Calendar No. 173

109TH CONGRESS 1ST SESSION

S. 1420

[Report No. 109–107]

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

IN THE SENATE OF THE UNITED STATES

July 18, 2005

Mr. Enzi (for himself, Mr. Kennedy, Mr. Burr, Mr. DeWine, Ms. Mikulski, Mr. Dodd, Mrs. Murray, and Mr. Hatch) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

July 25, 2005

Reported by Mr. ENZI, with an amendment

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

A BILL

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,
- 3 **SECTION 1. SHORT TITLE.**
- 4 This Act may be cited as the "Medical Device User
- 5 Fee Stabilization Act of 2005".

1	SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND
2	COSMETIC ACT.
3	(a) DEVICE USER FEES.—Section 738 of the Federal
4	Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
5	ed
6	(1) in subsection (b)—
7	(A) after "2004;", by inserting "and"; and
8	(B) by striking "2005;" and all that fol-
9	lows through "2007" and inserting "2005";
10	(2) in subsection (e)—
11	(A) by striking paragraphs (1), (2), and
12	(3);
13	(B) by redesignating paragraphs (4), (5),
14	and (6) as paragraphs (1), (2), and (3), respec-
15	tively;
16	(C) in paragraph (1), as so redesignated,
17	by —
18	(i) striking the paragraph heading
19	and inserting "2007 INCREASE";
20	(ii) striking ", in addition to adjust-
21	ments under paragraphs (1) and (2), fur-
22	ther";
23	(iii) striking "established in sub-
24	section (b)" and inserting "under sub-
2.5	section (a)" and

1	(iv) striking "adjustment" each place
2	it appears and inserting "increase"; and
3	(D) in paragraph (2), as so redesignated,
4	by
5	(i) striking "establish, for the next fis-
6	cal year, and" and all that follows through
7	"the fees" and inserting "publish in the
8	Federal Register fees under subsection (a).
9	The fees';
10	(ii) striking "2003" and inserting
11	"2006"; and
12	(iii) striking "\$154,000." and insert-
13	ing "\$259,600, and the fees established for
14	fiscal year 2007 shall be based on a pre-
15	market application fee of \$281,600.";
16	(3) in subsection $(d)(2)(A)$ —
17	(A) in clause (i), by striking
18	"\$30,000,000" and inserting "\$75,000,000";
19	and
20	(B) by striking clause (ii) and inserting the
21	following:
22	"(ii) Adjustments.—
23	"(I) IN GENERAL.—If the Sec-
24	retary has evidence from actual expe-
25	rience that the \$75,000,000 threshold

1	established in clause (i) results in a
2	reduction in revenues from premarket
3	applications, premarket reports, and
4	supplements that is 26 percent or
5	more than would occur without small
6	business exemptions and lower fee
7	rates, the Secretary may—
8	"(aa) use the operating re-
9	serves in an amount not to ex-
10	eeed the lesser of—
11	"(AA) 10 percent of the
12	fees collected in fiscal year
13	2005; or
14	"(BB) \$2,500,000; and
15	"(bb) upon the exhaustion of
16	the amount described under item
17	(aa), adjust the \$75,000,000
18	threshold as provided for under
19	subclause (II).
20	"(II) Adjustment of thresh-
21	OLD. To adjust the threshold de-
22	scribed in subclause (I)(bb), the Sec-
23	retary shall publish a notice in the
24	Federal Register setting out the ra-
25	tionale for the adjustment, and the

1	new threshold. Such adjusted thresh-
2	old may not be less than \$30,000,000
3	and may not be retroactive.";
4	(4) in subsection $(e)(2)(\Lambda)$, by striking
5	"\$30,000,000" and inserting "\$75,000,000";
6	(5) in subsection $(g)(1)$ —
7	(A) in subparagraph (B)—
8	(i) by striking clause (i) and inserting
9	the following:
10	"(i) For fiscal year 2005, the Sec-
11	retary is expected to meet all of the per-
12	formance goals identified for the fiscal year
13	if the amount so appropriated for such fis-
14	eal year, excluding the amount of fees ap-
15	propriated for such fiscal year, is equal to
16	or greater than \$205,720,000 multiplied
17	by the adjustment factor applicable to the
18	fiscal year."; and
19	(ii) in clause (ii), by striking the mat-
20	ter preceding subclause (I) and inserting
21	the following:
22	"(ii) For fiscal year 2005, if the
23	amount so appropriated for such fiscal
24	year, excluding the amount of fees appro-
25	priated for such fiscal year, is more than

1	1 percent less than the amount that ap-
2	plies under clause (i), the following ap-
3	plies:"; and
4	(B) in subparagraph (C)—
5	(i) in the matter preceding clause (i),
6	by
7	(I) striking "2003 through" and
8	inserting "2005 and"; and
9	(II) inserting "more than 1 per-
10	cent" after "years, is"; and
11	(ii) in clause (ii), by striking "sum"
12	and inserting "amount";
13	(6) in subsection $(h)(3)$ —
14	(A) in subparagraph (C), by striking the
15	semicolon and inserting "; and"; and
16	(B) by striking subparagraphs (D) and (E)
17	and inserting the following:
18	"(D) such sums as may be necessary for
19	each of fiscal years 2006 and 2007."; and
20	(7) by striking "subsection (e)(5)" each place it
21	appears and inserting "subsection (e)(2)".
22	(b) MISBRANDED DEVICES.—
23	(1) Reprocessed Devices.—Section 502(u) of
24	the Federal Food, Drug, and Cosmetic Act (21
25	U.S.C. 352(u)) is amended to read as follows:

1	"(u)(1) Subject to paragraph (2), if it is a reproc-
2	essed single-use device, unless it, or an attachment there-
3	to, prominently and conspicuously bears the name of the
4	manufacturer of the reprocessed device, a generally recog-
5	nized abbreviation of such name, or a unique and generally
6	recognized symbol identifying such manufacturer.
7	"(2) The Secretary may by guidance waive any re-
8	quirement under paragraph (1) for a reprocessed device
9	or category of reprocessed devices if the Secretary deter-
10	mines that compliance with such a requirement—
11	"(A) is not feasible due to the physical charac-
12	teristics of the device or eategory of devices; or
13	"(B) would compromise the provision of reason-
14	able assurance of the safety or effectiveness of the
15	device or eategory of devices.".
16	(2) Guidance.—Not later than 150 days after
17	the date of enactment of this Act, the Secretary of
18	Health and Human Services shall issue guidance
19	specifying the device or category of devices that
20	qualify for a waiver under section 502(u) of the Fed-
21	eral Food, Drug, and Cosmetic Act (21 U.S.C.
22	352(u)) (as amended by paragraph (1)).
23	(3) Effective date.—Section 301(b) of Pub-
24	lie Law 107–250 (116 Stat. 1616), as amended by

1	section 2(e) of Public Law 108–214 (118 Stat. 575),
2	is amended by—
3	(A) striking "36 months after the date of
4	enactment of this Act" and inserting "9 months
5	after the date of enactment of the Medical De-
6	vice User Fee Stabilization Act of 2005"; and
7	(B) inserting "reprocessed and" before
8	"introduced".
9	SECTION 1. SHORT TITLE.
10	This Act may be cited as the "Medical Device User
11	Fee Stabilization Act of 2005".
12	SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND
13	COSMETIC ACT.
14	(a) Device User Fees.—Section 738 of the Federal
15	Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
16	ed—
17	(1) in subsection (b)—
18	(A) after "2004;", by inserting "and"; and
19	(B) by striking "2005;" and all that follows
20	through "2007" and inserting "2005";
21	(2) in subsection (c)—
22	(A) by striking the heading and inserting
23	"Annual Fee Setting.—";
24	(B) by striking paragraphs (1), (2), (3),
25	and (4):

1	(C) by redesignating paragraphs (5) and
2	(6) as paragraphs (1) and (2), respectively;
3	(D) in paragraph (1), as so redesignated,
4	<i>by</i> —
5	(i) striking the heading and inserting
6	"In general.—";
7	(ii) striking "establish, for the next fis-
8	cal year, and" and all that follows through
9	"the fees" and inserting "publish in the
10	Federal Register fees under subsection (a).
11	The fees";
12	(iii) striking "2003" and inserting
13	"2006"; and
14	(iv) striking "\$154,000." and inserting
15	"\$259,600, and the fees established for fiscal
16	year 2007 shall be based on a premarket
17	application fee of \$281,600."; and
18	(E) by adding at the end the following:
19	"(3) Supplement.—
20	"(A) In general.—For fiscal years 2006
21	and 2007, the Secretary may use unobligated
22	carryover balances from fees collected in previous
23	fiscal years to ensure that sufficient fee revenues
24	are available in that fiscal year, so long as the
25	Secretary maintains unobligated carryover bal-

1	ances of not less than 1 month of operating re-
2	serves for the first month of fiscal year 2008.
3	"(B) Notice to congress.—Not later
4	than 14 days before the Secretary anticipates the
5	use of funds described in subparagraph (A), the
6	Secretary shall provide notice to the Committee
7	on Health, Education, Labor, and Pensions and
8	the Committee on Appropriations of the Senate
9	and the Committee on Energy and Commerce
10	and the Committee on Appropriations of the
11	House of Representatives.";
12	(3) in subsection (d)—
13	(A) in paragraph (1), by inserting after the
14	first sentence the following: "For the purposes of
15	this paragraph, the term 'small business' means
16	an entity that reported \$30,000,000 or less of
17	gross receipts or sales in its most recent Federal
18	income tax return for a taxable year, including
19	such returns of all of its affiliates, partners, and
20	parent firms."; and
21	(B) in paragraph (2)(A), by—
22	(i) striking "(i) In General.—";
23	(ii) striking "subsection," and insert-
24	ing "paragraph,";

1	(iii) striking "\$30,000,000" and in-
2	serting "\$100,000,000"; and
3	(iv) striking clause (ii);
4	(4) in subsection $(e)(2)(A)$, by striking
5	"\$30,000,000" and inserting "\$100,000,000";
6	(5) in subsection $(g)(1)$ —
7	(A) in subparagraph (B)—
8	(i) by striking clause (i) and inserting
9	$the\ following:$
10	"(i) For fiscal year 2005, the Secretary
11	is expected to meet all of the performance
12	goals identified for the fiscal year if the
13	amount so appropriated for such fiscal
14	year, excluding the amount of fees appro-
15	priated for such fiscal year, is equal to or
16	greater than \$205,720,000 multiplied by the
17	adjustment factor applicable to the fiscal
18	year."; and
19	(ii) in clause (ii), by striking the mat-
20	ter preceding subclause (I) and inserting the
21	following:
22	"(ii) For fiscal year 2005, if the
23	amount so appropriated for such fiscal
24	year, excluding the amount of fees appro-
25	priated for such fiscal year, is more than 1

1	percent less than the amount that applies
2	under clause (i), the following applies:";
3	$(B) \ in \ subparagraph \ (C)$ —
4	(i) in the matter preceding clause (i),
5	by—
6	(I) striking "2003 through" and
7	inserting "2005 and"; and
8	(II) inserting "more than 1 per-
9	cent" after "years, is"; and
10	(ii) in clause (ii), by striking "sum"
11	and inserting "amount"; and
12	(C) in $subparagraph$ (D)(i), by inserting
13	"more than 1 percent" after "year, is";
14	(6) in subsection $(h)(3)$ —
15	(A) in subparagraph (C), by striking the
16	semicolon and inserting "; and"; and
17	(B) by striking subparagraphs (D) and (E)
18	and inserting the following:
19	"(D) such sums as may be necessary for
20	each of fiscal years 2006 and 2007."; and
21	(7) by striking "subsection (c)(5)" each place it
22	appears and inserting "subsection $(c)(1)$ ".
23	(b) Annual Reports.—Section 103 of the Medical
24	Device User Fee and Modernization Act of 2002 (Public
25	Law 107–250 (116 Stat. 1600)) is amended—

1	(1) by striking "Beginning with" and inserting
2	"(a) In General.—Beginning with"; and
3	(2) by adding at the end the following:
4	"(b) Additional Information.—For fiscal years
5	2006 and 2007, the report described under subsection (a)(2)
6	shall include—
7	"(1) information on the number of different
8	types of applications and notifications, and the total
9	amount of fees paid for each such type of application
10	or notification, from businesses with gross receipts or
11	sales from \$0 to \$100,000,000, with such businesses
12	categorized in \$10,000,000 intervals; and
13	"(2) a certification by the Secretary that the
14	amounts appropriated for salaries and expenses of the
15	Food and Drug Administration for such fiscal year
16	and obligated by the Secretary for the performance of
17	any function relating to devices that is not for the
18	process for the review of device applications, as de-
19	fined in paragraph (5) of section 737 of the Federal
20	Food, Drug, and Cosmetic Act (21 U.S.C. 379i), are
21	not less than such amounts for fiscal year 2002 multi-
22	plied by the adjustment factor, as defined in para-
23	graph (7) of such section 737.".
24	(c) Misbranded Devices.—

1	(1) In general.—Section 502(u) of the Federal
2	Food, Drug, and Cosmetic Act (21 U.S.C. 352(u)) is
3	amended to read as follows:
4	"(u)(1) Subject to paragraph (2), if it is a reprocessed
5	single-use device, unless it, or an attachment thereto, promi-
6	nently and conspicuously bears the name of the manufac-
7	turer of the reprocessed device, a generally recognized abbre-
8	viation of such name, or a unique and generally recognized
9	symbol identifying such manufacturer.
10	"(2) If the original device or an attachment thereto
11	does not prominently and conspicuously bear the name of
12	the manufacturer of the original device, a generally recog-
13	nized abbreviation of such name, or a unique and generally
14	recognized symbol identifying such manufacturer, a reproc-
15	essed device may satisfy the requirements of paragraph (1)
16	through the use of a detachable label on the packaging that
17	identifies the manufacturer and is intended to be affixed
18	to the medical record of a patient.".
19	(2) Guidance.—Not later than 180 days after
20	the date of enactment of this Act, the Secretary of
21	Health and Human Services shall issue guidance to
22	identify circumstances in which the name of the man-
23	ufacturer of the original device, a generally recognized
24	abbreviation of such name, or a unique and generally
25	recognized symbol identifying such manufacturer, is

1	not "prominent and conspicuous", as used in section					
2	502(u) of Federal Food, Drug, and Cosmetic Act (as					
3	amended by paragraph (1)).					
4	(d) Effective Date.—Section 301(b) of the Medical					
5	Device User Fee and Modernization Act of 2002 (Public					
6	Law 107–250 (116 Stat. 1616)), as amended by section 2(c)					
7	of Public Law 108–214 (118 Stat. 575), is amended to read					
8	as follows:					
9	"(b) Effective Date.—Section 502(u) of the Federal					
10	Food, Drug, and Cosmetic Act (as amended by section 2(c)					
11	of the Medical Device User Fee Stabilization Act of 2005)—					
12	"(1) shall be effective—					
13	"(A) with respect to devices described under					
14	paragraph (1) of such section, 12 months after					
15	the date of enactment of the Medical Device User					
16	Fee Stabilization Act of 2005, or the date on					
17	which the original device first bears the name of					
18	the manufacturer of the original device, a gen-					
19	erally recognized abbreviation of such name, or					
20	a unique and generally recognized symbol identi-					
21	fying such manufacturer, whichever is later; and					
22	"(B) with respect to devices described under					
23	paragraph (2) of such section 502(u), 12 months					
24	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.".

Calendar No. 173

109TH CONGRESS S. 1420
1ST SESSION [Report No. 109-107]

A BILL

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

Reported with an amendment July 25, 2005