

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

**H. R. 3423**

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**AN ACT**

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device user fees.



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## AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device user fees.

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 Device User  
3 Fee Stabilization Act of 2005”.

4 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
5 **COSMETIC ACT.**

6 (a) **DEVICE USER FEES.**—Section 738 of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-  
8 ed—

9 (1) in subsection (b)—

10 (A) after “2004;”, by inserting “and”; and

11 (B) by striking “2005;” and all that fol-  
12 lows through “2007” and inserting “2005”;

13 (2) in subsection (c)—

14 (A) by striking the heading and inserting  
15 “Annual Fee Setting.—”;

16 (B) by striking paragraphs (1), (2), (3),  
17 and (4);

18 (C) by redesignating paragraphs (5) and  
19 (6) as paragraphs (1) and (2), respectively;

20 (D) in paragraph (1), as so redesignated,  
21 by—

22 (i) striking the heading and inserting  
23 “**IN GENERAL.**—”;

24 (ii) striking “establish, for the next  
25 fiscal year, and” and all that follows  
26 through “the fees” and inserting “publish

1 in the Federal Register fees under sub-  
2 section (a). The fees”;

3 (iii) striking “2003” and inserting  
4 “2006”; and

5 (iv) striking “\$154,000.” and insert-  
6 ing “\$259,600, and the fees established for  
7 fiscal year 2007 shall be based on a pre-  
8 market application fee of \$281,600.”; and  
9 (E) by adding at the end the following:

10 “(3) SUPPLEMENT.—

11 “(A) IN GENERAL.—For fiscal years 2006  
12 and 2007, the Secretary may use unobligated  
13 carryover balances from fees collected in pre-  
14 vious fiscal years to ensure that sufficient fee  
15 revenues are available in that fiscal year, so  
16 long as the Secretary maintains unobligated  
17 carryover balances of not less than 1 month of  
18 operating reserves for the first month of fiscal  
19 year 2008.

20 “(B) NOTICE TO CONGRESS.—Not later  
21 than 14 days before the Secretary anticipates  
22 the use of funds described in subparagraph (A),  
23 the Secretary shall provide notice to the Com-  
24 mittee on Health, Education, Labor, and Pen-  
25 sions and the Committee on Appropriations of

1 the Senate and the Committee on Energy and  
2 Commerce and the Committee on Appropria-  
3 tions of the House of Representatives.”;

4 (3) in subsection (d)—

5 (A) in paragraph (1), by inserting after  
6 the first sentence the following: “For the pur-  
7 poses of this paragraph, the term ‘small busi-  
8 ness’ means an entity that reported  
9 \$30,000,000 or less of gross receipts or sales in  
10 its most recent Federal income tax return for a  
11 taxable year, including such returns of all of its  
12 affiliates, partners, and parent firms.”; and

13 (B) in paragraph (2)(A), by—

- 14 (i) striking “(i) **IN GENERAL.**—”;
- 15 (ii) striking “subsection,” and insert-  
16 ing “paragraph,”;
- 17 (iii) striking “\$30,000,000” and in-  
18 serting “\$100,000,000”; and
- 19 (iv) striking clause (ii);

20 (4) in subsection (e)(2)(A), by striking  
21 “\$30,000,000” and inserting “\$100,000,000”;

22 (5) in subsection (g)(1)—

23 (A) in subparagraph (B)—

- 24 (i) by striking clause (i) and inserting  
25 the following:

1           “(i) For fiscal year 2005, the Sec-  
2           retary is expected to meet all of the per-  
3           formance goals identified for the fiscal year  
4           if the amount so appropriated for such fis-  
5           cal year, excluding the amount of fees ap-  
6           propriated for such fiscal year, is equal to  
7           or greater than \$205,720,000 multiplied  
8           by the adjustment factor applicable to the  
9           fiscal year.”; and

10           (ii) in clause (ii), by striking the mat-  
11           ter preceding subclause (I) and inserting  
12           the following:

13           “(ii) For fiscal year 2005, if the  
14           amount so appropriated for such fiscal  
15           year, excluding the amount of fees appro-  
16           priated for such fiscal year, is more than  
17           1 percent less than the amount that ap-  
18           plies under clause (i), the following ap-  
19           plies:”;

20           (B) in subparagraph (C)—

21           (i) in the matter preceding clause (i),  
22           by—

23                   (I) striking “2003 through” and  
24                   inserting “2005 and”; and

1 (II) inserting “more than 1 per-  
2 cent” after “years, is”; and

3 (ii) in clause (ii), by striking “sum”  
4 and inserting “amount”; and

5 (C) in subparagraph (D)(i), by inserting  
6 “more than 1 percent” after “year, is”;

7 (6) in subsection (h)(3)—

8 (A) in subparagraph (C), by striking the  
9 semicolon and inserting “; and”; and

10 (B) by striking subparagraphs (D) and (E)  
11 and inserting the following:

12 “(D) such sums as may be necessary for  
13 each of fiscal years 2006 and 2007.”; and

14 (7) by striking “subsection (c)(5)” each place it  
15 appears and inserting “subsection (c)(1)”.

16 (b) ANNUAL REPORTS.—Section 103 of the Medical  
17 Device User Fee and Modernization Act of 2002 (Public  
18 Law 107–250 (116 Stat. 1600)) is amended—

19 (1) by striking “Beginning with” and inserting  
20 “(a) In General.—Beginning with”; and

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

22 “(b) ADDITIONAL INFORMATION.—For fiscal years  
23 2006 and 2007, the report described under subsection

24 (a)(2) shall include—

1           “(1) information on the number of different  
2 types of applications and notifications, and the total  
3 amount of fees paid for each such type of applica-  
4 tion or notification, from businesses with gross re-  
5 ceipts or sales from \$0 to \$100,000,000, with such  
6 businesses categorized in \$10,000,000 intervals; and

7           “(2) a certification by the Secretary that the  
8 amounts appropriated for salaries and expenses of  
9 the Food and Drug Administration for such fiscal  
10 year and obligated by the Secretary for the perform-  
11 ance of any function relating to devices that is not  
12 for the process for the review of device applications,  
13 as defined in paragraph (5) of section 737 of the  
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 379i), are not less than such amounts for fiscal year  
16 2002 multiplied by the adjustment factor, as defined  
17 in paragraph (7) of such section 737.”.

18 (c) MISBRANDED DEVICES.—

19           (1) IN GENERAL.—Section 502(u) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
21 352(u)) is amended to read as follows:

22           “(u)(1) Subject to paragraph (2), if it is a repro-  
23 cessed single-use device, unless it, or an attachment there-  
24 to, prominently and conspicuously bears the name of the  
25 manufacturer of the reprocessed device, a generally recog-

1 nized abbreviation of such name, or a unique and generally  
2 recognized symbol identifying such manufacturer.

3 “(2) If the original device or an attachment thereto  
4 does not prominently and conspicuously bear the name of  
5 the manufacturer of the original device, a generally recog-  
6 nized abbreviation of such name, or a unique and generally  
7 recognized symbol identifying such manufacturer, a re-  
8 processed device may satisfy the requirements of para-  
9 graph (1) through the use of a detachable label on the  
10 packaging that identifies the manufacturer and is in-  
11 tended to be affixed to the medical record of a patient.”.

12 (2) GUIDANCE.—Not later than 180 days after  
13 the date of enactment of this Act, the Secretary of  
14 Health and Human Services shall issue guidance to  
15 identify circumstances in which the name of the  
16 manufacturer of the original device, a generally rec-  
17 ognized abbreviation of such name, or a unique and  
18 generally recognized symbol identifying such manu-  
19 facturer, is not “prominent and conspicuous”, as  
20 used in section 502(u) of Federal Food, Drug, and  
21 Cosmetic Act (as amended by paragraph (1)).

22 (d) EFFECTIVE DATE.—Section 301(b) of the Med-  
23 ical Device User Fee and Modernization Act of 2002  
24 (Public Law 107–250 (116 Stat. 1616)), as amended by

1 section 2(c) of Public Law 108–214 (118 Stat. 575), is  
2 amended to read as follows:

3 “(b) EFFECTIVE DATE.—Section 502(u) of the Fed-  
4 eral Food, Drug, and Cosmetic Act (as amended by sec-  
5 tion 2(c) of the Medical Device User Fee Stabilization Act  
6 of 2005)—

7 “(1) shall be effective—

8 “(A) with respect to devices described  
9 under paragraph (1) of such section, 12 months  
10 after the date of enactment of the Medical De-  
11 vice User Fee Stabilization Act of 2005, or the  
12 date on which the original device first bears the  
13 name of the manufacturer of the original de-  
14 vice, a generally recognized abbreviation of such  
15 name, or a unique and generally recognized  
16 symbol identifying such manufacturer, which-  
17 ever is later; and

18 “(B) with respect to devices described  
19 under paragraph (2) of such section 502(u), 12  
20 months after such date of enactment; and

1           “(2) shall apply only to devices reprocessed and  
2 introduced or delivered for introduction in interstate  
3 commerce after such applicable effective date.”.

Passed the House of Representatives July 26, 2005.

Attest:

*Clerk.*