108TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { 108–433

MEDICAL DEVICES TECHNICAL CORRECTIONS ACT

MARCH 9, 2004.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany S. 1881]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

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)(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 percent 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 (5)(B), in the first sentence, by striking "or poses" and all that follows through the period and inserting "poses a threat to public health, fails to act in a manner that is consistent with the purposes of this

subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection.";

(C) 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 "accredited" and all that follows through the period and inserting "(accredited under paragraph (2) and identified under clause (ii)(II)) as a person authorized to conduct such inspections of device establishments."; 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";

(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

(III) in the fourth sentence, by striking "granted until" and inserting "granted or deemed to be granted until"; 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";

(D) 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 other" and inserting "and with other"; and

(ii) in the second sentence—

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

(II) by inserting "relevant" after "together with all other";

(E) in paragraph (6)(B)(iv)—

(i) by inserting "(I)" after "(iv)"; and

(ii) by adding at the end the following:

"(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.";

(F) 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";

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

(H) in paragraph (12)—

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

"(A) the number of inspections conducted by accredited persons pursuant to this subsection 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.—

(A) PROHIBITED ACTS.—Section 301(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(gg)), as amended by section 201(d) of Public Law 107–250 (116 Stat. 1609), is amended to read as follows:

"(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.".

(B) ELECTRONIC LABELING.—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—

(i) 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";

(ii) by inserting a comma after "means";

(iii) by striking "requirements of law and, that" and inserting "requirements of law, and that";

(iv) by striking "the manufacturer affords health care facilities the opportunity" and inserting "the manufacturer affords such users the opportunity"; and

(v) by striking "the health care facility".

(c) TITLE III; ADDITIONAL AMENDMENTS.—

(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107–250 (116 Stat. 1616), is amended by striking "18 months" and inserting "36 months".

(2) PREMARKET NOTIFICATION.—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—

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

(B) in paragraph (2)—

(i) in subparagraph (B), by striking ", adulterated" and inserting "or adulterated"; and

(ii) 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 paragraph (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"; and

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

SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DEVICES INTENDED FOR CHILDREN.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children. The report shall include any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices.

PURPOSE AND SUMMARY

S. 1881 makes technical and conforming changes to the Medical Device User Fee and Modernization Act of 2002.

BACKGROUND AND NEED FOR LEGISLATION

On October 26, 2002, President Bush signed into law the Medical Device User Fee and Modernization Act of 2002 (P.L. 107–250). This legislation provided increased resources to the Food and Drug Administration (FDA) through user fees and made other significant reforms to the FDA in order to improve the quality and speed of medical device approvals, but is in need of technical corrections.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On March 3, 2004, the Full Committee met in open markup session and favorably ordered S. 1881 reported to the House, as amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering S. 1881 reported. A motion by Mr. Barton to order S. 1881 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of S. 1881 is to make technical and conforming changes to the Medical Device User Fee and Modernization Act of 2002.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that S. 1881, the Medical Device Technical Corrections Act, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 8, 2004.

Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1881, the Medical Devices Technical Corrections Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

S. 1881—Medical Devices Technical Corrections Act

S. 1881 would make technical changes regarding the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250). CBO estimates that enacting S. 1881 would have a negligible impact on the Federal budget and have no effect on direct spending or receipts.

The act would clarify the existing statute underlying the Food and Drug Administration's (FDA's) user fee program for medical devices. We anticipate that those modifications would not significantly change the costs for FDA to administer the program, nor would it affect user fee collections. S. 1881 also would require the Secretary of Health and Human Services to conduct a study on the availability of medical devices for children. Assuming the availability of appropriated funds, CBO estimates that implementing S. 1881 would cost less than $500,000 a year.

This legislation contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on State, local, or tribal governments.

The CBO staff contact for this estimate is Julia Christensen. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates the short title as the "Medical Device Technical Corrections Act."

Section 2. Technical amendments regarding Public Law 107–250

Section 2 makes several technical changes to the Medical Device User Fee and Modernization Act of 2002 (P.L. 107–250). It renum-

bers and conforms the appropriate sections of the Federal Food, Drug, and Cosmetic Act, making grammatical corrections, inserting periods, and correcting comma placement.

Section 2 clarifies the distinction between a "panel track supplement" for which substantial clinical data is required to demonstrate a reasonable assurance of safety and effectiveness and a "180-day supplement" for which such data is not required. Next, section 2 clarifies that premarket reports are within the definition of "process for the review of device applications." Further, section 2 clarifies the term "affiliate" to include international as well as domestic affiliates in the user fee program.

Section 2 makes technical changes clarifying that the third party inspection program applies to 510(h) inspections of establishments and inspections of foreign facilities required to register with the Food and Drug Administration (FDA). Section 2 ensures that facilities can work with third party inspectors to allow them to complete a full 510(h) inspection over the course of a two year period. Section 2 clarifies the law and allows entities to certify that a foreign country recognizes the third party conducting the inspection, instead of requiring a statement that such a country recognizes FDA's inspectional authority. Section 2 also ensures that companies can use third party inspectors for two consecutive 510(h) inspections before requesting special permission from the Secretary for the third such inspection. Finally, section 2 makes important modifications to section 301 by providing an 18-month implementation delay for all branding requirements and clarifies the definition of modular review to be consistent with the FDA's modular review program.

Section 3. Report on barriers to availability of devices intended for children

Section 3 requests that the FDA complete a report on the barriers to the availability of devices intended for pediatric patients, and provide policy recommendations as to what could be changed in existing law to address this issue.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

[(gg) The knowing failure of a person accredited under paragraph (2) of section 704(g) to comply with paragraph (7)(E) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.]

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

SEC. 501. * * *

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MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—
(a) * * *

* * * * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities *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* may be made available solely by electronic means, provided that the labeling complies with all applicable [requirements of law and, that] *requirements of law, and that* [the manufacturer affords health care facilities the opportunity] *the manufacturer affords such users the opportunity* to request the labeling in paper form, and after such request, promptly provides [the health care facility] the requested information without additional cost.

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REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES

SEC. 510. (a) As used in this section—
(1) * * *

* * * * * * *

(o)(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) * * *

(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o)[, adulterated] *or adulterated* under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

* * * * * * *

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) * * *

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o)[, adulterated] *or adulterated* under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

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(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or [semicritical] *semi-*

critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

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PREMARKET APPROVAL

General Requirement

SEC. 515. (a) * * *

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Application for Premarket Approval

(c)(1) * * *

* * * * * * *

[(3)**]** *(4)*(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 738(g), the Secretary does not have the authority to collect fees under section 738(a).

(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), **[**unless an issue of safety**]** *unless a significant issue of safety* or effectiveness provides the Secretary reason to review such accepted portion.

(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is required to correct these deficiencies, unless the applicant is no longer pursuing the application.".

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

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FACTORY INSPECTION

SEC. 704. (a)(1) * * *

* * * * * * *

(g)(1) Not later than one year after the date of the enactment of this subsection, the Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of **[**conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices that are required in section 510(h), or inspections of such establishments required to register pursuant to section 510(i).**]** *conducting inspections of establishments that manufacture, prepare, propagate, compound, or proc-*

ess 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). The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections.

* * * * * * *

(5)(A) * * *

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, [or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this subsection.] *poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection.* The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspections by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection [of the establishment pursuant to subsection (h) or (i) of section 510] *described in paragraph (1)* as "no action indicated" or "voluntary action indicated".

(ii) With respect to [each inspection] *inspections* to be conducted by an accredited person *during a 2-year period—*

(I) the owner or operator of the establishment submits to the Secretary a notice requesting clearance to use [such a person] *an accredited person* to conduct the inspection, and the Secretary provides such clearance; and

* * * * * * *

(iii) With respect to the devices that are manufactured, prepared, propagated, compounded, or processed by the establishment, at least one of such devices is marketed in the United States, [and the following additional conditions are met:] *and 1 or both of the following additional conditions are met:*

(I) At least one of such devices is marketed, or is intended to be marketed, in one or more foreign countries, one of which countries certifies, accredits, or otherwise recognizes the person [accredited under paragraph (2) and identified under subclause (II) of this clause.] *(accredited under paragraph (2) and identified under clause (ii)(II)) as a person authorized to conduct such inspections of device establishments.*

(II) The owner or operator of the establishment submits to the Secretary a statement that the law of a country in which such a device is marketed, or is intended to be marketed, recognizes an inspection of the establishment by the Secretary *or by a person accredited under paragraph (2)*, and not later than 30 days after receiving such statement,

the Secretary informs the owner or operator of the establishment that the owner or operator may submit a notice requesting clearance under clause (ii).

(iv)(I) In the case of an inspection to be conducted pursuant to *section* 510(h), persons accredited under paragraph (2) did not conduct **[**the two immediately preceding inspections of the establishment**]** *inspections of the establishment during the previous 4 years*, except that the establishment may petition the Secretary for a waiver of such condition. Such a waiver may be granted only if the petition states a commercial reason for the waiver; the Secretary determines that the public health would be served by granting the waiver; and the Secretary has conducted an inspection of the establishment during the four-year period preceding the date on which the notice under clause (ii) is submitted to the Secretary. Such a waiver is deemed to be granted only if **[**the petition states a commercial reason for the waiver;**]** the Secretary has not determined that the public health would *not* be served by granting the waiver; and the owner or operator of the device establishment has requested in writing, not later than 18 months following the most recent inspection of such establishment by a person accredited under paragraph (2), that the Secretary inspect the establishment and the Secretary has not conducted an inspection within 30 months after the most recent inspection. With respect to such a waiver that is granted or deemed to be granted, no additional such waiver may be **[**granted until**]** *granted or deemed to be granted until* after the Secretary has conducted an inspection of the establishment.

(II) In the case of an inspection to be conducted *of a device establishment required to register* pursuant to *section* 510(i), the Secretary periodically conducts inspections of the establishment.

* * * * * * *

(B)(i) * * *

* * * * * * *

(iii) The compliance data to be submitted by a device establishment under clause (ii) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h)**[**, and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other**]** *and with other* applicable provisions of this Act. Such data shall include complete reports of **[**inspections**]** *inspectional findings* regarding good manufacturing practice or other quality control audits that, during the preceding two-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other *relevant* compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(iv)*(I)* Not later than 60 days after receiving compliance data under clause (iii) from a device establishment, the Secretary shall

provide or deny clearance under subparagraph (A). The Secretary may deny clearance if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of clause (iii). The Secretary shall provide to the establishment a statement of such reasons for such determination. If the Secretary fails to provide such statement to the establishment within such 60-day period, the establishment is deemed to have such clearance.

(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.

* * * * * * *

(C)(i) * * *

(ii) If the Secretary denies a petition under clause (i), the device establishment involved may, after the expiration of one year after such denial, again petition the Secretary for a determination of eligibility for inspection by persons accredited by the Secretary under paragraph (2). If the Secretary denies such petition, the Secretary shall provide the establishment with such reasons for such denial within 60 days after the denial. If, as of the expiration of 48 months after the receipt of the first petition, the establishment has not been inspected by the Secretary **[**in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable**]**, the establishment is eligible for further inspections by accredited persons.

* * * * * * *

(10)(A) * * *

(B)(i) * * *

* * * * * * *

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress **[**a reporting**]** *a report* describing the findings made through such determinations.

* * * * * * *

(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

[(A) the number of inspections pursuant to subsections (h) and (i) of section 510 conducted by accredited persons and the number of inspections pursuant to such subsections conducted by Federal employees;**]**

(A) the number of inspections conducted by accredited persons pursuant to this subsection 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);

* * * * * * *

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is

being presented to the Secretary, and whether that information is of a quality consistent with information [obtained by the Secretary pursuant to subsection (h) or (i) of section 510;] *obtained by the Secretary pursuant to inspections conducted by Federal employees;*

* * * * * * *

SUBCHAPTER C—FEES

* * * * * * *

PART 3—FEES RELATING TO DEVICES

SEC. 737. DEFINITIONS.

For purposes of this subchapter:

(1) * * *

* * * * * * *

(4)(A) * * *

(B) The term "panel-track supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, [and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness] *and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness*.

* * * * * * *

(D) The term "real-time supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, [manufacturing,] sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

* * * * * * *

(5) The term "process for the review of device applications" means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) * * *

* * * * * * *

(J) Evaluation of postmarket studies required as a condition of an approval of [a premarket application under section 515 or section 351 of the Public Health Service Act.] *a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.*

* * * * * * *

(8) [The term "affiliate" means a business entity that has a relationship with a second business entity] *The term 'affiliate' means a business entity that has a relationship with a second*

business entity (whether domestic or international) if, directly or indirectly—

(A) * * *

* * * * * * *

SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

[(a) TYPES OF FEES.—Beginning on] *(a) TYPES OF FEES.—*

(1) IN GENERAL.—Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002, the Secretary shall assess and collect fees in accordance with [this section as follows:] *this section.*

[(1) PREMARKET APPLICATION,] *(2) PREMARKET APPLICATION,* premarket report, supplement, and submission fee.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and [subsection (d),] *subsections (d) and (e),* each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(5) for the fiscal year involved in accordance with the following:

(i) * * *

* * * * * * *

(iv) For a 180-day supplement, a fee equal to 21.5 percent of the fee that applies under [clause (i), subject to any adjustment under subsection (c)(3).] *clause (i).*

* * * * * * *

(vii) For a premarket notification submission, a fee equal to 1.42 percent of the fee that applies under [clause (i), subject to any adjustment under subsection (c)(3) and any adjustment under subsection (e)(2)(C)(ii).] *clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).*

* * * * * * *

(D) REFUNDS.—

(i) APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any [application] *application, report,* or supplement that is refused for filing.

(ii) APPLICATION WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any [application] *application, report,* or supplement that is withdrawn prior to the filing decision of the Secretary.

* * * * * * *

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

(1) IN GENERAL.—The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. In addition, for subsequent premarket applications, premarket reports, and supplements

where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vi) of [subsection (a)(1)(A)] *subsection (a)(2)(A)* may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) * * *

(B) EVIDENCE OF QUALIFICATION.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent [firms. which show] *firms, which show* an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, partners, and parent firms, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

* * * * * * *

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—[Where] *For fiscal year 2004 and each subsequent fiscal year, where* the Secretary finds that the applicant involved is a small business, the fee specified in [subsection (a)(1)(A)(vii)] *subsection (a)(2)(A)(vii)* may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) * * *

(B) EVIDENCE OF QUALIFICATION.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent [firms. which show] *firms, which show* an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, partners, and parent firms, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

(C) REDUCED FEES.—

(i) IN GENERAL.—[Where] *For fiscal year 2004 and each subsequent fiscal year, where* the Secretary finds

that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 80 percent of the fee that applies under ⟦subsection (a)(1)(A)(vii)⟧ *subsection (a)(2)(A)(vii)*, as adjusted under clause (ii) and as established under subsection (c)(5).

(ii) ADJUSTMENT PER FEE REVENUE AMOUNT.—For fiscal year 2004 and each subsequent fiscal year, the Secretary, in setting the revenue amount under subsection (c)(5) for premarket notification submissions, shall determine the revenue amount that would apply if all such submissions for the fiscal year involved paid a fee equal to 1.42 percent of the amount that applies under ⟦subsection (a)(1)(A)(i)⟧ *subsection (a)(2)(A)(i)* for premarket applications, and shall adjust the fee under ⟦subsection (a)(1)(A)(vii)⟧ *subsection (a)(2)(A)(vii)* for premarket notification submissions such that the reduced fees collected under clause (i) of this subparagraph, when added to fees for such submissions that are not paid at the reduced rate, will equal such revenue amount for the fiscal year.

* * * * * * *

(f) EFFECT OF FAILURE TO PAY FEES.—A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted ⟦for filing⟧ by the Secretary until all fees owed by such person have been paid.

* * * * * * *

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) * * *

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) * * *

(B) COMPLIANCE.—⟦The Secretary⟧

(i) IN GENERAL.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications—

⟦(i)⟧ *(I)* are not more than 3 percent below the level specified in subparagraph (A)(ii); or

⟦(ii)(I)⟧ *(II)(aa)* are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

⟦(II)⟧ *(bb)* such costs are not more than 5 percent below the level specified in such subparagraph.

(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in

subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

* * * * * * *

(j) WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under [subsection (a)(1)(D),] *subsection (a)(2)(D),* a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

* * * * * * *

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

(Public Law 107–250)

* * * * * * *

TITLE I—FEES RELATED TO MEDICAL DEVICES

* * * * * * *

SEC. 102. ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [(21 U.S.C. 379F et seq.)] *(21 U.S.C. 379f et seq.)* is amended by adding at the end the following part:

* * * * * * *

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

(1) IN GENERAL.—A person submitting a premarket report]

(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report to the Secretary of Health and Human Services is exempt from the fee under [section 738(a)(1)(A)(ii)] *section 738(a)(2)(A)(ii)* of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section) if—

[(A)] *(1)* the premarket report is the first such report submitted to the Secretary by the person; and

[(B)] *(2)* before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.

[(2) DEFINITIONS.—For purposes of paragraph (1), the terms "device", "premarket application", and "premarket report" have the same meanings as apply to such terms for purposes of section 738 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section).]

* * * * * * *

TITLE II—AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES

* * * * * * *

SEC. 210. PEDIATRIC EXPERTISE REGARDING CLASSIFICATION-PANEL REVIEW OF PREMARKET APPLICATIONS.

Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c))[, as amended by section 302(c)(2)(A) of this Act, is amended in paragraph (3) by adding] *is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding* at the end the following: "Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.".

* * * * * * *

SEC. 212. STUDY BY INSTITUTE OF MEDICINE OF POSTMARKET SURVEILLANCE REGARDING PEDIATRIC POPULATIONS.

(a) * * *

(b) CERTAIN MATTERS.—The Secretary shall ensure that determinations made in the study under subsection (a) include determinations of—

(1) * * *

(2) whether the postmarket surveillance by the Food and Drug Administration of medical devices used in pediatric populations is sufficient to provide adequate safeguards for such populations, taking into account the Secretary's monitoring of commitments made at the time of approval of medical devices[, such as phase IV trials,] and the Secretary's monitoring and use of adverse reaction reports, registries, and other postmarket surveillance activities.

* * * * * * *

TITLE III—ADDITIONAL AMENDMENTS

SEC. 301. IDENTIFICATION OF MANUFACTURER OF MEDICAL DEVICES.

(a) * * *

(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect [18 months] *36 months* after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date.

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