

108TH CONGRESS
1ST SESSION

S. 1881

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**
2 **LAW 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
6 seq.), as added by section 102 of Public Law 107-250
7 (116 Stat. 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
11 to provide a reasonable assurance of safety and
12 effectiveness” and inserting “and for which sub-
13 stantial clinical data are necessary to provide a
14 reasonable assurance of safety and effective-
15 ness”;

16 (B) in paragraph (4)(D), by striking
17 “manufacturing,”;

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

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

1 and inserting “The term ‘affiliate’ means a
2 business entity that has a relationship with a
3 second business entity (whether domestic or
4 international)”;

5 (2) in section 738—

6 (A) in subsection (a)(1)—

7 (i) in subparagraph (A)—

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

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

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

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

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

25 (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 strik-
 8 ing “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 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”;

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

1 (III) in the fourth sentence, by
2 striking “granted until” and inserting
3 “granted or deemed to be granted
4 until”; and

5 (v) in clause (iv)(II)—

6 (I) by inserting “of a device es-
7 tablishment required to register” after
8 “to be conducted”; and

9 (II) by inserting “section” after
10 “pursuant to”;

11 (C) in paragraph (6)(B)(iii)—

12 (i) in the first sentence, by striking “,
13 and data otherwise describing whether the
14 establishment has consistently been in
15 compliance with sections 501 and 502”;
16 and

17 (ii) in the second sentence—

18 (I) by striking “inspections” and
19 inserting “inspectional findings”; and

20 (II) by inserting “relevant” after
21 “together with all other”;

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

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

3 (F) in paragraph (12)—

4 (i) by striking subparagraph (A) and
5 inserting the following:

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

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

17 (2) OTHER CORRECTIONS.—

18 (A) PROHIBITED ACTS.—Section 301(gg)
19 of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 331(gg)), as amended by section
21 201(d) of Public Law 107–250 (116 Stat.
22 1609), is amended to read as follows:

23 “(gg) The knowing failure to comply with paragraph
24 (7)(E) of section 704(g); the knowing inclusion by a per-
25 son accredited under paragraph (2) of such section of false

1 information in an inspection report under paragraph
 2 (7)(A) of such section; or the knowing failure of such a
 3 person to include material facts in such a report.”.

4 (B) ELECTRONIC LABELING.—Section
 5 502(f) of the Federal Food, Drug, and Cos-
 6 metic Act (21 U.S.C. 352(f)), as amended by
 7 section 206 of Public Law 107–250 (116 Stat.
 8 1613), is amended, in the last sentence—

9 (i) by inserting “or by a health care
 10 professional and required labeling for in
 11 vitro diagnostic devices intended for use by
 12 health care professionals or in blood estab-
 13 lishments” after “in health care facilities”;

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

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

19 (iv) by striking “the manufacturer af-
 20 fords health care facilities the opportunity”
 21 and inserting “the manufacturer affords
 22 such users the opportunity”; and

23 (v) by striking “the health care facil-
 24 ity”.

25 (c) TITLE III; ADDITIONAL AMENDMENTS.—

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

4 (2) PREMARKET NOTIFICATION.—Section
5 510(o) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 360(o)), as added by section 302(b) of
7 Public Law 107–250 (116 Stat. 1616), is
8 amended—

9 (A) in paragraph (1)(B), by striking “,
10 adulterated” and inserting “or adulterated”;
11 and

12 (B) in paragraph (2)—

13 (i) in subparagraph (B), by striking “,
14 adulterated” and inserting “or adulter-
15 ated”; and

16 (ii) in subparagraph (E), by striking
17 “semicritical” and inserting “semi-crit-
18 ical”.

19 (d) MISCELLANEOUS CORRECTIONS.—

20 (1) CERTAIN AMENDMENTS TO SECTION 515.—

21 (A) IN GENERAL.—

22 (i) TECHNICAL CORRECTION.—Section
23 515(e) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 360e(c)), as
25 amended by sections 209 and 302(c)(2)(A)

1 of Public Law 107–250 (116 Stat. 1613,
2 1618), is amended by redesignating para-
3 graph (3) (as added by section 209 of such
4 Public Law) as paragraph (4).

5 (ii) MODULAR REVIEW.—Section
6 515(e)(4)(B) of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C.
8 360e(e)(4)(B)) is amended by striking
9 “unless an issue of safety” and inserting
10 “unless a significant issue of safety”.

11 (B) CONFORMING AMENDMENT.—Section
12 210 of Public Law 107–250 (116 Stat. 1614)
13 is amended by striking “, as amended” and all
14 that follows through “by adding” and inserting
15 “is amended in paragraph (3), as redesignated
16 by section 302(c)(2)(A) of this Act, by adding”.

17 (2) CERTAIN AMENDMENTS TO SECTION 738.—

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

22 (i) in the matter preceding paragraph

23 (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 PPLICATION,” 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)”; and
3 (II) in clause (ii), by striking
4 “subsection (a)(1)(A)(i)” and insert-
5 ing “subsection (a)(2)(A)(i)”; and
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”; and

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

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

12 Not later than 180 days after the date of enactment
13 of this Act, the Secretary of Health and Human Services
14 shall submit to the Committee on Health, Education,
15 Labor, and Pensions of the Senate and the Committee on
16 Energy and Commerce of the House of Representatives
17 a report on the barriers to the availability of devices in-
18 tended for the treatment or diagnosis of diseases and con-
19 ditions that affect children. The report shall include any
20 recommendations of the Secretary of Health and Human
21 Services for changes to existing statutory authority, regu-

1 lations, or agency policy or practice to encourage the in-
2 vention and development of such devices.

Passed the Senate November 25, 2003.

Attest:

Secretary.

108TH CONGRESS
1ST SESSION

S. 1881

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.