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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Medical Device User Fee Stabilization Act of 2005".~~

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

(a) DEVICE USER FEES.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in subsection (b)—

(A) after ''2004;'', by inserting ''and''; and

(B) by striking ''2005;'' and all that follows through ''2007'' and inserting ''2005'';

(2) in subsection (c)—

(A) by striking paragraphs (1), (2), and (3);

(B) by redesignating paragraphs (4), (5), and (6) as paragraphs (1), (2), and (3), respectively;

(C) in paragraph (1), as so redesignated, by—

(i) striking the paragraph heading and inserting ''2007 INCREASE'';

(ii) striking '', in addition to adjustments under paragraphs (1) and (2), further'';

(iii) striking ''established in subsection (b)'' and inserting ''under subsection (a)''; and

(iv) striking ''adjustment'' each place it appears and inserting ''increase''; and

(D) in paragraph (2), as so redesignated, by—

(i) striking ''establish, for the next fiscal year, and'' and all that follows through ''the fees'' and inserting ''publish in the Federal Register fees under subsection (a). The fees'';

(ii) striking ''2003'' and inserting ''2006''; and

(iii) striking ''$154,000.'' and inserting ''$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of $281,600.'';

(3) in subsection (d)(2)(A)—

(A) in clause (i), by striking ''$30,000,000'' and inserting ''$75,000,000''; and

(B) by striking clause (ii) and inserting the following:

''(ii) ADJUSTMENTS.—

''(I) IN GENERAL.—If the Secretary has evidence from actual experience that the $75,000,000 threshold

established in clause (i) results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 26 percent or more than would occur without small business exemptions and lower fee rates, the Secretary may—

"(aa) use the operating reserves in an amount not to exceed the lesser of—

"(AA) 10 percent of the fees collected in fiscal year 2005; or

"(BB) $2,500,000; and

"(bb) upon the exhaustion of the amount described under item (aa), adjust the $75,000,000 threshold as provided for under subclause (II).

"(II) ADJUSTMENT OF THRESHOLD.—To adjust the threshold described in subclause (I)(bb), the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the

new threshold. Such adjusted threshold may not be less than $30,000,000 and may not be retroactive.'';

(4) in subsection (e)(2)(A), by striking ''$30,000,000'' and inserting ''$75,000,000'';

(5) in subsection (g)(1)—

(A) in subparagraph (B)—

(i) by striking clause (i) and inserting the following:

''(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than $205,720,000 multiplied by the adjustment factor applicable to the fiscal year.''; and

(ii) in clause (ii), by striking the matter preceding subclause (I) and inserting the following:

''(ii) For fiscal year 2005, if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated 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:

''(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

''(2) The Secretary may by guidance waive any requirement under paragraph (1) for a reprocessed device or category of reprocessed devices if the Secretary determines that compliance with such a requirement—

''(A) is not feasible due to the physical characteristics of the device or category of devices; or

''(B) would compromise the provision of reasonable assurance of the safety or effectiveness of the device or category of devices.''.

(2) GUIDANCE.—Not later than 150 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance specifying the device or category of devices that qualify for a waiver under section 502(u) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(u)) (as amended by paragraph (1)).

(3) EFFECTIVE DATE.—Section 301(b) of Public Law 107–250 (116 Stat. 1616), as amended by

~~section 2(c) of Public Law 108–214 (118 Stat. 575), is amended by—~~

~~(A) striking "36 months after the date of enactment of this Act" and inserting "9 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005"; and~~

~~(B) inserting "reprocessed and" before "introduced".~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Device User Fee Stabilization Act of 2005".

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

(a) DEVICE USER FEES.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in subsection (b)—

(A) after "2004;", by inserting "and"; and

(B) by striking "2005;" and all that follows through "2007" and inserting "2005";

(2) in subsection (c)—

(A) by striking the heading and inserting "ANNUAL FEE SETTING.—";

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

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

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

(i) striking the heading and inserting "IN GENERAL.—";

(ii) striking "establish, for the next fiscal year, and" and all that follows through "the fees" and inserting "publish in the Federal Register fees under subsection (a). The fees";

(iii) striking "2003" and inserting "2006"; and

(iv) striking "$154,000." and inserting "$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of $281,600."; and

(E) by adding at the end the following:

"(3) SUPPLEMENT.—

"(A) IN GENERAL.—For fiscal years 2006 and 2007, the Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover bal-

ances of not less than 1 month of operating reserves for the first month of fiscal year 2008.

"(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.";

(3) in subsection (d)—

(A) in paragraph (1), by inserting after the first sentence the following: "For the purposes of this paragraph, the term 'small business' means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms."; and

(B) in paragraph (2)(A), by—

(i) striking "(i) IN GENERAL.—";

(ii) striking "subsection," and inserting "paragraph,";

(iii) striking "$30,000,000" and inserting "$100,000,000"; and

(iv) striking clause (ii);

(4) in subsection (e)(2)(A), by striking "$30,000,000" and inserting "$100,000,000";

(5) in subsection (g)(1)—

(A) in subparagraph (B)—

(i) by striking clause (i) and inserting the following:

"(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than $205,720,000 multiplied by the adjustment factor applicable to the fiscal year."; and

(ii) in clause (ii), by striking the matter preceding subclause (I) and inserting the following:

"(ii) For fiscal year 2005, if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is more than 1

percent less than the amount that applies under clause (i), the following applies:";

(B) in subparagraph (C)—

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

(I) striking "2003 through" and inserting "2005 and"; and

(II) inserting "more than 1 percent" after "years, is"; and

(ii) in clause (ii), by striking "sum" and inserting "amount"; and

(C) in subparagraph (D)(i), by inserting "more than 1 percent" after "year, is";

(6) in subsection (h)(3)—

(A) in subparagraph (C), by striking the semicolon and inserting "; and"; and

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

"(D) such sums as may be necessary for each of fiscal years 2006 and 2007."; and

(7) by striking "subsection (c)(5)" each place it appears and inserting "subsection (c)(1)".

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

(1) by striking "Beginning with" and inserting "(a) IN GENERAL.—Beginning with"; and

(2) by adding at the end the following:

"(b) ADDITIONAL INFORMATION.—For fiscal years 2006 and 2007, the report described under subsection (a)(2) shall include—

"(1) information on the number of different types of applications and notifications, and the total amount of fees paid for each such type of application or notification, from businesses with gross receipts or sales from $0 to $100,000,000, with such businesses categorized in $10,000,000 intervals; and

"(2) a certification by the Secretary that the amounts appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year and obligated by the Secretary for the performance of any function relating to devices that is not for the process for the review of device applications, as defined in paragraph (5) of section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i), are not less than such amounts for fiscal year 2002 multiplied by the adjustment factor, as defined in paragraph (7) of such section 737.".

(c) MISBRANDED DEVICES.—

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

"(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

"(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.".

(2) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance to identify circumstances in which the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, is

not "prominent and conspicuous", as used in section 502(u) of Federal Food, Drug, and Cosmetic Act (as amended by paragraph (1)).

(d) EFFECTIVE DATE.—Section 301(b) of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250 (116 Stat. 1616)), as amended by section 2(c) of Public Law 108–214 (118 Stat. 575), is amended to read as follows:

"(b) EFFECTIVE DATE.—Section 502(u) of the Federal Food, Drug, and Cosmetic Act (as amended by section 2(c) of the Medical Device User Fee Stabilization Act of 2005)—

"(1) shall be effective—

"(A) with respect to devices described under paragraph (1) of such section, 12 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005, or the date on which the original device first bears the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, whichever is later; and

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

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

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