the  
19 same time, but under no circumstances later than three  
20 weeks after the last day of the inspection. The report to  
21 the Secretary shall be accompanied by all written inspec-  
22 tion observations previously provided to the designated  
23 representative of the establishment.

24 “(D) Any statement or representation made by an  
25 employee or agent of a device establishment to a person

1 accredited under paragraph (2) to conduct inspections  
2 shall be subject to section 1001 of title 18, United States  
3 Code.

4 “(E) If at any time during an inspection by an ac-  
5 credited person the accredited person discovers a condition  
6 that could cause or contribute to an unreasonable risk to  
7 the public health, the accredited person shall immediately  
8 notify the Secretary of the identification of the device es-  
9 tablishment subject to inspection and such condition.

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

15 “(9) Nothing in this subsection affects the authority  
16 of the Secretary to inspect any device establishment pur-  
17 suant to this Act.

18 “(10)(A) For fiscal year 2005 and each subsequent  
19 fiscal year, no device establishment may be inspected dur-  
20 ing the fiscal year involved by a person accredited under  
21 paragraph (2) if—

22 “(i) of the amounts appropriated for salaries  
23 and expenses of the Food and Drug Administration  
24 for the preceding fiscal year (referred to in this sub-  
25 paragraph as the ‘first prior fiscal year’), the

1 amount obligated by the Secretary for inspections of  
2 device establishments by the Secretary was less than  
3 the adjusted base amount applicable to such first  
4 prior fiscal year; and

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

13 “(B)(i) Subject to clause (ii), the Comptroller Gen-  
14 eral of the United States shall determine the amount that  
15 was obligated by the Secretary for fiscal year 2002 for  
16 compliance activities of the Food and Drug Administra-  
17 tion with respect to devices (referred to in this subpara-  
18 graph as the ‘compliance budget’), and of such amount,  
19 the amount that was obligated for inspections by the Sec-  
20 retary of device establishments (referred to in this sub-  
21 paragraph as the ‘inspection budget’).

22 “(ii) For purposes of determinations under clause (i),  
23 the Comptroller General shall not include in the compli-  
24 ance budget or the inspection budget any amounts obli-  
25 gated for inspections of device establishments conducted

1 as part of the process of reviewing applications under sec-  
2 tion 515.

3 “(iii) Not later than March 31, 2003, the Comptroller  
4 General shall complete the determinations required in this  
5 subparagraph and submit to the Secretary and the Con-  
6 gress a reporting describing the findings made through  
7 such determinations.

8 “(C) For purposes of this paragraph:

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

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

16 “(iii) The term ‘adjusted base amount’, with re-  
17 spect to applicability to fiscal year 2004 or any sub-  
18 sequent fiscal year, means the adjusted based  
19 amount applicable to the preceding year increased by  
20 5 percent.

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

23 “(12) No later than four years after the enactment  
24 of this subsection the Comptroller General shall report to  
25 the Committee on Energy and Commerce of the House

1 of Representatives and the Committee on Health, Edu-  
2 cation, Labor and Pensions of the Senate—

3 “(A) the number of inspections pursuant to  
4 subsections (h) and (i) of section 510 conducted by  
5 accredited persons and the number of inspections  
6 pursuant to such subsections conducted by Federal  
7 employees;

8 “(B) the number of persons who sought accred-  
9 itation under this subsection, as well as the number  
10 of persons who were accredited under this sub-  
11 section;

12 “(C) the reasons why persons who sought ac-  
13 creditation, but were denied accreditation, were de-  
14 nied;

15 “(D) the number of audits conducted by the  
16 Secretary of accredited persons, the quality of in-  
17 spections conducted by accredited persons, whether  
18 accredited persons are meeting their obligations  
19 under this Act, and whether the number of audits  
20 conducted is sufficient to permit these assessments;

21 “(E) whether this subsection is achieving the  
22 goal of ensuring more information about device es-  
23 tablishment compliance is being presented to the  
24 Secretary, and whether that information is of a  
25 quality consistent with information obtained by the

1 Secretary pursuant to subsection (h) or (i) of section  
2 510;

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

7 “(G) whether the Congress should continue,  
8 modify, or terminate the program under this sub-  
9 section.

10 “(13) The Secretary shall include in the annual re-  
11 port required under section 903(g) the names of all ac-  
12 credited persons and the particular activities under this  
13 subsection for which each such person is accredited and  
14 the name of each accredited person whose accreditation  
15 has been withdrawn during the year.

16 “(14) Notwithstanding any provision of this sub-  
17 section, this subsection does not have any legal effect on  
18 any agreement described in section 803(b) between the  
19 Secretary and a foreign country.”.

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

23 (1) in paragraph (1), in the first sentence, by  
24 striking “A person accredited” and all that follows  
25 through “shall maintain records” and inserting the

1 following: “An accredited person described in para-  
2 graph (3) shall maintain records”;

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

6 (3) by adding at the end the following para-  
7 graph:

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

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

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

13 (c) CIVIL MONEY PENALTY.—Section 303(g)(1)(A)  
14 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 333(g)(1)(A)) is amended by adding at the end the fol-  
16 lowing: “For purposes of the preceding sentence, a person  
17 accredited under paragraph (2) of section 704(g) who is  
18 substantially not in compliance with the standards of ac-  
19 creditation under such section, or who poses a threat to  
20 public health or fails to act in a manner that is consistent  
21 with the purposes of such section, shall be considered to  
22 have violated a requirement of this Act that relates to de-  
23 vices.”.

1 (d) PROHIBITED ACTS.—Section 301 of the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
3 ed by adding at the end the following:

4 “(gg) The knowing failure of a person accredited  
5 under paragraph (2) of section 704(g) to comply with  
6 paragraph (7)(E) of such section; the knowing inclusion  
7 by such a person of false information in an inspection re-  
8 port under paragraph (7)(A) of such section; or the know-  
9 ing failure of such a person to include material facts in  
10 such a report.”.

11 (e) CONFORMING AMENDMENT.—Section 510(h) of  
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 360(h)) is amended by inserting after “duly designated  
14 by the Secretary” the following: “, or by persons accred-  
15 ited to conduct inspections under section 704(g),”.

16 **SEC. 202. THIRD PARTY REVIEW OF PREMARKET NOTIFICA-**  
17 **TION.**

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

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

24 (2) by adding at the end the following sub-  
25 section:

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

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

11               “(2) the number of devices reviewed under this  
12 section that were ultimately cleared by the Sec-  
13 retary;

14               “(3) the number of devices reviewed under this  
15 section that were ultimately not cleared by the Sec-  
16 retary;

17               “(4) the average time period for a review under  
18 this section (including the time it takes for the Sec-  
19 retary to review a recommendation of an accredited  
20 person under subsection (a) and determine the ini-  
21 tial device classification);

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

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

5           “(7) whether the quality of reviews under this  
6           section for devices for which no guidance has been  
7           issued is qualitatively inferior to reviews by the Sec-  
8           retary for devices for which no guidance has been  
9           issued;

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

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

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

20          “(11) any suggestions for continuation, modi-  
21          fication (including contraction or expansion of device  
22          eligibility), or termination of this section that the  
23          Secretary determines to be appropriate.”.

1 **SEC. 203. DEBARMENT OF ACCREDITED PERSONS.**

2 Section 306 of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 335a) is amended by adding at the end  
4 the following subsection:

5 “(m) DEVICES; MANDATORY DEBARMENT REGARD-  
6 ING THIRD-PARTY INSPECTIONS AND REVIEWS.—

7 “(1) IN GENERAL.—If the Secretary finds that  
8 a person has been convicted of a felony under sec-  
9 tion 301(gg), the Secretary shall debar such person  
10 from being accredited under section 523(b) or  
11 704(g)(2) and from carrying out activities under an  
12 agreement described in section 803(b).

13 “(2) DEBARMENT PERIOD.—The Secretary  
14 shall debar a person under paragraph (1) for the fol-  
15 lowing periods:

16 “(A) The period of debarment of a person  
17 (other than an individual) shall not be less than  
18 1 year or more than 10 years, but if an act  
19 leading to a subsequent debarment under such  
20 paragraph occurs within 10 years after such  
21 person has been debarred under such para-  
22 graph, the period of debarment shall be perma-  
23 nent.

24 “(B) The debarment of an individual shall  
25 be permanent.

1           “(3) TERMINATION OF DEBARMENT; JUDICIAL  
2 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),  
3 (e), (i), (j), and (l)(1) apply with respect to a person  
4 (other than an individual) or an individual who is  
5 debarred under paragraph (1) to the same extent  
6 and in the same manner as such subsections apply  
7 with respect to a person who is debarred under sub-  
8 section (a)(1), or an individual who is debarred  
9 under subsection (a)(2), respectively.”.

10 **SEC. 204. DESIGNATION AND REGULATION OF COMBINA-**  
11 **TION PRODUCTS.**

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

14           (1) in paragraph (1) -

15                   (A) in the first sentence, by striking “shall  
16 designate a component of the Food and Drug  
17 Administration” and inserting “shall in accord-  
18 ance with this subsection assign an agency cen-  
19 ter”; and

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

23           (2) by redesignating paragraph (4) as para-  
24 graph (5);

1           (3) by inserting after paragraph (3) the fol-  
2           lowing paragraph:

3           “(4)(A) Not later than 60 days after the date of the  
4           enactment of this paragraph, the Secretary shall establish  
5           within the Office of the Commissioner of Food and Drugs  
6           an office to ensure the prompt assignment of combination  
7           products to agency centers, the timely and effective pre-  
8           market review of such products, and consistent and appro-  
9           priate postmarket regulation of like products subject to  
10          the same statutory requirements to the extent permitted  
11          by law. Additionally, the office shall, in determining  
12          whether a product is to be designated a combination prod-  
13          uct, consult with the component within the Office of the  
14          Commissioner of Food and Drugs that is responsible for  
15          such determinations. Such office (referred to in this para-  
16          graph as the ‘Office’) shall have appropriate scientific and  
17          medical expertise, and shall be headed by a director.

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

22          “(C)(i) In carrying out this subsection, the Office  
23          shall ensure timely and effective premarket reviews by  
24          overseeing the timeliness of and coordinating reviews in-  
25          volving more than one agency center.

1       “(ii) 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       “(D) In carrying out this subsection, the Office shall  
7 ensure the consistency and appropriateness of postmarket  
8 regulation of like products subject to the same statutory  
9 requirements to the extent permitted by law.

10       “(E)(i) Any dispute regarding the timeliness of the  
11 premarket review of a combination product may be pre-  
12 sented to the Office for resolution, unless the dispute is  
13 clearly premature.

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

22       “(F) The Secretary, acting through the Office, shall  
23 review each agreement, guidance, or practice of the Sec-  
24 retary that is specific to the assignment of combination  
25 products to agency centers and shall determine whether

1 the agreement, guidance, or practice is consistent with the  
2 requirements of this subsection. In carrying out such re-  
3 view, the Secretary shall consult with stakeholders and the  
4 directors of the agency centers. After such consultation,  
5 the Secretary shall determine whether to continue in ef-  
6 fect, modify, revise, or eliminate such agreement, guid-  
7 ance, or practice, and shall publish in the Federal Register  
8 a notice of the availability of such modified or revised  
9 agreement, guidance or practice. Nothing in this para-  
10 graph shall be construed as preventing the Secretary from  
11 following each agreement, guidance, or practice until con-  
12 tinued, modified, revised, or eliminated.

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

18 “(i) describing the numbers and types of com-  
19 bination products under review and the timeliness in  
20 days of such assignments, reviews, and dispute reso-  
21 lutions;

22 “(ii) identifying the number of premarket re-  
23 views of such products that involved a consulting  
24 agency center; and

1           “(iii) describing improvements in the consist-  
2           ency of postmarket regulation of combination prod-  
3           ucts.

4           “(H) Nothing in this paragraph shall be construed  
5           to limit the regulatory authority of any agency center.”;  
6           and

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

9           (A) by redesignating subparagraphs (A)  
10           and (B) as subparagraphs (B) and (C), respec-  
11           tively; and

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

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

17   **SEC. 205. REPORT ON CERTAIN DEVICES.**

18           Not later than one year after the date of enactment  
19           of this Act, the Secretary of Health and Human Services  
20           shall report to the appropriate committees of Congress on  
21           the timeliness and effectiveness of device premarket re-  
22           views by centers other than the Center for Devices and  
23           Radiological Health. Such report shall include information  
24           on the times required to log in and review original submis-  
25           sions and supplements, times required to review manufac-

1 turers' replies to submissions, and times to approve or  
2 clear such devices. Such report shall contain the Sec-  
3 retary's recommendations on any measures needed to im-  
4 prove performance including, but not limited to, the alloca-  
5 tion of additional resources. Such report also shall include  
6 the Secretary's specific recommendation on whether re-  
7 sponsibility for regulating such devices should be reas-  
8 signed to those persons within the Food and Drug Admin-  
9 istration who are primarily charged with regulating other  
10 types of devices, and whether such a transfer could have  
11 a deleterious impact on the public health and on the safety  
12 of such devices.

13 **SEC. 206. ELECTRONIC LABELING.**

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

1 **SEC. 207. ELECTRONIC REGISTRATION.**

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

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

13 **SEC. 208. INTENDED USE.**

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

17 **SEC. 209. MODULAR REVIEW.**

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

21 “(3)(A) Prior to the submission of an application  
22 under this subsection, the Secretary shall accept and re-  
23 view any portion of the application that the applicant and  
24 the Secretary agree is complete, ready, and appropriate  
25 for review, except that such requirement does not apply,  
26 and the Secretary has discretion whether to accept and

1 review such portion, during any period in which, under  
2 section 738(g), the Secretary does not have the authority  
3 to collect fees under section 738(a).

4 “(B) Each portion of a submission reviewed under  
5 subparagraph (A) and found acceptable by the Secretary  
6 shall not be further reviewed after receipt of an application  
7 that satisfies the requirements of paragraph (1), unless  
8 an issue of safety or effectiveness provides the Secretary  
9 reason to review such accepted portion.

10 “(C) Whenever the Secretary determines that a por-  
11 tion of a submission under subparagraph (A) is unaccept-  
12 able, the Secretary shall, in writing, provide to the appli-  
13 cant a description of any deficiencies in such portion and  
14 identify the information that is required to correct these  
15 deficiencies, unless the applicant is no longer pursuing the  
16 application.”.

17 **SEC. 210. PEDIATRIC EXPERTISE REGARDING CLASSIFICA-**  
18 **TION-PANEL REVIEW OF PREMARKET APPLI-**  
19 **CATIONS.**

20 Section 515(c) of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C. 360e(c)), as amended by section  
22 302(c)(2)(A) of this Act, is amended in paragraph (3) by  
23 adding at the end the following: “Where appropriate, the  
24 Secretary shall ensure that such panel includes, or  
25 consults with, one or more pediatric experts.”.

1 **SEC. 211. INTERNET LIST OF CLASS II DEVICES EXEMPTED**  
2 **FROM REQUIREMENT OF PREMARKET NOTI-**  
3 **FICATION.**

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

11 **SEC. 212. STUDY BY INSTITUTE OF MEDICINE OF**  
12 **POSTMARKET SURVEILLANCE REGARDING**  
13 **PEDIATRIC POPULATIONS.**

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

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

1           (1) whether postmarket surveillance studies of  
2           implanted medical devices are of long enough dura-  
3           tion to evaluate the impact of growth and develop-  
4           ment for the number of years that the child will  
5           have the implant, and whether the studies are ade-  
6           quate to evaluate how children’s active lifestyles may  
7           affect the failure rate and longevity of the implant;  
8           and

9           (2) whether the postmarket surveillance by the  
10          Food and Drug Administration of medical devices  
11          used in pediatric populations is sufficient to provide  
12          adequate safeguards for such populations, taking  
13          into account the Secretary’s monitoring of commit-  
14          ments made at the time of approval of medical de-  
15          vices, such as phase IV trials, and the Secretary’s  
16          monitoring and use of adverse reaction reports, reg-  
17          istries, and other postmarket surveillance activities.

18          (c) REPORT TO CONGRESS.—The Secretary shall en-  
19          sure that, not later than four years after the date of the  
20          enactment of this Act, a report describing the findings of  
21          the study under subsection (a) is submitted to the Con-  
22          gress. The report shall include any recommendations of  
23          the Secretary for administrative or legislative changes to  
24          the system of postmarket surveillance referred to in such  
25          subsection.

1 **SEC. 213. GUIDANCE REGARDING PEDIATRIC DEVICES.**

2 Not later than 270 days after the date of the enact-  
3 ment of this Act, the Secretary of Health and Human  
4 Services shall issue guidance on the following:

5 (1) The type of information necessary to pro-  
6 vide reasonable assurance of the safety and effective-  
7 ness of medical devices intended for use in pediatric  
8 populations.

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

12 **SEC. 214. BREAST IMPLANTS; STUDY BY COMPTROLLER**

13 **GENERAL.**

14 (a) IN GENERAL.—The Comptroller General of the  
15 United States shall conduct a study to determine the fol-  
16 lowing with respect to breast implants:

17 (1) The content of information typically pro-  
18 vided by health professionals to women who consult  
19 with such professionals on the issue of whether to  
20 undergo breast implant surgery.

21 (2) Whether such information is provided by  
22 physicians or other health professionals, and whether  
23 the information is provided verbally or in writing,  
24 and at what point in the process of determining  
25 whether to undergo surgery is such information pro-  
26 vided.

1           (3) Whether the information presented, as a  
2 whole, provides a complete and accurate discussion  
3 of the risks and benefits of breast implants, and the  
4 extent to which women who receive such information  
5 understand the risks and benefits.

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

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

12                 (A) The content of information provided to  
13 the women during the process of obtaining the  
14 informed consent of the women to be subjects,  
15 and the extent to which such information is up-  
16 dated.

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

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

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

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

7 **SEC. 215. BREAST IMPLANTS; RESEARCH THROUGH NA-**  
8 **TIONAL INSTITUTES OF HEALTH.**

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

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

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

21 “(a) IN GENERAL.—The Director of NIH may con-  
22 duct or support research to examine the long-term health  
23 implications of silicone breast implants, both gel and sa-  
24 line filled. Such research studies may include the fol-  
25 lowing:

1           “(1) Developing and examining techniques to  
2           measure concentrations of silicone in body fluids and  
3           tissues.

4           “(2) Surveillance of recipients of silicone breast  
5           implants, including long-term outcomes and local  
6           complications.

7           “(b) 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                           **TITLE III—ADDITIONAL** 11                           **AMENDMENTS**

### 12           **SEC. 301. IDENTIFICATION OF MANUFACTURER OF MED-** 13                           **ICAL DEVICES.**

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

17           “(u) If it is a device, unless it, or an attachment  
18           thereto, prominently and conspicuously bears the name of  
19           the manufacturer of the device, a generally recognized ab-  
20           breviation of such name, or a unique and generally recog-  
21           nized symbol identifying such manufacturer, except that  
22           the Secretary may waive any requirement under this para-  
23           graph for the device if the Secretary determines that com-  
24           pliance with the requirement is not feasible for the device

1 or would compromise the provision of reasonable assur-  
2 ance of the safety or effectiveness of the device.”.

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

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

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

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

14 “(v) If it is a reprocessed single-use device, unless  
15 all labeling of the device prominently and conspicuously  
16 bears the statement ‘Reprocessed device for single use. Re-  
17 processed by \_\_\_\_.’ The name of the manufacturer of the  
18 reprocessed device shall be placed in the space identifying  
19 the person responsible for reprocessing.”.

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

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

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

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

24 “(B) In the case of each report under sub-  
25 section (k) that was submitted to the Secretary be-

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

1 submission is withdrawn, the device can no longer be  
2 legally marketed.

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

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

14 “(2) With respect to critical or semi-critical repro-  
15 cessed single-use devices that, under subsection (l) or (m),  
16 are exempt from the requirement of submitting reports  
17 under subsection (k):

18 “(A) The Secretary shall identify such devices  
19 or types of devices for which such exemptions should  
20 be terminated in order to provide a reasonable as-  
21 surance of the safety and effectiveness of the de-  
22 vices. The Secretary shall publish in the Federal  
23 Register a list of the devices or types of devices so  
24 identified, and shall revise the list as appropriate.  
25 The exemption for each device or type included on

1 the list is terminated upon the publication of the  
2 list. For each report under subsection (k) submitted  
3 pursuant to this subparagraph the Secretary shall  
4 require the validation data described in paragraph  
5 (1)(A).

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

1 to a predicate device. Upon a determination that a  
2 device is not substantially equivalent to a predicate  
3 device, the device can no longer be legally marketed.

4 “(C) In the case of semi-critical devices, the ini-  
5 tial list under subparagraph (A) shall be published  
6 not later than 18 months after the effective date of  
7 this subsection. In the case of critical devices, the  
8 initial list under such subparagraph shall be pub-  
9 lished not later than six months after such effective  
10 date.

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 (c) PREMARKET REPORT.—Section 515 of the Fed-  
22 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is  
23 amended—

24 (1) in subsection (a), in the matter after and  
25 below paragraph (2), by inserting before the period

1 the following: “or, as applicable, an approval under  
2 subsection (c)(2) of a report seeking premarket ap-  
3 proval”; and

4 (2) in subsection (c)—

5 (A) by redesignating paragraph (2) as  
6 paragraph (3); and

7 (B) by inserting after paragraph (1) the  
8 following paragraph:

9 “(2)(A) Any person may file with the Secretary a re-  
10 port seeking premarket approval for a class III device re-  
11 ferred to in subsection (a) that is a reprocessed single-  
12 use device. Such a report shall contain the following:

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

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

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

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

22 “(v) Full reports of all information, published  
23 or known to or which should be reasonably known  
24 to the applicant, concerning investigations which

1 have been made to show whether or not the device  
2 is safe or effective.

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

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

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

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

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

18 “(xi) Any additional data and information, in-  
19 cluding information of the type required in para-  
20 graph (1) for an application under such paragraph,  
21 that the Secretary determines is necessary to deter-  
22 mine whether there is reasonable assurance of safety  
23 and effectiveness for the reprocessed device.

24 “(xii) Validation data described in section  
25 510(o)(1)(A) that demonstrates that the reasonable

1 assurance of the safety or effectiveness of the device  
2 will remain after the maximum number of times the  
3 device is reprocessed as intended by the person sub-  
4 mitting such report.

5 “(B) In the case of a class III device referred to in  
6 subsection (a) that is a reprocessed single-use device:

7 “(i) Subparagraph (A) of this paragraph ap-  
8 plies in lieu of paragraph (1).

9 “(ii) Subject to clause (i), the provisions of this  
10 section apply to a report under subparagraph (A) to  
11 the same extent and in the same manner as such  
12 provisions apply to an application under paragraph  
13 (1).

14 “(iii) Each reference in other sections of this  
15 Act to an application under this section, other than  
16 such a reference in section 737 or 738, shall be con-  
17 sidered to be a reference to a report under subpara-  
18 graph (A).

19 “(iv) Each reference in other sections of this  
20 Act to a device for which an application under this  
21 section has been approved, or has been denied, sus-  
22 pended, or withdrawn, other than such a reference  
23 in section 737 or 738, shall be considered to be a  
24 reference to a device for which a report under sub-

1 paragraph (A) has been approved, or has been de-  
2 nied, suspended, or withdrawn, respectively.”.

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

6 “(1)(1) The term ‘single-use device’ means a device  
7 that is intended for one use, or on a single patient during  
8 a single procedure.

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

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

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

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

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

9       **SEC. 303. MEDWATCH.**

10       Not later than 6 months after the date of the enact-  
11 ment of this Act, the Secretary of Health and Human  
12 Services shall modify the MedWatch mandatory and vol-  
13 untary forms to facilitate the reporting of information by  
14 user facilities or distributors as appropriate relating to re-  
15 processed single-use devices, including the name of the re-  
16 processor and whether the device has been reused.

      Passed the House of Representatives October 16,  
2002.

Attest:

*Clerk.*



107TH CONGRESS  
2D SESSION

**H. R. 5651**

---

---

**AN ACT**

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