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108TH CONGRESS
1ST SESSION

S. 1881

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 SENATE OF THE UNITED STATES

NOVEMBER 18, 2003

Mr. ALEXANDER (for himself, Mrs. MURRAY, Mr. ENZI, and Mr. GREGG) 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 to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

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 Devices Technical Corrections Act''.

SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW 107–250.

(a) TITLE I; FEES RELATING TO MEDICAL DEVICES.—Part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as added by section 102 of Public Law 107–250 (116 Stat. 1589), is amended—

(1) in section 737—

(A) in paragraph (4)(B), by striking ''and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness'' and inserting ''and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness'';

(B) in paragraph (4)(D), by striking ''manufacturing,'';

(C) in paragraph (5)(J), by striking ''a premarket application'' and all that follows and inserting ''a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.''; and

(D) in paragraph (8), by striking ''The term 'affiliate' means a business entity that has a relationship with a second business entity''

and inserting ''The term 'affiliate' means a business entity that has a relationship with a second business entity (whether domestic or international)''; and

(2) in section 738—

(A) in subsection (a)(1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i) by striking ''subsection (d),'' and inserting ''subsections (d) and (e),'';

(II) in clause (iv), by striking ''clause (i),'' and all that follows and inserting ''clause (i).''; and

(III) in clause (vii), by striking ''clause (i),'' and all that follows and inserting ''clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).''; and

(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking ''application'' and inserting ''application, report,'';

(B) in subsection (d)(2)(B), beginning in the second sentence, by striking ''firms. which show'' and inserting ''firms, which show'';

(C) in subsection (e)—

(i) in paragraph (1), by striking ''Where'' and inserting ''For fiscal year 2004 and each subsequent fiscal year, where''; and

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking ''firms. which show'' and inserting ''firms, which show''; and

(II) in subparagraph (C)(i), by striking ''Where'' and inserting ''For fiscal year 2004 and each subsequent fiscal year, where'';

(D) in subsection (f), by striking ''for filing''; and

(E) in subsection (h)(2)—

(i) by striking subparagraph (A)(ii) and inserting the following:

''(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human

Services to be engaged in such process) over such costs for fiscal year 2002 when multiplied by the adjustment factor (the determination of the costs of the resources allocated for the process for the review of device applications for fiscal year 2003 through 2007, for purposes of this subparagraph, shall not include costs paid from fees collected under this section).''; and

(ii) in subparagraph (B)—

(I) in clause (ii), by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively;

(II) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(III) by striking ''The Secretary'' and inserting the following:

''(i) IN GENERAL.—The Secretary''; and

(IV) by adding at the end the following:

''(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 per-

cent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.''.

(b) TITLE II; AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES.—

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

(A) in paragraph (1), in the first sentence, by striking ''conducting inspections'' and all that follows and inserting ''conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i).'';

(B) in paragraph (6)(A)—

(i) in clause (i), by striking ''of the establishment pursuant to subsection (h) or (i) of section 510'' and inserting ''described in paragraph (1)'';

(ii) in clause (ii)—

(I) in the matter preceding subclause (I)—

(aa) by striking ''each inspection'' and inserting ''inspections''; and

(bb) by inserting ''during a 2-year period'' after ''person''; and

(II) in subclause (I), by striking ''such a person'' and inserting ''an accredited person'';

(iii) in clause (iii)—

(I) in the matter preceding subclause (I), by striking ''and the following additional conditions are met:'' and inserting ''and 1 or both of the following additional conditions are met:'';

(II) in subclause (I), by striking ''under subclause (II) of this clause'' and inserting ''under clause (ii)(II)''; and

(III) in subclause (II), by inserting ''or by a person accredited under

paragraph (2)'' after ''by the Secretary'';

(iv) in clause (iv)(I)—

(I) in the first sentence—

(aa) by striking ''the two immediately preceding inspections of the establishment'' and inserting ''inspections of the establishment during the previous 4 years''; and

(bb) by inserting ''section'' after ''pursuant to''; and

(II) in the third sentence—

(aa) by striking ''the petition states a commercial reason for the waiver;''; and

(bb) by inserting ''not'' after ''the Secretary has not determined that the public health would''; and

(v) in clause (iv)(II)—

(I) by inserting ''of a device establishment required to register'' after ''to be conducted''; and

(II) by inserting ''section'' after ''pursuant to'';

(C) in paragraph (6)(B)(iii)—

(i) in the first sentence, by striking '', and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502''; and

(ii) in the second sentence—

(I) by striking ''inspections'' and inserting ''inspectional findings''; and

(II) by striking '', together with all other compliance data the Secretary deems necessary'';

(D) in paragraph (6)(C)(ii), by striking ''in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable'';

(E) in paragraph (10)(B)(iii), by striking ''a reporting'' and inserting ''a report''; and

(F) in paragraph (12)—

(i) by striking subparagraph (A) and inserting the following:

''(A) the number of inspections conducted by accredited persons pursuant to this sub-

section and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);''; and

(ii) in subparagraph (E), by striking ''obtained by the Secretary'' and all that follows and inserting ''obtained by the Secretary pursuant to inspections conducted by Federal employees;''.

(2) OTHER CORRECTIONS.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section 206 of Public Law 107–250 (116 Stat. 1613), is amended, in the last sentence—

(A) by inserting ''or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments'' after ''in health care facilities'';

(B) by inserting a comma after ''means'';

(C) by striking ''requirements of law and, that'' and inserting ''requirements of law, and that'';

(D) by striking ''the manufacturer affords health care facilities the opportunity'' and in-

serting ''the manufacturer affords such users the opportunity''; and

(E) by striking ''the health care facility''.

(c) TITLE III; ADDITIONAL AMENDMENTS.—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(o)), as added by section 302(b) of Public Law 107–250 (116 Stat. 1616), is amended—

(1) in paragraph (1)(B), by striking '', adulterated'' and inserting ''or adulterated''; and

(2) in paragraph (2)—

(A) in subparagraph (B), by striking '', adulterated'' and inserting ''or adulterated''; and

(B) in subparagraph (E), by striking ''semicritical'' and inserting ''semi-critical''.

(d) MISCELLANEOUS CORRECTIONS.—

(1) CERTAIN AMENDMENTS TO SECTION 515.—

(A) IN GENERAL.—

(i) TECHNICAL CORRECTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), as amended by sections 209 and 302(c)(2)(A) of Public Law 107–250 (116 Stat. 1613, 1618), is amended by redesignating para-

graph (3) (as added by section 209 of such Public Law) as paragraph (4).

(ii) MODULAR REVIEW.—Section 515(c)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is amended by striking ''unless an issue of safety'' and inserting ''unless a significant issue of safety''.

(B) CONFORMING AMENDMENT.—Section 210 of Public Law 107–250 (116 Stat. 1614) is amended by striking '', as amended'' and all that follows through ''by adding'' and inserting ''is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding''.

(2) CERTAIN AMENDMENTS TO SECTION 738.—

(A) IN GENERAL.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)), as amended by subsection (a), is amended—

(i) in the matter preceding paragraph (1)—

(I) by striking ''(a) TYPES OF FEES.—Beginning on'' and inserting the following:

''(a) TYPES OF FEES.—

''(1) IN GENERAL.—Beginning on''; and

(II) by striking ''this section as follows:'' and inserting ''this section.''; and

(ii) by striking ''(1) PREMARKET APPLICATION,'' and inserting the following: ''(2) PREMARKET APPLICATION,''.

(B) CONFORMING AMENDMENTS.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

(i) in subsection (d)(1), in the last sentence, by striking ''subsection (a)(1)(A)'' and inserting ''subsection (a)(2)(A)'';

(ii) in subsection (e)(1), by striking ''subsection (a)(1)(A)(vii)'' and inserting ''subsection (a)(2)(A)(vii)'';

(iii) in subsection (e)(2)(C)—

(I) in each of clauses (i) and (ii), by striking ''subsection (a)(1)(A)(vii)'' and inserting ''subsection (a)(2)(A)(vii)''; and

(II) in clause (ii), by striking ''subsection (a)(1)(A)(i)'' and inserting ''subsection (a)(2)(A)(i)''; and

(iv) in subsection (j), by striking ''subsection (a)(1)(D),'' and inserting ''subsection (a)(2)(D),''.

(C) ADDITIONAL CONFORMING AMENDMENT.—Section 102(b)(1) of Public Law 107–250 (116 Stat. 1600) is amended, in the matter preceding subparagraph (A), by striking ''section 738(a)(1)(A)(ii)'' and inserting ''section 738(a)(2)(A)(ii)''.

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

(A) in section 102(a) (116 Stat. 1589), by striking ''(21 U.S.C. 379F et seq.)'' and inserting ''(21 U.S.C. 379f et seq.)'';

(B) in section 102(b) (116 Stat. 1600)—

(i) by striking paragraph (2);

(ii) in paragraph (1), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

(iii) by striking:

''(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

''(1) IN GENERAL.—A person submitting a premarket report'' and inserting:

''(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report'';

(C) in section 212(b)(2) (116 Stat. 1614), by striking '', such as phase IV trials,''; and

(D) in section 301(b) (116 Stat. 1616), by striking ''18 months'' and inserting ''36 months''.

SEC. 3. HUMANITARIAN DEVICE EXEMPTION AND PEDIATRIC PRODUCTS.

(a) AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 520(m)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(3)) is amended to read as follows:

''(3) Excluding devices intended for the treatment or diagnosis of diseases or conditions that affect pediatric patients, no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. The exclusion from the prohibition under the previous sentence for devices intended for the treatment or diagnosis of diseases or conditions that affect pediatric patients, shall not

apply in the case of a request for an exemption under paragraph (2) made on or after October 1, 2007. In this paragraph, the term 'pediatric patient' means a patient who is 14 years of age or younger at the time of diagnosis or treatment.''.

(b) REPORT.—Not later than October 1, 2006, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) in ensuring the development of devices designed to treat or diagnose diseases or conditions that affect fewer than 4,000 pediatric patients in the United States. Such report shall include the number and importance of devices for pediatric patients that are receiving exemptions under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)).

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