

# Union Calendar No. 250

108TH CONGRESS  
2D SESSION

# S. 1881

[Report No. 108–433]

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2003

Referred to the Committee on Energy and Commerce

MARCH 9, 2004

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

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

[For text of Senate passed bill, see copy of bill as referred in the House of Representatives  
on December 8, 2003]

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## AN ACT

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,*

3       **SECTION 1. SHORT TITLE.**

4       *This Act may be cited as the “Medical Devices Tech-*  
5       *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-*

ness entity that has a relationship with a second business entity (whether domestic or international)”; and

(2) in section 738—

(A) in subsection (a)(1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause

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

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

(III) in clause (vii), by striking “clause (i),” and all that follows and inserting “clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).”; and

(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking “application” and inserting “application, report,”;

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

(C) in subsection (e)—

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

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking “firms. which show” and inserting “firms, which show”; and

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

(D) in subsection (f), by striking “for filing”; and

(E) in subsection (h)(2)(B)—

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

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

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

“(i) IN GENERAL.—The Secretary”;  
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 (5)(B), in the first sen-  
24                   tence, by striking “or poses” and all that follows  
25                   through the period and inserting “poses a threat

1        *to public health, fails to act in a manner that*  
 2        *is consistent with the purposes of this subsection,*  
 3        *or where the Secretary determines that there is*  
 4        *a financial conflict of interest in the relationship*  
 5        *between the accredited person and the owner or*  
 6        *operator of a device establishment that the ac-*  
 7        *credited person has inspected under this sub-*  
 8        *section.”;*

9                *(C) in paragraph (6)(A)—*

10                *(i) in clause (i), by striking “of the es-*  
 11                *tablishment pursuant to subsection (h) or*  
 12                *(i) of section 510” and inserting “described*  
 13                *in paragraph (1)”;*

14                *(ii) in clause (ii)—*

15                *(I) in the matter preceding sub-*  
 16                *clause (I)—*

17                *(aa) by striking “each in-*  
 18                *spection” and inserting “inspec-*  
 19                *tions”;* and

20                *(bb) by inserting “during a*  
 21                *2-year period” after “person”;*  
 22                and

23                *(II) in subclause (I), by striking*  
 24                *“such a person” and inserting “an ac-*  
 25                *credited person”;*

1 *(iii) in clause (iii)—*

2 *(I) in the matter preceding sub-*  
 3 *clause (I), by striking “and the fol-*  
 4 *lowing additional conditions are met:”*  
 5 *and inserting “and 1 or both of the fol-*  
 6 *lowing additional conditions are met.”;*

7 *(II) in subclause (I), by striking*  
 8 *“accredited” and all that follows*  
 9 *through the period and inserting “(ac-*  
 10 *credited under paragraph (2) and*  
 11 *identified under clause (ii)(II)) as a*  
 12 *person authorized to conduct such in-*  
 13 *spections of device establishments.”;*  
 14 *and*

15 *(III) in subclause (II), by insert-*  
 16 *ing “or by a person accredited under*  
 17 *paragraph (2)” after “by the Sec-*  
 18 *retary”;*

19 *(iv) in clause (iv)(I)—*

20 *(I) in the first sentence—*

21 *(aa) by striking “the two im-*  
 22 *mediately preceding inspections of*  
 23 *the establishment” and inserting*  
 24 *“inspections of the establishment*  
 25 *during the previous 4 years”; and*

1                   (bb) by inserting “section”  
2                   after “pursuant to”;

3                   (II) in the third sentence—

4                   (aa) by striking “the petition  
5                   states a commercial reason for the  
6                   waiver;”; and

7                   (bb) by inserting “not” after  
8                   “the Secretary has not determined  
9                   that the public health would”; and

10                  (III) in the fourth sentence, by  
11                  striking “granted until” and inserting  
12                  “granted or deemed to be granted  
13                  until”; and

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

15                  (I) by inserting “of a device estab-  
16                  lishment required to register” after “to  
17                  be conducted”; and

18                  (II) by inserting “section” after  
19                  “pursuant to”;

20                  (D) in paragraph (6)(B)(iii)—

21                  (i) in the first sentence, by striking “,  
22                  and data otherwise describing whether the  
23                  establishment has consistently been in com-  
24                  pliance with sections 501 and 502 and  
25                  other” and inserting “and with other”; and



1                   (ii) in the second sentence—

2                   (I) by striking “inspections” and  
3                   inserting “inspectional findings”; and

4                   (II) by inserting “relevant” after  
5                   “together with all other”;

6                   (E) in paragraph (6)(B)(iv)—

7                   (i) by inserting “(I)” after “(iv)”; and

8                   (ii) by adding at the end the following:

9           “(II) If, during the two-year period following clear-  
10   ance under subparagraph (A), the Secretary determines  
11   that the device establishment is substantially not in compli-  
12   ance with this Act, the Secretary may, after notice and a  
13   written response, notify the establishment that the eligi-  
14   bility of the establishment for the inspections by accredited  
15   persons has been suspended.”;

16                   (F) 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                   (G) in paragraph (10)(B)(iii), by striking  
21                   “a reporting” and inserting “a report”; and

22                   (H) in paragraph (12)—

23                   (i) by striking subparagraph (A) and  
24                   inserting the following:

1           “(A) *the number of inspections conducted by ac-*  
 2           *credited persons pursuant to this subsection and the*  
 3           *number of inspections conducted by Federal employees*  
 4           *pursuant to section 510(h) and of device establish-*  
 5           *ments required to register under section 510(i);”*; and

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

11           (2) *OTHER CORRECTIONS.—*

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

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

23                      (B)    *ELECTRONIC LABELING.—Section*  
 24                      *502(f) of the Federal Food, Drug, and Cosmetic*  
 25                      *Act (21 U.S.C. 352(f)), as amended by section*

206 of Public Law 107–250 (116 Stat. 1613), is amended, in the last sentence—

(i) by inserting “or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments” after “in health care facilities”;

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

(iii) by striking “requirements of law and, that” and inserting “requirements of law, and that”;

(iv) by striking “the manufacturer affords health care facilities the opportunity” and inserting “the manufacturer affords such users the opportunity”; and

(v) by striking “the health care facility”.

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

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

(2) *PREMARKET NOTIFICATION.*—Section 510(o) 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.





**Union Calendar No. 250**

108TH CONGRESS  
2D SESSION

**S. 1881**

**[Report No. 108-433]**

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## **AN ACT**

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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MARCH 9, 2004

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