109TH CONGRESS
1ST SESSION

S. 1420

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, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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

(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'';

(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)(2)''.

(b) MISBRANDED DEVICES.—

(1) REPROCESSED DEVICES.—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) 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''.

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