

108TH CONGRESS
1ST SESSION

H. R. 3493

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.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 17, 2003

Mr. GREENWOOD (for himself and Ms. ESHOO) introduced the following bill;
which was referred to the Committee on Energy and Commerce

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Devices Tech-
5 nical Corrections Act of 2003”.

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

3 (a) TITLE I; FEES RELATING TO MEDICAL DE-
4 VICES.—

5 (1) TYPES OF FEES.—Section 738 of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C.
7 379j), as added by section 102 of Public Law 107-
8 250 (116 Stat. 1589), is amended by amending sub-
9 section (a) to read as follows:

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

14 “(1) PREMARKET APPLICATION, PREMARKET
15 REPORT, SUPPLEMENT, AND SUBMISSION FEE.—Ex-
16 cept as provided in paragraph (2) and subsections
17 (d) and (e), each person who submits any of the fol-
18 lowing, on or after October 1, 2002, shall be subject
19 to a fee established under subsection (c)(5) for the
20 fiscal year involved in accordance with the following:

21 “(A) A premarket application.

22 “(B) For a premarket report, a fee equal
23 to the fee that applies under subparagraph (A).

24 “(C) For a panel track supplement, a fee
25 equal to the fee that applies under subpara-
26 graph (A).

1 “(D) For a 180-day supplement, a fee
2 equal to 21.5 percent of the fee that applies
3 under subparagraph (A).

4 “(E) For a real-time supplement, a fee
5 equal to 7.2 percent of the fee that applies
6 under subparagraph (A).

7 “(F) For an efficacy supplement, a fee
8 equal to the fee that applies under subpara-
9 graph (A).

10 “(G) For a premarket notification submis-
11 sion, a fee equal to 1.42 percent of the fee that
12 applies under subparagraph (A), subject to any
13 adjustment under subsection (e)(2)(C)(ii).

14 “(2) EXCEPTIONS.—

15 “(A) HUMANITARIAN DEVICE EXEMP-
16 TION.—An application under section 520(m) is
17 not subject to any fee under paragraph (1).

18 “(B) FURTHER MANUFACTURING USE.—
19 No fee shall be required under paragraph (1)
20 for the submission of a premarket application
21 under section 351 of the Public Health Service
22 Act for a product licensed for further manufac-
23 turing use only.

24 “(C) STATE OR FEDERAL GOVERNMENT
25 SPONSORS.—No fee shall be required under

1 paragraph (1) for a premarket application, pre-
2 market report, supplement, or premarket notifi-
3 cation submission submitted by a State or Fed-
4 eral Government entity unless the device in-
5 volved is to be distributed commercially.

6 “(D) PREMARKET NOTIFICATIONS BY
7 THIRD PARTIES.—No fee shall be required
8 under paragraph (1) for a premarket notifica-
9 tion submission reviewed by an accredited per-
10 son pursuant to section 523.

11 “(E) PEDIATRIC CONDITIONS OF USE.—

12 “(i) IN GENERAL.—No fee shall be re-
13 quired under paragraph (1) for a pre-
14 market application, premarket report, or
15 premarket notification submission if the
16 proposed conditions of use for the device
17 involved are solely for a pediatric popu-
18 lation. No fee shall be required under such
19 subparagraph for a supplement if the sole
20 purpose of the supplement is to propose
21 conditions of use for a pediatric popu-
22 lation.

23 “(ii) SUBSEQUENT PROPOSAL OF
24 ADULT CONDITIONS OF USE.—In the case
25 of a person who submits a premarket ap-

1 plication or premarket report for which,
2 under clause (i), a fee under paragraph (1)
3 is not required, any supplement to such
4 application that proposes conditions of use
5 for any adult population is subject to the
6 fee that applies under such subparagraph
7 for a premarket application.

8 “(3) PAYMENT.—The fee required by para-
9 graph (1) shall be due upon submission of the pre-
10 market application, premarket report, supplement,
11 or premarket notification submission, except that in-
12 voices for applications submitted on or after October
13 1, 2002, and before the date on which appropria-
14 tions under subsection (h)(3) for fiscal year 2003
15 first become available shall be payable within 30
16 days of the issuance of such invoices. Applicants
17 submitting portions of applications pursuant to sec-
18 tion 515(c)(3) shall pay such fees upon submission
19 of the first portion of such applications. The fees
20 credited to fiscal year 2003 under this section shall
21 include all fees payable from October 1, 2002,
22 through September 30, 2003.

23 “(4) REFUNDS.—

24 “(A) APPLICATION REFUSED FOR FIL-
25 ING.—The Secretary shall refund 75 percent of

1 the fee paid under paragraph (1) for any appli-
2 cation, report, or supplement that is refused for
3 filing.

4 “(B) APPLICATION WITHDRAWN BEFORE
5 FILING.—The Secretary shall refund 75 percent
6 of the fee paid under paragraph (1) for any ap-
7 plication, report, or supplement that is with-
8 drawn prior to the filing decision of the Sec-
9 retary.

10 “(C) APPLICATION WITHDRAWN BEFORE
11 FIRST ACTION.—After receipt of a request for a
12 refund of the fee paid under paragraph (1) for
13 a premarket application, premarket report, or
14 supplement that is withdrawn after filing but
15 before a first action, the Secretary may return
16 some or all of the fee. The amount of refund,
17 if any, shall be based on the level of effort al-
18 ready expended on the review of such applica-
19 tion, report, or supplement. The Secretary shall
20 have sole discretion to refund a fee or portion
21 of the fee under this subparagraph. A deter-
22 mination by the Secretary concerning a refund
23 under this paragraph shall not be reviewable.”.

24 (2) OTHER CORRECTIONS RELATING TO
25 FEES.—Part 3 of subchapter C of chapter VII of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 379i et seq.), as added by section 102 of Public Law
3 107–250 (116 Stat. 1589), is amended—

4 (A) in section 737—

5 (i) in paragraph (4)—

6 (I) in subparagraph (B), by
7 striking “and for which” and all that
8 follows and inserting the following:
9 “and for which substantial clinical
10 data are necessary to provide a rea-
11 sonable assurance of safety and effec-
12 tiveness.”; and

13 (II) in subparagraph (D), by
14 striking “manufacturing,”;

15 (ii) in paragraph (5)(J), by striking
16 “a premarket application” and all that fol-
17 lows and inserting the following: “a pre-
18 market application or premarket report
19 under section 515 or a premarket applica-
20 tion under section 351 of the Public
21 Health Service Act.”; and

22 (iii) in paragraph (8), in the matter
23 preceding subparagraph (A), by inserting
24 “(whether domestic or international)” after
25 “second business entity”; and

1 (B) in section 738—

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

6 (ii) in subsection (e)—

7 (I) in paragraph (1), by striking
8 “Where” and inserting “For fiscal
9 year 2004 and each subsequent fiscal
10 year, where”; and

11 (II) in paragraph (2)—

12 (aa) in subparagraph (B),
13 beginning in the second sentence,
14 by striking “firms. which show”
15 and inserting “firms, which
16 show”; and

17 (bb) in subparagraph (C)(i),
18 by striking “Where” and insert-
19 ing “For fiscal year 2004 and
20 each subsequent fiscal year,
21 where”;

22 (iii) in subsection (f), by striking “for
23 filing” and inserting “for review”; and

24 (iv) in subsection (h)(2)—

1 (I) in subparagraph (A), by strik-
2 ing clause (ii) and inserting the fol-
3 lowing:

4 “(ii) shall only be collected and avail-
5 able to defray increases in the costs of the
6 resources allocated for the purposes for the
7 review of device applications (including in-
8 creases in such costs for an additional
9 number of full-time equivalent positions in
10 the Department of Health and Human
11 Services to be engaged in such process)
12 over such costs for fiscal year 2002 when
13 multiplied by the adjustment factor.

14 For purposes of this subparagraph, the deter-
15 mination of the costs of the resources allocated
16 for the process for the review of device applica-
17 tions for fiscal year 2003 through 2007 shall
18 not include costs paid from fees collected under
19 this section.”; and

20 (II) in subparagraph (B), by in-
21 serting after and below clause (ii)((II)
22 the following:

23 “To the extent such costs are more than 5 per-
24 cent below the level specified in subparagraph

1 (A)(ii), fees may not be collected under this sec-
2 tion for that fiscal year.”.

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

5 (1) INSPECTIONS BY ACCREDITED PERSONS.—
6 Section 704(g) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 374(g)), as added by section
8 201 of Public Law 107–250 (116 Stat. 1602), is
9 amended—

10 (A) in paragraph (1), in the first sentence,
11 by striking “conducting inspections” and all
12 that follows and inserting the following: “con-
13 ducting inspections of establishments that man-
14 ufacture, prepare, propagate, compound, or
15 process class II or class III devices, which in-
16 spections are required in section 510(h) or are
17 inspections of such establishments required to
18 register under section 510(i).”;

19 (B) in paragraph (6)(A)—

20 (i) in the matter preceding clause (i),
21 by inserting “during a two-year period”
22 after “paragraph (2)”;

23 (ii) in clause (i), by striking “most re-
24 cent inspection” and all that follows
25 through “section 510 as” and inserting

1 “most recent inspection described in para-
2 graph (1) as”;

3 (iii) in clause (ii)—

4 (I) in the matter preceding sub-
5 clause (I), by striking “With respect
6 to” and all that follows and inserting
7 the following: “With respect to the in-
8 spections to be conducted by an ac-
9 credited person during such two-year
10 period—”;

11 (II) in subclause (I), by striking
12 “such a person to conduct the inspec-
13 tion,” and inserting “an accredited
14 person to conduct the inspections,”;
15 and

16 (III) in subclause (II), by strik-
17 ing “the inspection,” and inserting
18 “the inspections,”;

19 (iv) in clause (iii)—

20 (I) in the matter preceding sub-
21 clause (I), by striking “United
22 States,” and all that follows and in-
23 serting “United States, and—”;

24 (II) in subclause (I)—

1 (aa) by striking “At least
2 one” and inserting “at least
3 one”; and

4 (bb) by striking “identified
5 under subclause (II) of this
6 clause.” and inserting “identified
7 under clause (ii)(II); or”; and

8 (III) in subclause (II), by strik-
9 ing “The owner” and inserting “the
10 owner”; and

11 (v) in clause (iv)—

12 (I) in subclause (I), in the first
13 sentence, by striking “In the case of”
14 and all that follows through “except
15 that” and inserting the following: “In
16 the case of inspections to be con-
17 ducted pursuant to section 510(h),
18 persons accredited under paragraph
19 (2) did not conduct any inspection of
20 the establishment during the two pre-
21 ceding two-year periods referred to in
22 such section with respect to the estab-
23 lishment, except that”;

24 (II) in subclause (II), by striking “In
25 the case of” and all that follows through

1 “the Secretary” and inserting the fol-
2 lowing: “In the case of inspections to be
3 conducted of a device establishment re-
4 quired to register under section 510(i), the
5 Secretary”;

6 (C) in paragraph (6)(B)—

7 (i) in clause (iii)—

8 (I) by striking “and data other-
9 wise” in the first sentence and all that
10 follows through “reports of inspec-
11 tions regarding” in the second sen-
12 tence and inserting the following:
13 “and data describing compliance with
14 other applicable provisions of this Act.
15 Such data shall include reports of
16 inspectional findings regarding”; and

17 (II) in the second sentence, by
18 striking “establishment, together
19 with” and all that follows and insert-
20 ing “establishment.”; and

21 (ii) in clause (v), by adding at the end

22 the following subclause:

23 “(III) The agreement (or deemed agreement) of
24 the Secretary under this subparagraph to the selec-
25 tion of an accredited person is effective for the two-

1 year period referred to in the matter preceding
2 clause (i) of subparagraph (A), subject to paragraph
3 (5)(B).”;

4 (D) in paragraph (6)(C)(ii), in the last
5 sentence, by inserting before the period the fol-
6 lowing: “and may submit a notice under sub-
7 paragraph (A)”;

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

10 (F) in paragraph (12)—

11 (i) in subparagraph (A), by striking
12 “the number of” the first place such term
13 appears and all that follows and inserting
14 the following: “the number of inspections
15 conducted by accredited persons pursuant
16 to this subsection and the number of in-
17 spections conducted by Federal employees
18 pursuant to section 510(h) and of device
19 establishments required to register under
20 section 510(i);” and

21 (ii) in subparagraph (E), by striking
22 “obtained by the Secretary” and all that
23 follows and inserting “obtained by the Sec-
24 retary pursuant to inspections conducted
25 by Federal employees;”.

1 (2) OTHER CORRECTIONS.—Chapter V of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 351 et seq.), as amended by sections 204 and 206
4 of Public Law 107–250 (116 Stat. 1611, 1613), is
5 amended—

6 (A) in section 502(f), in the last sen-
7 tence—

8 (i) by striking “requirements of law
9 and, that” and inserting “requirements of
10 law, that”; and

11 (ii) by striking “and after such re-
12 quest, promptly provides” and inserting
13 “and that, after receiving such request, the
14 manufacturer promptly provides”; and

15 (B) in section 503(g)(4)(A), in the second
16 sentence, by striking “shall, in determining
17 whether” and all that follows through “consult”
18 and inserting the following: “shall, in deter-
19 mining whether the product to be assigned is
20 appropriately classified as a combination prod-
21 uct, consult”.

22 (c) TITLE III; ADDITIONAL AMENDMENTS.—

23 (1) IN GENERAL.—The Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 301 et seq.), as

1 amended by sections 301 and 302 of Public Law
2 107–250 (116 Stat. 1616), is amended—

3 (A) in section 502 (21 U.S.C. 352)—

4 (i) by striking paragraph (u); and

5 (ii) by redesignating paragraph (v) as
6 paragraph (u); and

7 (B) in section 510(o) (21 U.S.C. 360(o))—

8 (i) in paragraph (1)(B), in the third
9 sentence, by striking “misbranded under
10 section 502(o), adulterated under” and in-
11 sserting “misbranded under section 502(o)
12 or adulterated under”; and

13 (ii) in paragraph (2)—

14 (I) in subparagraph (B), in the
15 third sentence, by striking “mis-
16 branded under section 502(o), adul-
17 terated under” and inserting “mis-
18 branded under section 502(o) or adul-
19 terated under”; and

20 (II) in subparagraph (E), by
21 striking “semicritical” and inserting
22 “semi-critical”.

23 (2) CONFORMING AMENDMENT.—Section 301
24 of Public Law 107–250 (116 Stat. 1616) is amend-
25 ed by striking subsection (b).

1 (d) MISCELLANEOUS CORRECTIONS.—

2 (1) CERTAIN AMENDMENTS REGARDING SEC-
3 TION 515(c).—

4 (A) IN GENERAL.—Section 515(c) of the
5 Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 360e), as amended by sections 209 and
7 302(c)(2)(A) of Public Law 107–250 (116 Stat.
8 1613, 1618), is amended—

9 (i) by redesignating the second para-
10 graph (3) (added by section 209 of such
11 Public Law) as paragraph (4); and

12 (ii) in paragraph (4) (as so redesign-
13 ated), in subparagraph (B), by striking
14 “an issue” and inserting “a new issue”.

15 (B) CONFORMING AMENDMENT.—Section
16 210 of Public Law 107–250 (116 Stat. 1614)
17 is amended by striking “, as amended” and all
18 that follows through “by adding” and inserting
19 the following: “is amended in paragraph (3), as
20 redesignated by section 302(c)(2)(A) of this
21 Act, by adding”.

22 (2) CONFORMING AMENDMENTS REGARDING
23 REFERENCES TO SECTION 738(a).—

24 (A) IN GENERAL.—Section 738 of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 379j), as amended by subparagraph (A) of this
2 paragraph, is amended—

3 (i) in subsection (d)(1), in the last
4 sentence, by striking “clauses (i) through
5 (vi) of subsection (a)(1)(A)” and inserting
6 “subparagraphs (A) through (F) of sub-
7 section (a)(1)”;

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

11 (iii) in subsection (e)(2)(C)—

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

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

19 (iv) in subsection (j), by striking
20 “subsection (a)(1)(D),” and inserting
21 “subsection (a)(4),”.

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

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

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

5 (A) in section 102—

6 (i) in subsection (a) (116 Stat. 1589),
7 by striking “(21 U.S.C. 379F et seq.)”
8 and inserting “(21 U.S.C. 379f et seq.)”;
9 and

10 (ii) in subsection (b) (116 Stat.
11 1600), by striking paragraph (2);

12 (B) in section 212(b)(2) (116 Stat. 1614),
13 by striking “medical devices, such as phase IV
14 trials, and” and inserting “medical devices
15 and”; and

16 (C) in section 214(a)(3) (116 Stat. 1615),
17 by striking “discussion” and inserting “presen-
18 tation”.

19 (4) PUBLIC HEALTH SERVICE ACT.—Section
20 498C of the Public Health Service Act (42 U.S.C.
21 289g–3), as added by section 215(b) of Public Law
22 107–250 (116 Stat. 1615), is amended in subsection
23 (a) by striking “Director of NIH may” and inserting
24 “Director of NIH shall”.

1 (e) HUMANITARIAN DEVICE EXEMPTION; PEDIATRIC
2 PATIENTS.—Section 520(m)(3) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360j(m)(3)) is amend-
4 ed—

5 (1) by striking “(3) No person” and inserting
6 “(3)(A) Except as provided in subparagraph (B), no
7 person”; and

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

9 “(B)(i) Subparagraph (A) does not apply with re-
10 spect to any device intended for the treatment or diagnosis
11 of a pediatric condition.

12 “(ii) For purposes of this subsection:

13 “(I) The term ‘pediatric condition’ means a dis-
14 ease, disorder, or other condition unique to, more se-
15 rious, or more prevalent in pediatric patients.

16 “(II) The term ‘pediatric patient’ means a pa-
17 tient who is under 15 years of age at the time of
18 diagnosis or treatment.”.

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