

**Calendar No. 412**108<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**S. 1881**

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

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**IN THE SENATE OF THE UNITED STATES**

NOVEMBER 18, 2003

Mr. ALEXANDER (for himself, Mrs. MURRAY, Mr. GREGG, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

NOVEMBER 24, 2003

Reported by Mr. GREGG, with an amendment

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

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, 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.**

2 This Act may be cited as the “Medical Devices Tech-  
3 nical Corrections Act”.

4 **SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC**  
5 **LAW 107-250.**

6 (a) TITLE I; FEES RELATING TO MEDICAL DE-  
7 VICES.—Part 3 of subchapter C of chapter VII of the Fed-  
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379i et  
9 seq.), as added by section 102 of Public Law 107-250  
10 (116 Stat. 1589), is amended—

11 (1) in section 737—

12 (A) in paragraph (4)(B), by striking “and  
13 for which clinical data are generally necessary  
14 to provide a reasonable assurance of safety and  
15 effectiveness” and inserting “and for which sub-  
16 stantial clinical data are necessary to provide a  
17 reasonable assurance of safety and effective-  
18 ness”;

19 (B) in paragraph (4)(D), by striking  
20 “manufacturing.”;

21 (C) in paragraph (5)(J), by striking “a  
22 premarket application” and all that follows and  
23 inserting “a premarket application or pre-  
24 market report under section 515 or a pre-  
25 market application under section 351 of the  
26 Public Health Service Act.”; and

1           (D) in paragraph (8), by striking “The  
 2           term ‘affiliate’ means a business entity that has  
 3           a relationship with a second business entity”  
 4           and inserting “The term ‘affiliate’ means a  
 5           business entity that has a relationship with a  
 6           second business entity (whether domestic or  
 7           international)”; and

8           (2) in section 738—

9           (A) in subsection (a)(1)—

10           (i) in subparagraph (A)—

11           (I) in the matter preceding clause

12           (i) by striking “subsection (d),” and  
 13           inserting “subsections (d) and (e),”;

14           (II) in clause (iv), by striking

15           “clause (i),” and all that follows and  
 16           inserting “clause (i).”; and

17           (III) in clause (vii), by striking

18           “clause (i),” and all that follows and  
 19           inserting “clause (i), subject to any

20           adjustment under subsection  
 21           (c)(2)(C)(ii).”; and

22           (ii) in subparagraph (D), in each of

23           clauses (i) and (ii), by striking “applica-  
 24           tion” and inserting “application, report,”;

1           (B) in subsection (d)(2)(B), beginning in  
 2           the second sentence, by striking “firms. which  
 3           show” and inserting “firms, which show”;

4           (C) in subsection (c)—

5           (i) in paragraph (1), by striking  
 6           “Where” and inserting “For fiscal year  
 7           2004 and each subsequent fiscal year,  
 8           where”;

9           (ii) in paragraph (2)—

10           (I) in subparagraph (B), begin-  
 11           ning in the second sentence, by strik-  
 12           ing “firms. which show” and inserting  
 13           “firms, which show”; and

14           (II) in subparagraph (C)(i), by  
 15           striking “Where” and inserting “For  
 16           fiscal year 2004 and each subsequent  
 17           fiscal year, where”;

18           (D) in subsection (f), by striking “for fil-  
 19           ing”; and

20           (E) in subsection (h)(2)—

21           (i) by striking subparagraph (A)(ii)  
 22           and inserting the following:

23           “(ii) shall only be collected and avail-  
 24           able to defray increases in the costs of the  
 25           resources allocated for the process for the

1 review of device applications (including in-  
2 creases in such costs for an additional  
3 number of full-time equivalent positions in  
4 the Department of Health and Human  
5 Services to be engaged in such process)  
6 over such costs for fiscal year 2002 when  
7 multiplied by the adjustment factor (the  
8 determination of the costs of the resources  
9 allocated for the process for the review of  
10 device applications for fiscal year 2003  
11 through 2007, for purposes of this sub-  
12 paragraph, shall not include costs paid  
13 from fees collected under this section).”;  
14 and

15 (ii) in subparagraph (B)—

16 (I) in clause (ii), by redesignating  
17 subclauses (I) and (II) as items (aa)  
18 and (bb), respectively;

19 (II) by redesignating clauses (i)  
20 and (ii) as subclauses (I) and (II), re-  
21 spectively;

22 (III) by striking “The Secretary”  
23 and inserting the following:

24 “(i) IN GENERAL.—The Secretary”;

25 and

1 (IV) by adding at the end the fol-  
 2 lowing:

3 “(ii) MORE THAN 5 PERCENT.—To  
 4 the extent such costs are more than 5 per-  
 5 cent below the specified level in subpara-  
 6 graph (A)(ii), fees may not be collected  
 7 under this section for that fiscal year.”.

8 (b) TITLE II; AMENDMENTS REGARDING REGULA-  
 9 TION OF MEDICAL DEVICES.—

10 (1) INSPECTIONS BY ACCREDITED PERSONS.—

11 Section 704(g) of the Federal Food, Drug, and Cos-  
 12 metic Act (21 U.S.C. 374(g)), as added by section  
 13 201 of Public Law 107-250 (116 Stat. 1602), is  
 14 amended—

15 (A) in paragraph (1), in the first sentence,  
 16 by striking “conducting inspections” and all  
 17 that follows and inserting “conducting inspec-  
 18 tions of establishments that manufacture, pre-  
 19 pare, propagate, compound, or process class II  
 20 or class III devices, which inspections are re-  
 21 quired under section 510(h) or are inspections  
 22 of such establishments required to register  
 23 under section 510(i).”;

24 (B) in paragraph (6)(A)—

1 (i) in clause (i), by striking “of the es-  
2 tablishment pursuant to subsection (h) or  
3 (i) of section 510” and inserting “de-  
4 scribed in paragraph (1)”;

5 (ii) in clause (ii)—

6 (I) in the matter preceding sub-  
7 clause (I)—

8 (aa) by striking “each in-  
9 spection” and inserting “inspec-  
10 tions”; and

11 (bb) by inserting “during a  
12 2-year period” after “person”;  
13 and

14 (II) in subclause (I), by striking  
15 “such a person” and inserting “an ac-  
16 credited person”;

17 (iii) in clause (iii)—

18 (I) in the matter preceding sub-  
19 clause (I), by striking “and the fol-  
20 lowing additional conditions are met:”  
21 and inserting “and 1 or both of the  
22 following additional conditions are  
23 met:”;

24 (II) in subclause (I), by striking  
25 “under subclause (II) of this clause”

1 and inserting “under clause (ii)(II)”;

2 and

3 (III) in subclause (II), by insert-  
4 ing “or by a person accredited under  
5 paragraph (2)” after “by the Sec-  
6 retary”;

7 (iv) in clause (iv)(I)—

8 (I) in the first sentence—

9 (aa) by striking “the two  
10 immediately preceding inspec-  
11 tions of the establishment” and  
12 inserting “inspections of the es-  
13 tablishment during the previous  
14 4 years”; and

15 (bb) by inserting “section”  
16 after “pursuant to”; and

17 (II) in the third sentence—

18 (aa) by striking “the peti-  
19 tion states a commercial reason  
20 for the waiver;”; and

21 (bb) by inserting “not” after  
22 “the Secretary has not deter-  
23 mined that the public health  
24 would”; and

25 (v) in clause (iv)(II)—



1 (I) by inserting “of a device es-  
2 tablishment required to register” after  
3 “to be conducted”; and

4 (II) by inserting “section” after  
5 “pursuant to”;

6 (C) in paragraph (6)(B)(iii)—

7 (i) in the first sentence, by striking “,  
8 and data otherwise describing whether the  
9 establishment has consistently been in  
10 compliance with sections 501 and 502”;  
11 and

12 (ii) in the second sentence—

13 (I) by striking “inspections” and  
14 inserting “inspectional findings”; and

15 (II) by striking “, together with  
16 all other compliance data the Sec-  
17 retary deems necessary”;

18 (D) in paragraph (6)(C)(ii), by striking “in  
19 accordance with section 510(h), or has not dur-  
20 ing such period been inspected pursuant to sec-  
21 tion 510(i), as applicable”;

22 (E) in paragraph (10)(B)(iii), by striking  
23 “a reporting” and inserting “a report”; and

24 (F) in paragraph (12)—

1 (i) by striking subparagraph (A) and  
2 inserting the following:

3 “(A) the number of inspections conducted  
4 by accredited persons pursuant to this sub-  
5 section and the number of inspections con-  
6 ducted by Federal employees pursuant to sec-  
7 tion 510(h) and of device establishments re-  
8 quired to register under section 510(i);” and

9 (ii) in subparagraph (E), by striking  
10 “obtained by the Secretary” and all that  
11 follows and inserting “obtained by the Sec-  
12 retary pursuant to inspections conducted  
13 by Federal employees;”.

14 (2) OTHER CORRECTIONS.—Section 502(f) of  
15 the Federal Food, Drug, and Cosmetic Act (21  
16 U.S.C. 352(f)), as amended by section 206 of Public  
17 Law 107–250 (116 Stat. 1613), is amended, in the  
18 last sentence—

19 (A) by inserting “or by a health care pro-  
20 fessional and required labeling for in vitro diag-  
21 nostic devices intended for use by health care  
22 professionals or in blood establishments” after  
23 “in health care facilities”;

24 (B) by inserting a comma after “means”;

1           (C) by striking “requirements of law and,  
2           that” and inserting “requirements of law, and  
3           that”;

4           (D) by striking “the manufacturer affords  
5           health care facilities the opportunity” and in-  
6           serting “the manufacturer affords such users  
7           the opportunity”; and

8           (E) by striking “the health care facility”.

9           (c) TITLE III; ADDITIONAL AMENDMENTS.—Section  
10          510(o) of the Federal Food, Drug, and Cosmetic Act (21  
11          U.S.C. 360(o)), as added by section 302(b) of Public Law  
12          107–250 (116 Stat. 1616), is amended—

13           (1) in paragraph (1)(B), by striking “, adulter-  
14           ated” and inserting “or adulterated”; and

15           (2) in paragraph (2)—

16           (A) in subparagraph (B), by striking “,  
17           adulterated” and inserting “or adulterated”;  
18           and

19           (B) in subparagraph (E), by striking  
20           “semicritical” and inserting “semi-critical”.

21          (d) MISCELLANEOUS CORRECTIONS.—

22           (1) CERTAIN AMENDMENTS TO SECTION 515.—

23           (A) IN GENERAL.—

24           (i) TECHNICAL CORRECTION.—Section  
25          515(e) of the Federal Food, Drug, and

1           Cosmetic Act (21 U.S.C. 360e(e)), as  
 2           amended by sections 209 and 302(e)(2)(A)  
 3           of Public Law 107-250 (116 Stat. 1613,  
 4           1618), is amended by redesignating para-  
 5           graph (3) (as added by section 209 of such  
 6           Public Law) as paragraph (4).

7           (ii) MODULAR REVIEW.—Section  
 8           515(e)(4)(B) of the Federal Food, Drug,  
 9           and Cosmetic Act (21 U.S.C.  
 10          360e(e)(4)(B)) is amended by striking  
 11          “unless an issue of safety” and inserting  
 12          “unless a significant issue of safety”.

13          (B) CONFORMING AMENDMENT.—Section  
 14          210 of Public Law 107-250 (116 Stat. 1614)  
 15          is amended by striking “, as amended” and all  
 16          that follows through “by adding” and inserting  
 17          “is amended in paragraph (3), as redesignated  
 18          by section 302(e)(2)(A) of this Act, by adding”.

19          (2) CERTAIN AMENDMENTS TO SECTION 738.—

20          (A) IN GENERAL.—Section 738(a) of the  
 21          Federal Food, Drug, and Cosmetic Act (21  
 22          U.S.C. 379j(a)), as amended by subsection (a),  
 23          is amended—

24                  (i) in the matter preceding paragraph

25                  (1)—

1                   (I) by striking “(a) TYPES OF  
2                   FEES.—Beginning on” and inserting  
3                   the following:

4                   “(a) TYPES OF FEES.—

5                   “(1) IN GENERAL.—Beginning on”; and

6                   (II) by striking “this section as  
7                   follows:” and inserting “this section.”;  
8                   and

9                   (ii) by striking “(1) PREMARKET AP-  
10                  PLICATION,” and inserting the following:

11                  “(2) PREMARKET APPLICATION.”

12                  (B) CONFORMING AMENDMENTS.—Section  
13                  738 of the Federal Food, Drug, and Cosmetic  
14                  Act (21 U.S.C. 379j), as amended by subpara-  
15                  graph (A), is amended—

16                  (i) in subsection (d)(1), in the last  
17                  sentence, by striking “subsection  
18                  (a)(1)(A)” and inserting “subsection  
19                  (a)(2)(A)”;

20                  (ii) in subsection (e)(1), by striking  
21                  “subsection (a)(1)(A)(vii)” and inserting  
22                  “subsection (a)(2)(A)(vii)”;

23                  (iii) in subsection (e)(2)(C)—

24                  (I) in each of clauses (i) and (ii),  
25                  by striking “subsection (a)(1)(A)(vii)”

1                   and           inserting       “subsection  
 2                   (a)(2)(A)(vii)”;  
 3                   (H) in clause (ii), by striking  
 4                   “subsection (a)(1)(A)(i)” and insert-  
 5                   ing “subsection (a)(2)(A)(i)”;  
 6                   (iv) in subsection (j), by striking  
 7                   “subsection (a)(1)(D),” and inserting  
 8                   “subsection (a)(2)(D),”.

9                   (C) ~~ADDITIONAL CONFORMING AMEND-~~  
 10                   ~~MENT.~~—Section 102(b)(1) of Public Law 107-  
 11                   250 (116 Stat. 1600) is amended, in the matter  
 12                   preceding subparagraph (A), by striking “sec-  
 13                   tion 738(a)(1)(A)(ii)” and inserting “section  
 14                   738(a)(2)(A)(ii)”.

15                   (3) ~~PUBLIC LAW 107-250.~~—Public Law 107-  
 16                   250 is amended—

17                   (A) in section 102(a) (116 Stat. 1589), by  
 18                   striking “(21 U.S.C. 379F et seq.)” and insert-  
 19                   ing “(21 U.S.C. 379f et seq.)”;

20                   (B) in section 102(b) (116 Stat. 1600)—

21                   (i) by striking paragraph (2);

22                   (ii) in paragraph (1), by redesignating  
 23                   subparagraphs (A) and (B) as paragraphs  
 24                   (1) and (2), respectively; and

25                   (iii) by striking:

1       “(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-  
2 MITTING PREMARKET REPORTS.—

3           “(1) IN GENERAL.—A person submitting a pre-  
4 market report” and inserting:

5       “(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-  
6 MITTING PREMARKET REPORTS.—A person submitting a  
7 premarket report”;

8           (C) in section 212(b)(2) (116 Stat. 1614),  
9 by striking “, such as phase IV trials,”; and

10          (D) in section 301(b) (116 Stat. 1616), by  
11 striking “18 months” and inserting “36  
12 months”.

13 **SEC. 3. HUMANITARIAN DEVICE EXEMPTION AND PEDI-**  
14 **ATRIC PRODUCTS.**

15       (a) AMENDMENT TO FEDERAL FOOD, DRUG, AND  
16 COSMETIC ACT.—Section 520(m)(3) of the Federal Food,  
17 Drug, and Cosmetic Act (21 U.S.C. 360j(m)(3)) is amend-  
18 ed to read as follows:

19       “(3) Excluding devices intended for the treatment or  
20 diagnosis of diseases or conditions that affect pediatric pa-  
21 tients, no person granted an exemption under paragraph  
22 (2) with respect to a device may sell the device for an  
23 amount that exceeds the costs of research and develop-  
24 ment, fabrication, and distribution of the device. The ex-  
25 clusion from the prohibition under the previous sentence

1 for devices intended for the treatment or diagnosis of dis-  
2 eases or conditions that affect pediatric patients, shall not  
3 apply in the case of a request for an exemption under  
4 paragraph (2) made on or after October 1, 2007. In this  
5 paragraph, the term ‘pediatric patient’ means a patient  
6 who is 14 years of age or younger at the time of diagnosis  
7 or treatment.”.

8 (b) REPORT.—Not later than October 1, 2006, the  
9 Comptroller General of the United States, in consultation  
10 with the Secretary of Health and Human Services, shall  
11 submit to Congress a report that addresses the effective-  
12 ness of section 520(m) of the Federal Food, Drug, and  
13 Cosmetic Act (21 U.S.C. 360j(m)) in ensuring the devel-  
14 opment of devices designed to treat or diagnose diseases  
15 or conditions that affect fewer than 4,000 pediatric pa-  
16 tients in the United States. Such report shall include the  
17 number and importance of devices for pediatric patients  
18 that are receiving exemptions under section 520(m) of the  
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 360j(m)).

21 **SECTION 1. SHORT TITLE.**

22 *This Act may be cited as the “Medical Devices Tech-*  
23 *nical Corrections Act”.*



1 **SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW**

2 **107-250.**

3 (a) *TITLE I; FEES RELATING TO MEDICAL DE-*  
4 *VICES.—Part 3 of subchapter C of chapter VII of the Fed-*  
5 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.),*  
6 *as added by section 102 of Public Law 107-250 (116 Stat.*  
7 *1589), is amended—*

8 (1) *in section 737—*

9 (A) *in paragraph (4)(B), by striking “and*  
10 *for which clinical data are generally necessary to*  
11 *provide a reasonable assurance of safety and ef-*  
12 *fectiveness” and inserting “and for which sub-*  
13 *stantial clinical data are necessary to provide a*  
14 *reasonable assurance of safety and effectiveness”;*

15 (B) *in paragraph (4)(D), by striking “man-*  
16 *ufacturing,”;*

17 (C) *in paragraph (5)(J), by striking “a*  
18 *premarket application” and all that follows and*  
19 *inserting “a premarket application or premarket*  
20 *report under section 515 or a premarket applica-*  
21 *tion under section 351 of the Public Health Serv-*  
22 *ice Act.”; and*

23 (D) *in paragraph (8), by striking “The*  
24 *term ‘affiliate’ means a business entity that has*  
25 *a relationship with a second business entity”*  
26 *and inserting “The term ‘affiliate’ means a busi-*

1           *ness entity that has a relationship with a second*  
 2           *business entity (whether domestic or inter-*  
 3           *national)”; and*

4           (2) *in section 738—*

5                   (A) *in subsection (a)(1)—*

6                           (i) *in subparagraph (A)—*

7                                   (I) *in the matter preceding clause*  
 8                                   (i) *by striking “subsection (d),” and*  
 9                                   *inserting “subsections (d) and (e),”;*

10                                  (II) *in clause (iv), by striking*  
 11                                  *“clause (i),” and all that follows and*  
 12                                  *inserting “clause (i).”;* and

13                                  (III) *in clause (vii), by striking*  
 14                                  *“clause (i),” and all that follows and*  
 15                                  *inserting “clause (i), subject to any ad-*  
 16                                  *justment under subsection*  
 17                                  *(e)(2)(C)(ii).”;* and

18                                  (ii) *in subparagraph (D), in each of*  
 19                                  *clauses (i) and (ii), by striking “applica-*  
 20                                  *tion” and inserting “application, report,”;*

21                                  (B) *in subsection (d)(2)(B), beginning in*  
 22                                  *the second sentence, by striking “firms. which*  
 23                                  *show” and inserting “firms, which show”;*

24                                  (C) *in subsection (e)—*

1           (i) in paragraph (1), by striking  
2           “Where” and inserting “For fiscal year  
3           2004 and each subsequent fiscal year,  
4           where”; and

5           (ii) in paragraph (2)—

6                 (I) in subparagraph (B), begin-  
7                 ning in the second sentence, by striking  
8                 “firms, which show” and inserting  
9                 “firms, which show”; and

10                (II) in subparagraph (C)(i), by  
11                striking “Where” and inserting “For  
12                fiscal year 2004 and each subsequent  
13                fiscal year, where”;

14           (D) in subsection (f), by striking “for fil-  
15           ing”; and

16           (E) in subsection (h)(2)(B)—

17                 (i) in clause (ii), by redesignating sub-  
18                 clauses (I) and (II) as items (aa) and (bb),  
19                 respectively;

20                 (ii) by redesignating clauses (i) and  
21                 (ii) as subclauses (I) and (II), respectively;

22                 (iii) by striking “The Secretary” and  
23                 inserting the following:

24                 “(i) IN GENERAL.—The Secretary”;  
25                 and

1                   (iv) by adding at the end the following:

2                   “(ii) *MORE THAN 5 PERCENT.*—To the  
3                   extent such costs are more than 5 percent  
4                   below the specified level in subparagraph  
5                   (A)(ii), fees may not be collected under this  
6                   section for that fiscal year.”.

7           (b) *TITLE II; AMENDMENTS REGARDING REGULATION*  
8 *OF MEDICAL DEVICES.*—

9                   (1) *INSPECTIONS BY ACCREDITED PERSONS.*—

10           Section 704(g) of the Federal Food, Drug, and Cos-  
11           metic Act (21 U.S.C. 374(g)), as added by section 201  
12           of Public Law 107–250 (116 Stat. 1602), is amend-  
13           ed—

14                   (A) in paragraph (1), in the first sentence,  
15                   by striking “conducting inspections” and all that  
16                   follows and inserting “conducting inspections of  
17                   establishments that manufacture, prepare, propa-  
18                   gate, compound, or process class II or class III  
19                   devices, which inspections are required under  
20                   section 510(h) or are inspections of such estab-  
21                   lishments required to register under section  
22                   510(i).”;

23                   (B) in paragraph (6)(A)—

24                   (i) in clause (i), by striking “of the es-  
25                   tablishment pursuant to subsection (h) or

- 1                   *(i) of section 510” and inserting “described*  
2                   *in paragraph (1)”;*
- 3                   *(ii) in clause (ii)—*
- 4                   *(I) in the matter preceding sub-*  
5                   *clause (I)—*
- 6                   *(aa) by striking “each in-*  
7                   *spection” and inserting “inspec-*  
8                   *tions”; and*
- 9                   *(bb) by inserting “during a*  
10                   *2-year period” after “person”;*  
11                   *and*
- 12                   *(II) in subclause (I), by striking*  
13                   *“such a person” and inserting “an ac-*  
14                   *credited person”;*
- 15                   *(iii) in clause (iii)—*
- 16                   *(I) in the matter preceding sub-*  
17                   *clause (I), by striking “and the fol-*  
18                   *lowing additional conditions are met:”*  
19                   *and inserting “and 1 or both of the fol-*  
20                   *lowing additional conditions are met.”;*
- 21                   *(II) in subclause (I), by striking*  
22                   *“under subclause (II) of this clause”*  
23                   *and inserting “under clause (ii)(II)”;*  
24                   *and*

1                   (III) in subclause (II), by insert-  
2                   ing “or by a person accredited under  
3                   paragraph (2)” after “by the Sec-  
4                   retary”;

5                   (iv) in clause (iv)(I)—

6                   (I) in the first sentence—

7                   (aa) by striking “the two im-  
8                   mediately preceding inspections of  
9                   the establishment” and inserting  
10                  “inspections of the establishment  
11                  during the previous 4 years”; and

12                  (bb) by inserting “section”  
13                  after “pursuant to”;

14                  (II) in the third sentence—

15                  (aa) by striking “the petition  
16                  states a commercial reason for the  
17                  waiver;”; and

18                  (bb) by inserting “not” after  
19                  “the Secretary has not determined  
20                  that the public health would”; and

21                  (III) in the fourth sentence, by  
22                  striking “granted until” and inserting  
23                  “granted or deemed to be granted  
24                  until”; and

25                  (v) in clause (iv)(II)—

- 1                   (I) by inserting “of a device estab-
- 2                   lishment required to register” after “to
- 3                   be conducted”; and
- 4                   (II) by inserting “section” after
- 5                   “pursuant to”;
- 6                   (C) in paragraph (6)(B)(iii)—
- 7                   (i) in the first sentence, by striking “,
- 8                   and data otherwise describing whether the
- 9                   establishment has consistently been in com-
- 10                  pliance with sections 501 and 502”; and
- 11                  (ii) in the second sentence—
- 12                  (I) by striking “inspections” and
- 13                  inserting “inspectional findings”; and
- 14                  (II) by inserting “relevant” after
- 15                  “together with all other”;
- 16                  (D) in paragraph (6)(C)(ii), by striking “in
- 17                  accordance with section 510(h), or has not dur-
- 18                  ing such period been inspected pursuant to sec-
- 19                  tion 510(i), as applicable”;
- 20                  (E) in paragraph (10)(B)(iii), by striking
- 21                  “a reporting” and inserting “a report”; and
- 22                  (F) in paragraph (12)—
- 23                  (i) by striking subparagraph (A) and
- 24                  inserting the following:

1           “(A) the number of inspections conducted by  
2           accredited persons pursuant to this subsection  
3           and the number of inspections conducted by Fed-  
4           eral employees pursuant to section 510(h) and of  
5           device establishments required to register under  
6           section 510(i);” and

7                       (ii) in subparagraph (E), by striking  
8                       “obtained by the Secretary” and all that  
9                       follows and inserting “obtained by the Sec-  
10                      retary pursuant to inspections conducted by  
11                      Federal employees;”.

12           (2) OTHER CORRECTIONS.—

13                       (A) PROHIBITED ACTS.—Section 301(gg) of  
14                      the Federal Food, Drug, and Cosmetic Act (21  
15                      U.S.C. 331(gg)), as amended by section 201(d) of  
16                      Public Law 107–250 (116 Stat. 1609), is amend-  
17                      ed to read as follows:

18           “(gg) The knowing failure to comply with paragraph  
19           (7)(E) of section 704(g); the knowing inclusion by a person  
20           accredited under paragraph (2) of such section of false in-  
21           formation in an inspection report under paragraph (7)(A)  
22           of such section; or the knowing failure of such a person to  
23           include material facts in such a report.”.

24                       (B) ELECTRONIC LABELING.—Section  
25                      502(f) of the Federal Food, Drug, and Cosmetic



1           *Act (21 U.S.C. 352(f)), as amended by section*  
2           *206 of Public Law 107–250 (116 Stat. 1613), is*  
3           *amended, in the last sentence—*

4                   (i) *by inserting “or by a health care*  
5                   *professional and required labeling for in*  
6                   *vitro diagnostic devices intended for use by*  
7                   *health care professionals or in blood estab-*  
8                   *lishments” after “in health care facilities”;*

9                   (ii) *by inserting a comma after*  
10                   *“means”;*

11                   (iii) *by striking “requirements of law*  
12                   *and, that” and inserting “requirements of*  
13                   *law, and that”;*

14                   (iv) *by striking “the manufacturer af-*  
15                   *fords health care facilities the opportunity”*  
16                   *and inserting “the manufacturer affords*  
17                   *such users the opportunity”;* and

18                   (v) *by striking “the health care facil-*  
19                   *ity”.*

20           (c) *TITLE III; ADDITIONAL AMENDMENTS.—*

21                   (1) *EFFECTIVE DATE.—Section 301(b) of Public*  
22                   *Law 107–250 (116 Stat. 1616), is amended by strik-*  
23                   *ing “18 months” and inserting “36 months”.*

24                   (2) *PREMARKET NOTIFICATION.—Section 510(o)*  
25                   *of the Federal Food, Drug, and Cosmetic Act (21*

1 U.S.C. 360(o)), as added by section 302(b) of Public  
 2 Law 107–250 (116 Stat. 1616), is amended—

3 (A) in paragraph (1)(B), by striking “,  
 4 adulterated” and inserting “or adulterated”; and

5 (B) in paragraph (2)—

6 (i) in subparagraph (B), by striking “,  
 7 adulterated” and inserting “or adulter-  
 8 ated”; and

9 (ii) in subparagraph (E), by striking  
 10 “semicritical” and inserting “semi-critical”.

11 (d) MISCELLANEOUS CORRECTIONS.—

12 (1) CERTAIN AMENDMENTS TO SECTION 515.—

13 (A) IN GENERAL.—

14 (i) TECHNICAL CORRECTION.—Section  
 15 515(c) of the Federal Food, Drug, and Cos-  
 16 metic Act (21 U.S.C. 360e(c)), as amended  
 17 by sections 209 and 302(c)(2)(A) of Public  
 18 Law 107–250 (116 Stat. 1613, 1618), is  
 19 amended by redesignating paragraph (3)  
 20 (as added by section 209 of such Public  
 21 Law) as paragraph (4).

22 (ii) MODULAR REVIEW.—Section  
 23 515(c)(4)(B) of the Federal Food, Drug, and  
 24 Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is  
 25 amended by striking “unless an issue of

1           *safety*” and inserting “*unless a significant*  
2           *issue of safety*”.

3           (B) *CONFORMING AMENDMENT.*—Section  
4           210 of Public Law 107–250 (116 Stat. 1614) is  
5           amended by striking “, as amended” and all that  
6           follows through “by adding” and inserting “is  
7           amended in paragraph (3), as redesignated by  
8           section 302(c)(2)(A) of this Act, by adding”.

9           (2) *CERTAIN AMENDMENTS TO SECTION 738.*—

10           (A) *IN GENERAL.*—Section 738(a) of the  
11           *Federal Food, Drug, and Cosmetic Act* (21  
12           U.S.C. 379j(a)), as amended by subsection (a), is  
13           amended—

14                   (i) *in the matter preceding paragraph*

15                   (1)—

16                           (I) *by striking “(a) TYPES OF*  
17                           *FEES.—Beginning on” and inserting*  
18                           *the following:*

19                   “(a) *TYPES OF FEES.*—

20                           “(1) *IN GENERAL.—Beginning on*”; and

21                                   (II) *by striking “this section as*  
22                                   *follows:” and inserting “this section.”;*  
23                                   and

1                   (ii) by striking “(1) *PREMARKET AP-*  
2                   *PLICATION,*” and inserting the following:  
3                   “(2) *PREMARKET APPLICATION,*”.

4                   (B) *CONFORMING AMENDMENTS.*—Section  
5                   738 of the *Federal Food, Drug, and Cosmetic Act*  
6                   (21 U.S.C. 379j), as amended by subparagraph  
7                   (A), is amended—

8                   (i) in subsection (d)(1), in the last sen-  
9                   tence, by striking “subsection (a)(1)(A)”  
10                  and inserting “subsection (a)(2)(A)”;

11                  (ii) in subsection (e)(1), by striking  
12                  “subsection (a)(1)(A)(vii)” and inserting  
13                  “subsection (a)(2)(A)(vii)”;

14                  (iii) in subsection (e)(2)(C)—

15                         (I) in each of clauses (i) and (ii),  
16                         by striking “subsection (a)(1)(A)(vii)”  
17                         and inserting “subsection  
18                         (a)(2)(A)(vii)”;

19                         (II) in clause (ii), by striking  
20                         “subsection (a)(1)(A)(i)” and inserting  
21                         “subsection (a)(2)(A)(i)”;

22                         (iv) in subsection (j), by striking “sub-  
23                         section (a)(1)(D),” and inserting “sub-  
24                         section (a)(2)(D),”.

1           (C) *ADDITIONAL CONFORMING AMEND-*  
 2           *MENT.—Section 102(b)(1) of Public Law 107–*  
 3           *250 (116 Stat. 1600) is amended, in the matter*  
 4           *preceding subparagraph (A), by striking “section*  
 5           *738(a)(1)(A)(ii)” and inserting “section*  
 6           *738(a)(2)(A)(ii)”.*

7           (3) *PUBLIC LAW 107–250.—Public Law 107–250*  
 8           *is amended—*

9           (A) *in section 102(a) (116 Stat. 1589), by*  
 10           *striking “(21 U.S.C. 379F et seq.)” and inserting*  
 11           *“(21 U.S.C. 379f et seq.)”;*

12           (B) *in section 102(b) (116 Stat. 1600)—*  
 13           (i) *by striking paragraph (2);*  
 14           (ii) *in paragraph (1), by redesignating*  
 15           *subparagraphs (A) and (B) as paragraphs*  
 16           *(1) and (2), respectively; and*  
 17           (iii) *by striking:*

18           “(b) *FEE EXEMPTION FOR CERTAIN ENTITIES SUB-*  
 19           *MITTING PREMARKET REPORTS.—*

20           “(1) *IN GENERAL.—A person submitting a pre-*  
 21           *market report” and inserting:*

22           “(b) *FEE EXEMPTION FOR CERTAIN ENTITIES SUB-*  
 23           *MITTING PREMARKET REPORTS.—A person submitting a*  
 24           *premarket report”; and*

1                   (C) in section 212(b)(2) (116 Stat. 1614),  
2                   by striking “, such as phase IV trials,”.

3 **SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DE-**  
4                   **VICES INTENDED FOR CHILDREN.**

5           Not later than 180 days after the date of enactment  
6 of this Act, the Secretary of Health and Human Services  
7 shall submit to the Committee on Health, Education, Labor,  
8 and Pensions of the Senate and the Committee on Energy  
9 and Commerce of the House of Representatives a report on  
10 the barriers to the availability of devices intended for the  
11 treatment or diagnosis of diseases and conditions that affect  
12 children. The report shall include any recommendations of  
13 the Secretary of Health and Human Services for changes  
14 to existing statutory authority, regulations, or agency pol-  
15 icy or practice to encourage the invention and development  
16 of such devices.



**Calendar No. 412**

108TH CONGRESS  
1ST SESSION

**S. 1881**

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

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NOVEMBER 24, 2003

Reported with an amendment