

108TH CONGRESS
2D SESSION

H. R. 3493

IN THE SENATE OF THE UNITED STATES

JANUARY 28, 2004

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

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,*

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 (e)(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 (e)—

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

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)(B)—

21 (i) in clause (ii), by redesignating sub-
22 clauses (I) and (II) as items (aa) and (bb),
23 respectively;

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

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

3 “(i) IN GENERAL.—The Secretary”;
4 and

5 (iv) by adding at the end the fol-
6 lowing:

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

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

14 (1) INSPECTIONS BY ACCREDITED PERSONS.—
15 Section 704(g) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 374(g)), as added by section
17 201 of Public Law 107–250 (116 Stat. 1602), is
18 amended—

19 (A) in paragraph (1), in the first sentence,
20 by striking “conducting inspections” and all
21 that follows and inserting “conducting inspec-
22 tions of establishments that manufacture, pre-
23 pare, propagate, compound, or process class II
24 or class III devices, which inspections are re-
25 quired under section 510(h) or are inspections

1 of such establishments required to register
2 under section 510(i).”;

3 (B) in paragraph (5)(B), in the first sen-
4 tence, by inserting after “standards of accredi-
5 tation,” the following: “or where the Secretary
6 has information indicating that the relationship
7 between the establishment and the accredited
8 person may create a conflict of interest,”;

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 “de-
13 scribed 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
6 following additional conditions are
7 met:”;

8 (II) in subclause (I), by striking
9 “identified under subclause (II) of
10 this clause” and inserting “identified
11 under clause (ii)(II) as a person au-
12 thorized to conduct inspections of de-
13 vice establishments”; and

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

18 (iv) in clause (iv)(I)—

19 (I) in the first sentence—

20 (aa) by striking “the two
21 immediately preceding inspec-
22 tions of the establishment” and
23 inserting “inspections of the es-
24 tablishment during the previous
25 4 years”; and

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

3 (II) in the third sentence—

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

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

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

15 (v) in clause (iv)(II)—

16 (I) by inserting “of a device es-
17 tablishment required to register” after
18 “to be conducted”; and

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

21 (vi) by adding at the end the following
22 clause:

23 “(v) The eligibility of the establishment for in-
24 spections by accredited persons has not been sus-
25 pended under subparagraph (B)(iv)(II).”;

1 (D) in paragraph (6)(B)(iii)—

2 (i) in the first sentence, by striking “,
3 and data otherwise describing whether the
4 establishment has consistently been in
5 compliance with sections 501 and 502”;

6 (ii) in the second sentence—

7 (I) by striking “inspections” and
8 inserting “inspectional findings”; and

9 (II) by inserting “relevant” after
10 “together with all other”; and

11 (iii)(I) by inserting “(I)” after “(iii)”;

12 (II) by adding at the end the fol-
13 lowing subclause:

14 “(II) In making a decision under this paragraph, the
15 Secretary may consider any information relevant to the
16 establishment’s compliance with any provision of this Act.
17 Nothing in the preceding sentence shall be construed to
18 expand the Secretary’s inspectional authority under sub-
19 section (a).”;

20 (E) in paragraph (6)(B)(iv)—

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

22 (ii) by adding at the end the following
23 subclause:

24 “(II) If, during the two-year period following clear-
25 ance under subparagraph (A) with respect to a device es-

1 tablishment, the Secretary obtains information indicating
2 significant deviations from compliance with this Act or im-
3 plementing regulations, the Secretary may, after notice
4 and an opportunity for a written response, notify the es-
5 tablishment that the eligibility of the establishment for in-
6 spections by accredited person has been suspended.”;

7 (F) in paragraph (6)(C)(ii), by striking “in
8 accordance with section 510(h), or has not dur-
9 ing such period been inspected pursuant to sec-
10 tion 510(i), as applicable”;

11 (G) in paragraph (10)(B)(iii), by striking
12 “a reporting” and inserting “a report”; and

13 (H) in paragraph (12)—

14 (i) by striking subparagraph (A) and
15 inserting the following:

16 “(A) the number of inspections conducted
17 by accredited persons pursuant to this sub-
18 section and the number of inspections con-
19 ducted by Federal employees pursuant to sec-
20 tion 510(h) and of device establishments re-
21 quired to register under section 510(i);” and

22 (ii) in subparagraph (E), by striking
23 “obtained by the Secretary” and all that
24 follows and inserting “obtained by the Sec-

1 retary pursuant to inspections conducted
2 by Federal employees;”.

3 (2) OTHER CORRECTIONS.—

4 (A) PROHIBITED ACTS.—Section 301(gg)
5 of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 331(gg)), as amended by section
7 201(d) of Public Law 107–250 (116 Stat.
8 1609), is amended to read as follows:

9 “(gg) The knowing failure to comply with paragraph
10 (7)(E) of section 704(g); the knowing inclusion by a per-
11 son accredited under paragraph (2) of such section of false
12 information in an inspection report under paragraph
13 (7)(A) of such section; or the knowing failure of such a
14 person to include material facts in such a report.”.

15 (B) ELECTRONIC LABELING.—Section
16 502(f) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 352(f)), as amended by
18 section 206 of Public Law 107–250 (116 Stat.
19 1613), is amended, in the last sentence—

20 (i) by inserting “or by a health care
21 professional and required labeling for in
22 vitro diagnostic devices intended for use by
23 health care professionals or in blood estab-
24 lishments” after “in health care facilities”;

- 1 (ii) by inserting a comma after
2 “means”;
3 (iii) by striking “requirements of law
4 and, that” and inserting “requirements of
5 law, and that”;
6 (iv) by striking “the manufacturer af-
7 fords health care facilities the opportunity”
8 and inserting “the manufacturer affords
9 such users the opportunity”; and
10 (v) by striking “the health care facil-
11 ity”.

12 (c) TITLE III; ADDITIONAL AMENDMENTS.—

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

16 (2) PREMARKET NOTIFICATION.—Section
17 510(o) of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360(o)), as added by section 302(b) of
19 Public Law 107–250 (116 Stat. 1616), is amend-
20 ed—

21 (A) in paragraph (1)(B), by striking “,
22 adulterated” and inserting “or adulterated”;
23 and

24 (B) in paragraph (2)—

1 (i) in subparagraph (B), by striking “,
2 adulterated” and inserting “or adulter-
3 ated”; and

4 (ii) in subparagraph (E), by striking
5 “semicritical” and inserting “semi-crit-
6 ical”.

7 (d) MISCELLANEOUS CORRECTIONS.—

8 (1) CERTAIN AMENDMENTS TO SECTION 515.—

9 (A) IN GENERAL.—

10 (i) TECHNICAL CORRECTION.—Section
11 515(c) of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 360e(c)), as
13 amended by sections 209 and 302(c)(2)(A)
14 of Public Law 107–250 (116 Stat. 1613,
15 1618), is amended by redesignating para-
16 graph (3) (as added by section 209 of such
17 Public Law) as paragraph (4).

18 (ii) MODULAR REVIEW.—Section
19 515(c)(4)(B) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C.
21 360e(c)(4)(B)) is amended by striking
22 “unless an issue of safety” and inserting
23 “unless a significant issue of safety”.

24 (B) CONFORMING AMENDMENT.—Section
25 210 of Public Law 107–250 (116 Stat. 1614)

1 is amended by striking “, as amended” and all
2 that follows through “by adding” and inserting
3 “is amended in paragraph (3), as redesignated
4 by section 302(c)(2)(A) of this Act, by adding”.

5 (2) CERTAIN AMENDMENTS TO SECTION 738.—

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

10 (i) in the matter preceding paragraph

11 (1)—

12 (I) by striking “(a) TYPES OF
13 FEES.—Beginning on” and inserting
14 the following:

15 “(a) TYPES OF FEES.—

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

17 (II) by striking “this section as
18 follows:” and inserting “this section.”;
19 and

20 (ii) by striking “(1) PREMARKET AP-
21 PPLICATION,” and inserting the following:

22 “(2) PREMARKET APPLICATION,”.

23 (B) CONFORMING AMENDMENTS.—Section
24 738 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 379j), as amended by subpara-
2 graph (A), is amended—

3 (i) in subsection (d)(1), in the last
4 sentence, by striking “subsection
5 (a)(1)(A)” and inserting “subsection
6 (a)(2)(A)”;

7 (ii) in subsection (e)(1), by striking
8 “subsection (a)(1)(A)(vii)” and inserting
9 “subsection (a)(2)(A)(vii)”;

10 (iii) in subsection (e)(2)(C)—

11 (I) in each of clauses (i) and (ii),
12 by striking “subsection (a)(1)(A)(vii)”
13 and inserting “subsection
14 (a)(2)(A)(vii)”;

15 (II) in clause (ii), by striking
16 “subsection (a)(1)(A)(i)” and insert-
17 ing “subsection (a)(2)(A)(i)”;

18 (iv) in subsection (j), by striking
19 “subsection (a)(1)(D),” and inserting
20 “subsection (a)(2)(D),”.

21 (C) ADDITIONAL CONFORMING AMEND-
22 MENT.—Section 102(b)(1) of Public Law 107–
23 250 (116 Stat. 1600) is amended, in the matter
24 preceding subparagraph (A), by striking “sec-

1 tion 738(a)(1)(A)(ii)” and inserting “section
2 738(a)(2)(A)(ii)”.

3 (3) PUBLIC LAW 107–250.—Public Law 107–
4 250 is amended—

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

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

9 (i) by striking paragraph (2);

10 (ii) in paragraph (1), by redesignating
11 subparagraphs (A) and (B) as paragraphs
12 (1) and (2), respectively; and

13 (iii) by striking:

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

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

18 “(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-
19 MITTING PREMARKET REPORTS.—A person submitting a
20 premarket report”; and

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

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

3 Not later than 180 days after the date of enactment
4 of this Act, the Secretary of Health and Human Services
5 shall submit to the Committee on Health, Education,
6 Labor, and Pensions of the Senate and the Committee on
7 Energy and Commerce of the House of Representatives
8 a report on the barriers to the availability of devices in-
9 tended for the treatment or diagnosis of diseases and con-
10 ditions that affect children. The report shall include any
11 recommendations of the Secretary of Health and Human
12 Services for changes to existing statutory authority, regu-
13 lations, or agency policy or practice to encourage the in-
14 vention and development of such devices.

Passed the House of Representatives January 27,
2004.

Attest:

JEFF TRANDAHL,
Clerk.