

[COMMITTEE PRINT]

110TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the medical device user fee provisions, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the medical device user fee provisions, and for other purposes.

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; REFERENCES IN ACT.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Medical Device User Fee Amendments of 2007”.

6 (b) **REFERENCES IN ACT.**—Except as otherwise spec-
7 ified, amendments made by this Act to a section or other

1 provision of law are amendments to such section or other
2 provision of the Federal Food, Drug, and Cosmetic Act.

3 **TITLE I—FEES RELATED TO**
4 **MEDICAL DEVICES**

5 **SEC. 101. DEFINITIONS.**

6 Section 737 (21 U.S.C. 379i) is amended—

7 (1) in paragraph (4)—

8 (A) in subparagraph (A), by striking “or
9 an efficacy supplement,” and inserting “an effi-
10 cacy supplement, or a 30-day notice,”; and

11 (B) by adding after subparagraph (E) the
12 following:

13 “(F) The term ‘30-day notice’ means a supple-
14 ment to an approved premarket application or pre-
15 market report under section 515 that is limited to
16 a request to make modifications to manufacturing
17 procedures or methods of manufacture affecting the
18 safety and effectiveness of the device.”;

19 (2) by redesignating paragraphs (5), (6), (7),
20 and (8) as paragraphs (7), (8), (9), and (11), re-
21 spectively;

22 (3) by inserting after paragraph (4), as amend-
23 ed by paragraph (1) of this section, the following:

24 “(5) The term ‘request for classification infor-
25 mation’ means a request made under section 513(g)

1 for information respecting the class in which a de-
2 vice has been classified or the requirements applica-
3 ble to a device.

4 “(6) The term ‘annual fee’, with respect to peri-
5 odic reporting concerning a class III device, means
6 the annual fee associated with periodic reports re-
7 quired by a PMA approval order (as described in
8 section 814.82(a)(7) of title 21, Code of Federal
9 Regulations (or any successor regulation)).”;

10 (4) in paragraph (9), as so redesignated—

11 (A) by striking “April of the preceding fis-
12 cal year” and inserting “October of the pre-
13 ceding fiscal year”; and

14 (B) by striking “April 2002” and inserting
15 “October 2001”;

16 (5) by inserting after paragraph (9), as so
17 amended, the following:

18 “(10) The term ‘person’ includes an affiliate
19 thereof.”; and

20 (6) by inserting after paragraph (11), as redesi-
21 gnated under paragraph (2) of this section, the fol-
22 lowing:

23 “(12) The term ‘establishment subject to reg-
24 istration’ means an establishment that is required to

1 register with the Secretary under section 510 and is
2 one of the following types of establishments:

3 “(A) MANUFACTURER.—An establishment
4 that makes by any means any article that is a
5 device, as defined in section 201(h), including
6 an establishment that sterilizes or otherwise
7 makes such article for or on behalf of a speci-
8 fication developer or any other person.

9 “(B) SINGLE-USE DEVICE REPROC-
10 ESSOR.—An establishment that performs manu-
11 facturing operations on a single-use device.

12 “(C) SPECIFICATION DEVELOPER.—An es-
13 tablishment that develops specifications for a
14 device that is distributed under the establish-
15 ment’s name but which performs no manufac-
16 turing, including an establishment that, in addi-
17 tion to developing specifications, also arranges
18 for the manufacturing of devices labeled with
19 another establishment’s name by a contract
20 manufacturer.”.

21 **SEC. 102. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

22 (a) TYPES OF FEES.—

23 (1) IN GENERAL.—Section 738(a)(2) (21
24 U.S.C. 379j(a)(2)) is amended—

1 (A) by amending the paragraph heading to
2 read as follows:

3 “(2) PREMARKET APPLICATION, PREMARKET
4 REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND
5 ANNUAL FEE FOR PERIODIC REPORTING CON-
6 CERNING A CLASS III DEVICE.—”.

7 (2) FEE AMOUNTS.—Section 738(a)(2)(A) (21
8 U.S.C. 379j(a)(2)(A)) is amended—

9 (A) in clause (iii), by striking “a fee equal
10 to the fee that applies” and inserting “a fee
11 equal to 75 percent of the fee that applies”;

12 (B) in clause (iv), by striking “21.5 per-
13 cent” and inserting “15 percent”;

14 (C) in clause (v), by striking “7.2 percent”
15 and inserting “7 percent”;

16 (D) by redesignating clauses (vi) and (vii)
17 as clauses (vii) and (viii), respectively;

18 (E) by inserting after clause (v), as
19 amended under this paragraph, the following:

20 “(vi) For a 30-day notice, a fee equal
21 to 1.6 percent of the fee that applies under
22 clause (i).”;

23 (F) in clause (viii), as so redesignated, by
24 striking “1.42 percent” and inserting “1.84
25 percent”; and

1 (G) by inserting after such clause (viii) the
2 following:

3 “(ix) For a request for classification
4 information, a fee equal to 1.35 percent of
5 the fee that applies under clause (i).

6 “(x) For periodic reporting concerning
7 a class III device, the annual fee shall be
8 equal to 3.5 percent of the fee that applies
9 under clause (i).”.

10 (3) PAYMENT.—Section 738(a)(2)(C) (21
11 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

12 “(C) PAYMENT.—The fee required by sub-
13 paragraph (A) shall be due upon submission of
14 the premarket application, premarket report,
15 supplement, or premarket notification submis-
16 sion, 30-day notice, request for classification in-
17 formation, or periodic reporting concerning a
18 class III device. Applicants submitting portions
19 of applications pursuant to section 515(e)(3)
20 shall pay such fees upon submission of the first
21 portion of such applications.”.

22 (4) REFUNDS.—Section 738(a)(2)(D) (21
23 U.S.C. 379j(a)(2)(D)) is amended by adding after
24 clause (iii) the following:

1 “(iv) MODULAR APPLICATIONS WITH-
2 DRAWN BEFORE FIRST ACTION.—The Sec-
3 retary shall refund 75 percent of the appli-
4 cation fee paid for a modular application
5 submitted under section 515(c)(4) that is
6 withdrawn before a second module is sub-
7 mitted and before a first action on the first
8 module. If the modular application is with-
9 drawn after a second or subsequent module
10 is submitted but before any first action,
11 the Secretary may return a portion of the
12 fee. The amount of refund, if any, shall be
13 based on the level of effort already ex-
14 pended on the review of the modules sub-
15 mitted.”.

16 (5) ANNUAL ESTABLISHMENT REGISTRATION
17 FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amend-
18 ed by adding after paragraph (2) the following:

19 “(3) ANNUAL ESTABLISHMENT REGISTRATION
20 FEE.—

21 “(A) IN GENERAL.—Except as provided in
22 subparagraph (B), each establishment subject
23 to registration shall be subject to a fee for each
24 initial or annual registration under section 510

1 beginning with its registration for fiscal year
 2 2008.

3 “(B) EXCEPTION.—No fee shall be re-
 4 quired under subparagraph (A) for an estab-
 5 lishment operated by a State or Federal govern-
 6 mental entity or an Indian tribe or tribal orga-
 7 nization, unless a device manufactured by the
 8 establishment is to be distributed commercially.

9 “(C) PAYMENT.—The fee required under
 10 subparagraph (A) shall be due once each fiscal
 11 year, upon the initial registration of the estab-
 12 lishment or upon the annual registration under
 13 section 510.”.

14 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.
 15 379j(b)) is amended to read as follows:

16 “(b) FEE AMOUNTS.—Except as provided in
 17 subsections (c), (d), and (e), the fees under sub-
 18 section (a) shall be based on the following fee
 19 amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Appli- cation	\$185,000	\$200,725	\$217,787	\$236,298	\$256,384
Establishment Registration	\$1,706	\$1,851	\$2,008	\$2,179	\$2,364”.

20 (c) ANNUAL FEE SETTING.—

1 (1) IN GENERAL.—Section 738(c) (21 U.S.C.
2 379j(c)(1)) is amended—

3 (A) in the subsection heading, by striking
4 “Annual Fee Setting” and inserting “ANNUAL
5 FEE SETTING”; and

6 (B) in paragraph (1), by striking the last
7 sentence.

8 (2) ADJUSTMENT OF ANNUAL ESTABLISHMENT
9 FEE.—Section 738(c) (21 U.S.C. 379j(c)), as
10 amended under paragraph (1), is further amended—

11 (A) by redesignating paragraphs (2) and
12 (3) as paragraphs (3) and (4), respectively;

13 (B) by inserting after paragraph (1) the
14 following:

15 “(2) ADJUSTMENT.—

16 “(A) IN GENERAL.—When setting fees for
17 fiscal year 2010, the Secretary may increase the
18 fee under subsection (a)(3)(A) (applicable to es-
19 tablishments subject to registration) only if the
20 Secretary estimates that the number of estab-
21 lishments submitting fees for fiscal year 2009 is
22 less than 12,250. The percentage increase shall
23 be the percentage by which the estimate of es-
24 tablishments submitting fees in fiscal year 2009
25 is less than 12,750, but in no case may the per-

1 centage increase be more than 8.5 percent over
2 that specified in subsection (b) for fiscal year
3 2010. If the Secretary makes any adjustment to
4 the fee under subsection (a)(3)(A) for fiscal
5 year 2010, then such fee for fiscal years 2011
6 and 2012 shall be adjusted so that such fee for
7 fiscal year 2011 is equal to the adjusted fee for
8 fiscal year 2010 increased by 8.5 percent, and
9 such fee for fiscal year 2012 is equal to the ad-
10 justed fee for fiscal year 2011 increased by 8.5
11 percent.

12 “(B) PUBLICATION.—For any adjustment
13 made under subparagraph (A), the Secretary
14 shall publish in the Federal Register the Sec-
15 retary’s determination to make the adjustment
16 and the rationale for the determination.”; and

17 (C) in paragraph (4), as redesignated
18 under this paragraph, in subparagraph (A)—

19 (i) by striking “For fiscal years 2006
20 and 2007, the Secretary” and inserting
21 “The Secretary”; and

22 (ii) by striking “for the first month of
23 fiscal year 2008” and inserting “for the
24 first month of the next fiscal year”.

1 (d) SMALL BUSINESSES; FEE WAIVER AND FEE RE-
2 Duction REGARDING PREMARKET APPROVAL.—

3 (1) IN GENERAL.—Section 738(d)(1) (21
4 U.S.C. 379j(d)(1)) is amended—

5 (A) by striking “, partners, and parent
6 firms”; and

7 (B) by striking “clauses (i) through (vi) of
8 subsection (a)(2)(A)” and inserting “clauses (i)
9 through (v) and clause (vii) of subsection
10 (a)(2)(A)”.

11 (2) RULES RELATING TO PREMARKET AP-
12 PROVAL FEES.—

13 (A) DEFINITION.—Section 738(d)(2)(A)
14 (21 U.S.C. 379j(d)(2)(A)) is amended by strik-
15 ing “, partners, and parent firms”.

16 (B) EVIDENCE OF QUALIFICATION.—Sec-
17 tion 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is
18 amended—

19 (i) by striking “(B) EVIDENCE OF
20 QUALIFICATION.—An applicant” and in-
21 serting the following:

22 “(B) EVIDENCE OF QUALIFICATION.—
23 “(i) IN GENERAL.—An applicant”;

1 (ii) by striking “The applicant shall
2 support its claim” and inserting the fol-
3 lowing:

4 “(ii) FIRMS SUBMITTING TAX RE-
5 TURNS TO THE UNITED STATES INTERNAL
6 REVENUE SERVICE.—The applicant shall
7 support its claim”;

8 (iii) by striking “partners, and parent
9 firms” each place it appears; and

10 (iv) by striking the last sentence and
11 inserting “If no tax forms are submitted
12 for any affiliate, the applicant shall certify
13 that the applicant has no affiliates.”; and

14 (v) by adding at the end the following:

15 “(ii) FIRMS NOT SUBMITTING TAX RE-
16 TURNS TO THE UNITED STATES INTERNAL
17 REVENUE SERVICE.—In the case of an ap-
18 plicant that has not previously submitted a
19 Federal income tax return, the applicant
20 and each of its affiliates shall demonstrate
21 that it meets the definition under subpara-
22 graph (A) by submission of a signed cer-
23 tification, in such form as the Secretary
24 may direct through a notice published in
25 the Federal Register, that the applicant or

1 affiliate meets the criteria for a small busi-
2 ness and a certification, in English, from
3 the national taxing authority of the coun-
4 try in which the applicant or, if applicable,
5 affiliate is headquartered. The certification
6 from such taxing authority shall bear the
7 official seal of such taxing authority and
8 shall provide the applicant's or affiliate's
9 gross receipts and sales for the most recent
10 year in both the local currency of such
11 country and in United States dollars, the
12 exchange rate used in converting such local
13 currency to dollars, and the dates during
14 which these receipts and sales were col-
15 lected. The applicant shall also submit a
16 statement signed by the head of the appli-
17 cant's firm or by its chief financial officer
18 that the applicant has submitted certifi-
19 cations for all of its affiliates, or that the
20 applicant has no affiliates.”.

21 (3) REDUCED FEES.—Section 738(d)(2)(C) (21
22 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

23 “(C) REDUCED FEES.—Where the Sec-
24 retary finds that the applicant involved meets
25 the definition under subparagraph (A), the fees

1 established under subsection (c)(1) may be paid
2 at a reduced rate of—

3 “(i) 25 percent of the fee established
4 under such subsection for a premarket ap-
5 plication, a premarket report, a supple-
6 ment, or periodic reporting concerning a
7 class III device; and

8 “(ii) 50 percent of the fee established
9 under such subsection for a 30-day notice
10 or a request for classification informa-
11 tion.”.

12 (e) SMALL BUSINESSES; FEE REDUCTION REGARD-
13 ING PREMARKET NOTIFICATION SUBMISSIONS.—

14 (1) IN GENERAL.—Section 738(e)(1) (21
15 U.S.C. 379j(e)(1)) is amended—

16 (A) by striking “2004” and inserting
17 “2008”; and

18 (B) by striking “(a)(2)(A)(vii)” and insert-
19 ing “(a)(2)(A)(viii)”.

20 (2) RULES RELATING TO PREMARKET NOTIFI-
21 CATION SUBMISSIONS.—

22 (A) DEFINITION.—Section 738(e)(2)(A)(1)
23 (21 U.S.C. 379j(e)(2)(A)(1)) is amended by
24 striking “, partners, and parent firms”.

1 (B) EVIDENCE OF QUALIFICATION.—Sec-
2 tion 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(A)) is
3 amended—

4 (i) by striking “(B) EVIDENCE OF
5 QUALIFICATION.—An applicant” and in-
6 serting the following:

7 “(B) EVIDENCE OF QUALIFICATION.—

8 “(i) IN GENERAL.—An applicant”;

9 (ii) by striking “The applicant shall
10 support its claim” and inserting the fol-
11 lowing:

12 “(ii) FIRMS SUBMITTING TAX RE-
13 TURNS TO THE UNITED STATES INTERNAL
14 REVENUE SERVICE.—The applicant shall
15 support its claim”;

16 (iii) by striking “, partners, and par-
17 ent firms” each place it appears;

18 (iv) by striking the last sentence and
19 inserting “If no tax forms are submitted
20 for any affiliate, the applicant shall certify
21 that the applicant has no affiliates.”; and

22 (v) by adding at the end the following:

23 “(ii) FIRMS NOT SUBMITTING TAX RE-
24 TURNS TO THE UNITED STATES INTERNAL
25 REVENUE SERVICE.—In the case of an ap-

1 plicant that has not previously submitted a
2 Federal income tax return, the applicant
3 and each of its affiliates shall demonstrate
4 that it meets the definition under subpara-
5 graph (A) by submission of a signed cer-
6 tification, in such form as the Secretary
7 may direct through a notice published in
8 the Federal Register, that the applicant or
9 affiliate meets the criteria for a small busi-
10 ness and a certification, in English, from
11 the national taxing authority of the coun-
12 try in which the applicant or, if applicable,
13 affiliate is headquartered. The certification
14 from such taxing authority shall bear the
15 official seal of such taxing authority and
16 shall provide the applicant's or affiliate's
17 gross receipts and sales for the most recent
18 year in both the local currency of such
19 country and in United States dollars, the
20 exchange rate used in converting such local
21 currency to dollars, and the dates during
22 which these receipts and sales were col-
23 lected. The applicant shall also submit a
24 statement signed by the head of the appli-
25 cant's firm or by its chief financial officer

1 that the applicant has submitted certifi-
2 cations for all of its affiliates, or that the
3 applicant has no affiliates.”.

4 (3) REDUCED FEES.—Section 738(e)(2)(C) (21
5 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

6 “(C) REDUCED FEES.—For fiscal year
7 2008 and each subsequent fiscal year, where
8 the Secretary finds that the applicant involved
9 meets the definition under subparagraph (A),
10 the fee for a premarket notification submission
11 may be paid at 50 percent of the fee that ap-
12 plies under subsection (a)(2)(A)(viii), and as es-
13 tablished under subsection (c)(1).”.

14 (f) EFFECT OF FAILURE TO PAY FEES.—Section
15 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

16 “(f) EFFECT OF FAILURE TO PAY FEES.—

17 “(1) NO ACCEPTANCE OF SUBMISSIONS.—A
18 premarket application, premarket report, supple-
19 ment, premarket notification submission, 30-day no-
20 tice, request for classification information, or peri-
21 odic reporting concerning a class III device sub-
22 mitted by a person subject to fees under subsection
23 (a)(2) and (a)(3) shall be considered incomplete and
24 shall not be accepted by the Secretary until all fees
25 owed by such person have been paid.

1 “(2) NO REGISTRATION.—Registration informa-
2 tion submitted under section 510 by an establish-
3 ment subject to registration shall be considered in-
4 complete and shall not be accepted by the Secretary
5 until the registration fee under subsection (a)(3)
6 owed for the establishment has been paid. Until the
7 fee is paid and the registration is complete, the es-
8 tablishment is deemed to have failed to register in
9 accordance with section 510.”.

10 (g) CONDITIONS.—Section 738(g) (21 U.S.C.
11 379j(g)) is amended—

12 (1) in paragraph (1)(D)—

13 (A) in the matter preceding clause (i), by
14 striking “For fiscal year 2007” and inserting
15 “For fiscal year 2007 and for each subsequent
16 year”;

17 (B) in clause (i), by striking “applicable to
18 fiscal year 2007” and inserting “applicable to
19 such fiscal year”; and

20 (C) in clause (ii)—

21 (i) by striking “subparagraph (C)”
22 and inserting “this subparagraph”; and

23 (ii) by striking “for fiscal year 2006”
24 and inserting “for the previous fiscal
25 year”; and

1 (2) by amending paragraph (2) to read as fol-
2 lows:

3 “(2) **AUTHORITY.**—If the Secretary does not
4 assess fees under subsection (a) during any portion
5 of a fiscal year because of subparagraph (C) or (D)
6 of paragraph (1) and if at a later date in such fiscal
7 year the Secretary may assess such fees, the Sec-
8 retary may assess and collect such fees, without any
9 modification in the rate for premarket applications,
10 supplements, premarket reports, premarket notifica-
11 tion submissions, 30-day notices, requests for classi-
12 fication information, periodic reporting concerning a
13 class III device, and establishment registrations at
14 any time in such fiscal year, notwithstanding the
15 provisions of subsection (a) relating to the date fees
16 are to be paid.”.

17 (h) **CREDITING AND AVAILABILITY OF FEES.**—

18 (1) **AUTHORIZATION OF APPROPRIATIONS.**—
19 Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amend-
20 ed to read as follows:

21 “(3) **AUTHORIZATIONS OF APPROPRIATIONS.**—
22 There are authorized to be appropriated for fees
23 under this section—

24 “(A) \$48,431,000 for fiscal year 2008;

25 “(B) \$52,547,000 for fiscal year 2009;

1 “(C) \$57,014,000 for fiscal year 2010;
2 “(D) \$61,860,000 for fiscal year 2011;
3 and
4 “(E) \$67,118,000 for fiscal year 2012.”.

5 (2) OFFSET.—Section 738(h)(4) (21 U.S.C.
6 379j(h)(3)) is amended to read as follows:

7 “(4) OFFSET.—If the cumulative amount of
8 fees collected during fiscal years 2008, 2009, and
9 2010, added to the amount estimated to be collected
10 for fiscal year 2011, which estimate shall be based
11 upon the amount of fees received by the Secretary
12 through June 30, 2011, exceeds the amount of fees
13 specified in aggregate in paragraph (3) for these
14 four fiscal years, the aggregate amount in excess
15 shall be credited to the appropriation account of the
16 Food and Drug Administration as provided in para-
17 graph (1), and shall be subtracted from the amount
18 of fees that would otherwise be authorized to be col-
19 lected under this section pursuant to appropriation
20 Acts for fiscal year 2012.”.

21 **SEC. 103. ANNUAL REPORTS.**

22 Beginning with fiscal year 2008, the Secretary shall
23 prepare and submit to the Committee on Energy and
24 Commerce of the House of Representatives and the Com-

1 mittee on Health, Education, Labor and Pensions of the
2 Senate a report concerning—

3 (1) the progress of the Food and Drug Admin-
4 istration in achieving the goals identified in the let-
5 ters from the Secretary of Health and Human Serv-
6 ices to the Committee on Energy and Commerce of
7 the House of Representatives and the Committee on
8 Health, Education, Labor, and Pensions of the Sen-
9 ate, as set forth in the Congressional Record during
10 such fiscal year, and the future plans of the Food
11 and Drug Administration for meeting the goals, not
12 later than 60 days after the end of each fiscal year
13 during which fees are collected under part 3 of chap-
14 ter VII of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 379i et seq.); and

16 (2) the implementation of the authority for
17 such fees during such fiscal year, and the use, by
18 the Food and Drug Administration, of the fees col-
19 lected during such fiscal year (including a descrip-
20 tion of the use of such fees for postmarket safety ac-
21 tivities), not later than 120 days after the end of
22 each fiscal year during which fees are collected
23 under the medical device user-fee program reauthor-
24 ized by this Act.

1 **SEC. 104. CONSULTATION.**

2 (a) IN GENERAL.—In developing recommendations to
3 the Congress for the goals and plans for meeting the goals
4 for the process for the review of medical device applica-
5 tions for fiscal years after fiscal year 2012, and for the
6 reauthorization of sections 737 and 738 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379i, 379j),
8 the Secretary of Health and Human Services (referred to
9 in this section as the “Secretary”) shall consult with the
10 Committee on Energy and Commerce of the House of
11 Representatives, the Committee on Health, Education,
12 Labor, and Pensions of the Senate, appropriate scientific
13 and academic experts, health care professionals, represent-
14 atives of patient and consumer advocacy groups, and the
15 regulated industry.

16 (b) RECOMMENDATIONS.—The Secretary shall pub-
17 lish in the Federal Register recommendations under sub-
18 section (a), after negotiations with the regulated industry
19 and patient and consumer advocacy groups; shall present
20 such recommendations to the congressional committees
21 specified in such subsection; shall hold a meeting at which
22 the public may present its views on such recommenda-
23 tions; and shall provide for a period of 30 days for the
24 public to provide written comments on such recommenda-
25 tions.

1 **SEC. 105. ADDITIONAL AUTHORIZATION OF APPROPRIA-**
2 **TIONS FOR POSTMARKET SAFETY INFORMA-**
3 **TION.**

4 For the purpose of collecting, developing, reviewing,
5 and evaluating postmarket safety information on medical
6 devices, there are authorized to be appropriated to the
7 Food and Drug Administration, in addition to the
8 amounts authorized by other provisions of law for such
9 purpose, such sums as may be necessary for each of fiscal
10 years 2008 through 2012.

11 **SEC. 106. EFFECTIVE DATE.**

12 The amendments made by this Act shall take effect
13 on the date of the enactment of this Act, except that fees
14 shall be assessed for all premarket applications, premarket
15 reports, supplements, and premarket notification submis-
16 sions received on or after October 1, 2007, regardless of
17 the date of enactment.

18 **SEC. 107. SUNSET CLAUSE.**

19 The amendments made by this Act cease to be effec-
20 tive October 1, 2012, except that section 4 (regarding an-
21 nual reports) ceases to be effective January 31, 2013.

1 **TITLE II—AMENDMENTS RE-**
2 **GARDING REGULATION OF**
3 **MEDICAL DEVICES**

4 **SEC. 201. EXTENSION OF AUTHORITY FOR THIRD PARTY**
5 **REVIEW OF PREMARKET NOTIFICATION.**

6 Section 523(c) (21 U.S.C. 360m(c)) is amended by
7 striking “2007” and inserting “2012”.

8 **SEC. 202. REGISTRATION.**

9 (a) ANNUAL REGISTRATION OF PRODUCERS OF
10 DRUGS AND DEVICES.—Section 510(b) (21 U.S.C.
11 360(b)) is amended—

- 12 (1) by striking “On or before” and inserting
13 “(1) On or before”;
14 (2) by striking “or a device or devices”; and
15 (3) by adding at the end the following:

16 “(2) During the period beginning on October 1 and
17 ending on December 31 of each year, every person who
18 owns or operates any establishment in any State engaged
19 in the manufacture, preparation, propagation,
20 compounding, or processing of a device or devices shall
21 register with the Secretary his name, places of business,
22 and all such establishments.”.

23 (b) REGISTRATION OF FOREIGN ESTABLISH-
24 MENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is
25 amended—

1 (1) by striking “(i)(1) On or before” and insert-
2 ing “(i)(1)(A) On or before”;

3 (2) by striking “processing of a drug or a de-
4 vice that is imported” and inserting “processing of
5 a drug that is imported”; and

6 (3) by striking “or device” each place it ap-
7 pears; and

8 (4) by adding at the end the following:

9 “(B) During the period beginning on October 1 and
10 ending on December 31 of each year, any establishment
11 within any foreign country engaged in the manufacture,
12 preparation, propagation, compounding, or processing of
13 a device that is imported or offered for import into the
14 United States shall, through electronic means in accord-
15 ance with the criteria of the Secretary, register with the
16 Secretary the name and place of business of the establish-
17 ment, the name of the United States agent for the estab-
18 lishment, the name of each importer of such device in the
19 United States that is known to the establishment, and the
20 name of each person who imports or offers for import such
21 device to the United States for purposes of importation.”.

1 **SEC. 203. FILING OF LISTS OF DRUGS AND DEVICES MANU-**
2 **FACTURED, PREPARED, PROPAGATED, AND**
3 **COMPOUNDED BY REGISTRANTS; STATE-**
4 **MENTS; ACCOMPANYING DISCLOSURES.**

5 Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended,
6 in the matter preceding subparagraph (A), by striking
7 “Each person” and all that follows through “the following
8 information:” and inserting “Each person who registers
9 with the Secretary under this section shall report to the
10 Secretary, with regard to drugs once during the month
11 of June of each year and once during the month of Decem-
12 ber of each year, and with regard to devices once each
13 year during the period beginning on October 1 and ending
14 on December 31, the following information:”.

15 **SEC. 204. ELECTRONIC REGISTRATION AND LISTING.**

16 Section 510(p) (21 U.S.C. 360(p)) is amended to
17 read as follows:

18 “(p)(1) With regard to any establishment engaged in
19 the manufacture, preparation, propagation, compounding,
20 or processing of a drug, registrations under subsections
21 (b), (c), (d), and (i) of this section (including the submis-
22 sion of updated information) shall be submitted to the
23 Secretary by electronic means, upon a finding by the Sec-
24 retary that the electronic receipt of such registrations is
25 feasible, unless the Secretary grants a request for waiver

1 of such requirement because use of electronic means is not
2 reasonable for the person requesting such waiver.

3 “(2) With regard to any establishment engaged in the
4 manufacture, preparation, propagation, compounding, or
5 processing of a device, the registration and listing infor-
6 mation required by this section shall be submitted to the
7 Secretary by electronic means, unless the Secretary grants
8 a waiver because electronic registration and listing is not
9 reasonable for the person requesting such waiver.”.

10 **SEC. 205. REPORT BY INSTITUTE OF MEDICINE.**

11 (a) IN GENERAL.—The Secretary of Health and
12 Human Services shall seek to enter into an agreement
13 with the Institute of Medicine under which the Institute
14 will perform a study on the appropriate use of the process
15 under section 510 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 360) to clear medical devices as safe
17 and effective, and not later than 1 year after the date of
18 the enactment of this Act, submit a report to the Congress
19 on the results of such study.

20 (b) OTHER APPROPRIATE ENTITY.—If the Institute
21 of Medicine declines to conduct the study under subsection
22 (a), the Secretary of Health and Human Services shall
23 enter into an agreement with another appropriate entity
24 to perform the study and submit the report described in
25 such subsection.