

**Union Calendar No. 413**

103D CONGRESS  
2D SESSION

**H. R. 4864**

[Report No. 103-751]

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to authorize a device application fee, and for other purposes.

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SEPTEMBER 26, 1994

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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## IN THE HOUSE OF REPRESENTATIVES

AUGUST 1, 1994

Mr. WAXMAN (for himself and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 26, 1994

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on August 1, 1994]

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize a device application fee, 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 AND REFERENCE.**

4 (a) *SHORT TITLE.*—*This Act may be cited as the*  
5 *“Medical Device User Fee Act of 1994”.*

1       (b) *REFERENCE.*—Whenever in this Act an amend-  
2       ment or repeal is expressed in terms of an amendment to,  
3       or repeal of, a section or other provision, the reference shall  
4       be considered to be made to a section or other provision  
5       of the Federal Food, Drug, and Cosmetic Act.

6       **SEC. 2. FINDINGS.**

7       *The Congress finds that—*

8               (1) *prompt approval and clearance of safe and*  
9               *effective devices is critical to the improvement of the*  
10              *public health so that patients may enjoy the benefits*  
11              *of devices to diagnose, treat, and prevent disease;*

12              (2) *the public health will be served by furnishing*  
13              *additional funds for the review of devices so that*  
14              *statutorily mandated deadlines may be met, and*

15              (3) *the fees authorized by the amendment made*  
16              *by section 3 will be dedicated—*

17                      (A) *toward expediting the review of device*  
18                      *applications, supplements, and substantial*  
19                      *equivalence submissions, and*

20                      (B) *for related activities as defined in the*  
21                      *amendment,*

22              *as set forth in goals identified in the letter of July 8,*  
23              *1994, from the Commissioner of Food and Drugs to*  
24              *the Committee on Energy and Commerce of the House*  
25              *of Representatives.*

1 **SEC. 3. FEES RELATING TO DEVICES.**

2 Chapter VII is amended by adding at the end of sub-  
3 chapter C the following:

4 **“PART 3—FEES RELATING TO DEVICES**

5 **“SEC. 741. DEFINITIONS.**

6 *“For purposes of this subchapter:*

7 *“(1) The term—*

8 *“(A) ‘device application’ means an applica-*  
9 *tion for approval of a device submitted under*  
10 *section 515(c) or section 351 of the Public Health*  
11 *Service Act, a supplement to such an applica-*  
12 *tion, or a submission for a device made under*  
13 *section 510(k) claiming the device is substan-*  
14 *tially equivalent as described in section*  
15 *513(f)(1)(A) (in this part referred to as a ‘device*  
16 *substantial equivalence submission’); and*

17 *“(B) ‘section 351 application’ means a de-*  
18 *vice application submitted under section 351 of*  
19 *the Public Health Service Act.*

20 *“(2) The term ‘supplement’ means a request to*  
21 *the Secretary to approve a change in a device appli-*  
22 *cation which has been approved under section 515(d)*  
23 *or section 351 of the Public Health Service Act.*

24 *“(3) The term ‘process for the review of device*  
25 *applications and related activities’ means the follow-*

1        *ing activities of the Secretary with respect to the re-*  
2        *view of device applications and related activities:*

3                *“(A) The activities necessary for the review*  
4                *of device applications and related activities.*

5                *“(B) The issuance of action letters which*  
6                *allow marketing of devices or which set forth in*  
7                *detail the specific deficiencies in such applica-*  
8                *tions and, where appropriate, the actions nec-*  
9                *essary to place such applications in condition for*  
10               *approval.*

11               *“(C) The inspection of device establishments*  
12               *and other facilities undertaken as part of the*  
13               *Secretary’s review of pending device applica-*  
14               *tions.*

15               *“(D) Any activity necessary for the review*  
16               *of applications for licensure of devices subject to*  
17               *section 351 of the Public Health Service Act, for*  
18               *the licensure of establishments where such devices*  
19               *are manufactured, and for the release of lots of*  
20               *such devices.*

21               *“(E) Review of device applications for an*  
22               *investigational new drug exemption under sec-*  
23               *tion 505(i) and for an investigational device ex-*  
24               *emption under section 520(g) and activities con-*

1           ducted in anticipation of the submission of an  
2           application under sections 505(i) and 520(g).

3           “(F) The development of guidance and pol-  
4           icy documents to improve the process for the re-  
5           view of device applications.

6           “(G) The development of test methods and  
7           standards in connection with the review of device  
8           applications and related activities.

9           “(H) The provision of technical assistance  
10          to device manufacturers in connection with the  
11          submission of a device application.

12          “(I) Any activity undertaken in connection  
13          with the export of a device.

14          “(J) Any activity undertaken under sections  
15          513 and 515(i) in connection with the initial  
16          classification and reclassification of a device and  
17          under section 515(b) in connection with any re-  
18          quirement for premarket approval of a device.

19          “(K) Monitoring of research on devices.

20          “(L) Any activities undertaken under sec-  
21          tions 519(a) and 519(b).

22          “(M) Postmarket studies required as a con-  
23          dition of an approval of a device application  
24          under section 515(d) or section 351 of the Public  
25          Health Service Act.

1           “(N) *Postmarket surveillance required*  
2           *under section 522.*

3           “(4) *The term ‘costs of resources allocated for the*  
4           *process for the review of device applications and re-*  
5           *lated activities’ means the expenses incurred in con-*  
6           *nection with the process for the review of device appli-*  
7           *cations and related activities for—*

8                   “(A) *officers and employees of the Food and*  
9                   *Drug Administration, employees under contract*  
10                  *with the Food and Drug Administration, advi-*  
11                  *sory committees, and costs related to such offi-*  
12                  *cers, employees, and committees,*

13                   “(B) *management of information, and the*  
14                  *acquisition, maintenance, and repair of com-*  
15                  *puter resources,*

16                   “(C) *leasing, maintenance, renovation, and*  
17                  *repair of facilities and acquisition, maintenance,*  
18                  *and repair of fixtures, furniture, scientific equip-*  
19                  *ment, and other necessary materials, services,*  
20                  *and supplies, and*

21                   “(D) *collection fees under section 742 and*  
22                  *accounting for resources allocated for the review*  
23                  *of device applications and related activities, in-*  
24                  *cluding activities related to the review of appli-*

1           cations for fee exceptions, waivers, and reduc-  
2           tions.

3           “(5) The term ‘adjustment factor’ applicable to a  
4           fiscal year is the lower of—

5                   “(A) the Consumer Price Index for all  
6                   urban consumers (all items; United States city  
7                   average) for August of the preceding fiscal year  
8                   divided by such Index for August 1994, or

9                   “(B) the total budget authority provided for  
10                  discretionary programs for the immediately pre-  
11                  ceding fiscal year (as reported in the Office of  
12                  Management and Budget sequestration preview  
13                  report, if available, required under section  
14                  254(d) of the Balanced Budget and Emergency  
15                  Deficit Control Act of 1985) divided by such  
16                  budget authority for fiscal year 1994 (as re-  
17                  ported in the Office of Management and Budget  
18                  final sequestration report submitted after the end  
19                  of the 103d Congress, 2d Session).

20           The term ‘budget authority’ in subparagraph (B) is  
21           as defined in section 3(2)(A) of the Balanced Budget  
22           and Emergency Deficit Control Act of 1985 (2 U.S.C.  
23           622(2)(A)), as in effect as of January 1, 1994.

1 **“SEC. 742. AUTHORITY TO ASSESS AND USE DEVICE USER**  
2 **FEES.**

3 “(a) *FEES.*—Beginning in fiscal year 1995, the Sec-  
4 retary shall assess and collect fees as follows:

5 “(1) *GENERAL RULE.*—Except as provided in  
6 paragraph (2), each person that submits, on or after  
7 90 days before the date of the enactment of the first  
8 appropriation under subsection (g)(4) for fees under  
9 this section, a device application shall be subject, in  
10 accordance with paragraph (3), to the fee prescribed  
11 by subsection (b). Before April 30, 1995, the Secretary  
12 shall establish guidelines for the combination of mul-  
13 tiple device applications in those situations where it  
14 is appropriate to combine the applications and assess  
15 a single fee. A single fee shall be assessed upon an ap-  
16 plication which is such a combination.

17 “(2) *EXCEPTION.*—

18 “(A) *FURTHER MANUFACTURING USE.*—No  
19 fee shall be required for the submission of a sec-  
20 tion 351 application for a product licensed for  
21 further manufacturing use only.

22 “(B) *PREVIOUSLY FILED APPLICATION OR*  
23 *SUPPLEMENT.*—If a device application was—

24 “(i) submitted by a person that paid  
25 the fee for such application,

26 “(ii) accepted for filing, and

1           “(iii) not approved or withdrawn  
2           (without a waiver under subsection (d)),  
3           the submission of a device application for the  
4           identical device by the same person (or the per-  
5           son’s licensee, assignee, or successor) shall not be  
6           subject to a fee under paragraph (1).

7           “(3) PAYMENT SCHEDULE.—

8           “(A) GENERAL RULE.—Except as provided  
9           in subparagraph (B)—

10           “(i) in the case of an application sub-  
11           mitted under section 515(c), an application  
12           for a device submitted under section 351 of  
13           the Public Health Service Act, or a supple-  
14           ment submitted with required clinical data,  
15           15 percent of the fee prescribed by sub-  
16           section (b) shall be due upon submission of  
17           such application or supplement and the re-  
18           mainder within 30 days of receipt of notice  
19           from the Secretary of acceptance of such ap-  
20           plication or supplement for filing or review,  
21           and

22           “(ii) in the case of the submission of a  
23           supplement for which clinical data are not  
24           required or a submission under section  
25           510(k), the fee prescribed under subsection

1           (b) shall be due within 30 days of receipt of  
2           notice from the Secretary of acceptance of  
3           such supplement or submission for filing or  
4           review.

5           “(B) EXCEPTIONS.—

6                   “(i) PENDING APPLICATIONS.—In the  
7                   case of a device application for which fees  
8                   are required under paragraph (1) and  
9                   which is pending on the date of the enact-  
10                  ment of the first appropriation under sub-  
11                  section (g)(4) for fees under this section, the  
12                  fee required by paragraph (1) shall be due  
13                  90 days after such date of enactment.

14                  “(ii) EXCESS OF AUTHORIZATION.—A  
15                  fee which is due after an amount of fees  
16                  equal to the authorization of appropriations  
17                  under subsection (g)(4) for the fiscal year in  
18                  which the fee is imposed has been collected  
19                  shall be due on November 1 in the following  
20                  fiscal year.

21           “(b) FEE AMOUNTS.—

22                   “(1) AMOUNT.—Except as provided in para-  
23                   graph (2) and subject to subsections (c), (d), (f), and  
24                   (g)(3)(A), the fees required under subsection (a) are as  
25                   follows:

1           “(A) \$52,000 for an application for a device  
2 submitted under section 515(c) or under section  
3 351 of the Public Health Service Act.

4           “(B) \$7,100 for a supplement for which  
5 clinical data are required.

6           “(C) \$4,500 for a supplement for which  
7 clinical data are not required.

8           “(D) \$3,200 for a device substantial equiva-  
9 lence submission under section 510(k).

10          “(2) SMALL BUSINESS EXCEPTION.—

11           “(A) APPLICATIONS AND SUBMISSIONS.—  
12 Any person employing fewer than 20 employees,  
13 including employees of affiliates, which does not  
14 have a device introduced or delivered for intro-  
15 duction into interstate commerce under a device  
16 application—

17           “(i) shall pay one-half the amount of  
18 the fee prescribed by paragraph (1)(A) one  
19 year after the date of final action by the  
20 Secretary on an application of such person  
21 which is subject to such fee, and

22           “(ii) shall pay the fee prescribed by  
23 paragraph (1)(D) for a submission made by  
24 such person under section 510(k) one year

1           *after the date of final action by the Sec-*  
2           *retary on such submission.*

3           “(B) *CERTIFICATION.*—*The Secretary shall*  
4           *require any person who applies to pay a fee in*  
5           *accordance with subparagraph (A) to certify*  
6           *such person’s qualification under such subpara-*  
7           *graph. The Secretary shall periodically publish*  
8           *in the Federal Register a list of persons making*  
9           *such certification.*

10           “(C) *DEFINITION.*—*For purposes of this*  
11           *paragraph, a person is an affiliate of another*  
12           *person when—*

13                   “(i) *one person controls, or has the*  
14                   *power to control, directly or indirectly, the*  
15                   *other person,*

16                   “(ii) *a third party controls, or has the*  
17                   *power to control, directly or indirectly, both*  
18                   *persons, or*

19                   “(iii) *an identity of interest between or*  
20                   *among such persons exists such that affili-*  
21                   *ation may be found.*

22           “(c) *ADJUSTMENTS.*—

23                   “(1) *FEE ADJUSTMENT.*—*Subject to the amount*  
24                   *appropriated for a fiscal year under subsection (g)(4),*  
25                   *the Secretary shall, in each fiscal year beginning after*

1 *fiscal year 1995, adjust the fees due in the fiscal year*  
2 *following the fiscal in which the adjustment is made*  
3 *to reflect the greater of—*

4 *“(A) the total percentage increase that oc-*  
5 *curred during the preceding fiscal year in the*  
6 *Consumer Price Index for all urban consumers*  
7 *(all items; United States city average) that ex-*  
8 *ceeds 3.5 percent, or*

9 *“(B) the total percentage increase for such*  
10 *preceding fiscal year in basic pay under the*  
11 *General Schedule in accordance with section*  
12 *5332 of title 5, United States Code, as adjusted*  
13 *by any locality-based comparability payment*  
14 *pursuant to section 5304 of such title for Federal*  
15 *employees stationed in the District of Columbia*  
16 *that exceeds 3.5 percent.*

17 *The Secretary shall, by notice published in the Fed-*  
18 *eral Register, make an adjustment under this para-*  
19 *graph before December 1 of each year.*

20 *“(2) LIMIT.—The total amount of fees charged,*  
21 *as adjusted under paragraph (1), for a fiscal year*  
22 *may not exceed the total costs for such fiscal year for*  
23 *the resources allocated for the process for the review*  
24 *of device applications and related activities.*

1       “(d) *FEE WAIVER OR REDUCTION.*—The Secretary  
2 shall grant a waiver from or a reduction of a fee for a per-  
3 son under subsection (a) if the person has submitted an ap-  
4 plication under section 515(c) or section 351 of the Public  
5 Health Service Act and if the Secretary finds—

6               “(1) that such application is a device applica-  
7 tion for a device which has a humanitarian device ex-  
8 emption under section 520(m), or

9               “(2)(A) such waiver or reduction is necessary to  
10 protect the public health, and

11               “(B) the assessment of the fee would present a  
12 significant barrier to innovation because of limited  
13 resources available to such person or other cir-  
14 cumstances.

15       “(e) *EFFECT OF FAILURE TO PAY FEES.*—A device  
16 application or supplement submitted by a person subject  
17 to fees under subsection (a) shall be considered incomplete  
18 and shall not be accepted for review by the Secretary until  
19 all fees owed by such person under subsection (a) have been  
20 paid. The Secretary may discontinue review of any device  
21 application submitted by a person if such person has not  
22 paid all fees owed under subsection (a).

23       “(f) *ASSESSMENT OF FEES.*—

1           “(1) *LIMITATION.*—*Fees may not be assessed*  
2           *under subsection (a) for a fiscal year beginning after*  
3           *fiscal year 1995 unless—*

4                   “(A) *appropriations for salaries and ex-*  
5                   *penses of the Food and Drug Administration for*  
6                   *such fiscal year (excluding the amount of fees*  
7                   *appropriated under chapter 7 of this Act, chap-*  
8                   *ter 97 of title 31, United States Code, or other*  
9                   *authority for such fiscal year) are equal to or*  
10                   *greater than the amount of appropriations for*  
11                   *the salaries and expenses of the Food and Drug*  
12                   *Administration for fiscal year 1994 (excluding*  
13                   *the amount of fees appropriated under chapter 7*  
14                   *of this Act, chapter 97 of title 31, United States*  
15                   *Code, or other authority for such fiscal year)*  
16                   *multiplied by the adjustment factor applicable to*  
17                   *the fiscal year involved, and*

18                   “(B) *the number of full-time equivalent po-*  
19                   *sitions at the Food and Drug Administration for*  
20                   *such year, whose salary is not paid for by fees*  
21                   *authorized under this section, is equal to or*  
22                   *greater than the number of full-time equivalent*  
23                   *positions during fiscal year 1994 multiplied by*  
24                   *the employee adjustment factor. For purposes of*  
25                   *this paragraph, the term ‘employee adjustment*

1           *factor' applicable to a fiscal year is the number*  
2           *of full-time equivalent positions for such fiscal*  
3           *year permitted under section 5(b) of the Federal*  
4           *Workforce Restructuring Act of 1994 (5 U.S.C.*  
5           *3101 note) divided by the number of such posi-*  
6           *tions for fiscal year 1994.*

7           “(2) *AUTHORITY.—If the Secretary does not as-*  
8           *sess fees under subsection (a) during any portion of*  
9           *a fiscal year because of paragraph (1) and if at a*  
10          *later date in such fiscal year the Secretary is author-*  
11          *ized to assess such fees, the Secretary may assess and*  
12          *collect such fees, without any modification in the rate*  
13          *to account for the time during which the Secretary*  
14          *could not collect such fees.*

15          “(g) *CREDITING AND AVAILABILITY OF FEES.—*

16                 “(1) *IN GENERAL.—Fees collected for a fiscal*  
17                 *year pursuant to subsection (a) shall be deposited in*  
18                 *an escrow account established by the Secretary of*  
19                 *Health and Human Services and shall be available*  
20                 *and credited to the appropriation account for salaries*  
21                 *and expenses of the Food and Drug Administration as*  
22                 *provided in paragraph (2)(A), and shall be available*  
23                 *in accordance with appropriation Acts until ex-*  
24                 *pended, without fiscal year limitation.*

25                 “(2) *USE OF FUNDS.—*

1           “(A) *ESCROW.*—

2                   “(i) *15 PERCENT.*—15 percent of the  
3                   *fee assessed for the submission of an appli-*  
4                   *cation under section 515(c), an application*  
5                   *for a device under section 351 of the Public*  
6                   *Health Service Act, or a supplement with*  
7                   *required clinical data shall be immediately*  
8                   *available upon receipt by the Secretary.*

9                   “(ii) *35 PERCENT.*—35 percent of the  
10                   *fee assessed on an application or supple-*  
11                   *ment described in clause (i) shall be avail-*  
12                   *able upon receipt of the fee after acceptance*  
13                   *of such application or supplement for filing.*

14                   “(iii) *50 PERCENT.*—50 percent of the  
15                   *fee assessed on an application or supple-*  
16                   *ment described in clause (i) shall be avail-*  
17                   *able upon completion of a comprehensive*  
18                   *substantive review of such application or*  
19                   *supplement.*

20                   “(iv) *OTHER SUPPLEMENTS AND SUB-*  
21                   *MISSIONS.*—50 percent of the fee assessed for  
22                   *the submission of a supplement for which*  
23                   *clinical data are not required or a submis-*  
24                   *sion under section 510(k) shall be imme-*  
25                   *diately available upon receipt by the Sec-*

1            *retary and the remainder of such fee shall*  
2            *be available upon completion of a com-*  
3            *prehensive, substantive review of the supple-*  
4            *ment or submission.*

5            *“(v) INTEREST ON ESCROW.—The*  
6            *amount of interest which may accrue on*  
7            *fees in the escrow account established under*  
8            *paragraph (1) shall be paid into the Gen-*  
9            *eral Fund of the Treasury.*

10           *“(B) LIMIT ON AVAILABILITY.—Not more*  
11           *than 5 percent of the projected fee receipts in*  
12           *any fiscal year may be used for activities de-*  
13           *scribed in subparagraphs (L) and (N) of section*  
14           *741(3), except that up to 15 percent of the pro-*  
15           *jected fee receipts in any fiscal year may be used*  
16           *for such activities after the Commissioner of the*  
17           *Food and Drug Administration issues a public*  
18           *notice that the Food and Drug Administration*  
19           *has met the applicable goals referenced in section*  
20           *2(3) of the Medical Device User Fee Act of 1994.*  
21           *If subsequent to such public notice the Food and*  
22           *Drug Administration is not meeting such*  
23           *goals—*

1           “(i) the Commissioner shall issue a  
2           public notice of the Food and Drug Admin-  
3           istration’s actual performance level, and

4           “(ii) not more than 5 percent of pro-  
5           jected fee receipts may be used for such ac-  
6           tivities until the Commissioner issues a sub-  
7           sequent notice that the Food and Drug Ad-  
8           ministration is again meeting such goals.

9           “(3) COLLECTIONS AND APPROPRIATION ACTS.—

10          *The fees authorized by this section—*

11           “(A) shall be collected in each fiscal year in  
12           an amount equal to the amount specified in ap-  
13           propriation Acts for such fiscal year, and

14           “(B) shall only be collected and available to  
15           defray increases in the costs of the resources allo-  
16           cated for the process for the review of device ap-  
17           plications and related activities (including in-  
18           creases in such costs for an additional number of  
19           full-time equivalent employees in the Department  
20           of Health and Human Services to be engaged in  
21           such process) over such costs for fiscal year 1994  
22           multiplied by the adjustment factor.

23           “(4) AUTHORIZATION OF APPROPRIATIONS.—

24          *There are authorized to be appropriated for fees under*  
25          *this section—*

1           “(A) \$23,000,000 for fiscal year 1995,

2           “(B) \$21,300,000 for fiscal year 1996,

3           “(C) \$23,000,000 for fiscal year 1997,

4           “(D) \$24,000,000 for fiscal year 1998, and

5           “(E) \$24,000,000 for fiscal year 1999,

6           *as adjusted to reflect the percentage adjustment of fees*  
7           *authorized under subsection (c)(1).*

8           “(h) *COLLECTION OF UNPAID FEES.*—*In any case*  
9           *where the Secretary does not receive payment of a fee for*  
10           *a pending application assessed under subsection (a) within*  
11           *30 days after it is due, such fee shall be treated as a claim*  
12           *of the United States Government subject to subchapter II*  
13           *of chapter 37 of title 31, United States Code.*

14           “(i) *POSITIONS.*—*Any employee whose salary is paid*  
15           *for by fees authorized under this section shall not be in-*  
16           *cluded in calculating any limit on full-time equivalent posi-*  
17           *tions or the grade levels for such positions.”.*

18           **SEC. 4. ANNUAL REPORTS.**

19           “(a) *FIRST REPORT.*—*Within 90 days after the end of*  
20           *each fiscal year during which fees are collected under part*  
21           *3 of subchapter C of chapter VII of the Federal Food, Drug,*  
22           *and Cosmetic Act, the Secretary of Health and Human*  
23           *Services shall submit a report stating the Food and Drug*  
24           *Administration’s progress in achieving the goals identified*  
25           *in section 2(3) of this Act during such fiscal year and the*

1 *Food and Drug Administration's future plans for meeting*  
2 *such goals. There shall be included in such report—*

3 *(1) a specific statement from the Secretary con-*  
4 *cerning the Food and Drug Administration's actions*  
5 *to reduce the backlog in the review of device applica-*  
6 *tions and meeting statutory review times applicable*  
7 *to submissions for devices, and*

8 *(2) the following data from the Center for De-*  
9 *vices and Radiological Health and the Center for Bio-*  
10 *logics Evaluation and Research:*

11 *(A) The number of device submissions found*  
12 *not fileable.*

13 *(B) Total elapsed time for review of device*  
14 *submissions.*

15 *(C) Total time for review of device submis-*  
16 *sions as calculated by such Center.*

17 *(D) The number of negative decisions for*  
18 *device submissions.*

19 *(E) The number of non-approveable letters*  
20 *for device submissions.*

21 *(F) The number of deficiency letters for de-*  
22 *vice submissions.*

23 *(G) The total number of device applications*  
24 *by type of application.*

1           (H) *The number of device applications*  
2 *withdrawn by the sponsor.*

3           (I) *The number of major amendments to de-*  
4 *vice applications and the number of device ap-*  
5 *plications subject to post-market requirements es-*  
6 *tablished as a condition of approval of a device*  
7 *application.*

8           (J) *The number of devices with post-ap-*  
9 *proval problems which resulted in one or more of*  
10 *the following actions: Withdrawal of approval or*  
11 *temporary suspension of an approved applica-*  
12 *tion under section 515 of the Federal Food,*  
13 *Drug, and Cosmetic Act, mandatory product re-*  
14 *call under section 518 of such Act, seizure under*  
15 *section 304 of such Act, or criminal prosecution*  
16 *under section 303 of such Act.*

17           (K) *Information for subparagraphs (A)*  
18 *through (J) for fiscal year 1994.*

19       (b) *SECOND REPORT.—Within 120 days after the end*  
20 *of each fiscal year during which such fees are collected, the*  
21 *Secretary of Health and Human Services shall submit a*  
22 *report on the implementation of the authority for such fees*  
23 *during such fiscal year and on the use of the Food and Drug*  
24 *Administration made of the fees collected during such fiscal*  
25 *year.*

1       (c) *ESCROW ACCOUNT REPORT.*—The Secretary of  
2 Health and Human Services shall report to the Congress  
3 annually—

4           (1) *the closing monthly balance of the escrow ac-*  
5 *count established under section 742(g)(2) of the Fed-*  
6 *eral Food, Drug, and Cosmetic Act,*

7           (2) *the monthly receipt of fees in such account re-*  
8 *ported for each fee established under section 742(b) of*  
9 *such Act, and*

10          (3) *the monthly accrual of interest in such ac-*  
11 *count*

12       (d) *COMMITTEES.*—The reports described in sub-  
13 sections (a), (b), and (c) shall be submitted to the Committee  
14 on Energy and Commerce of the House of Representatives  
15 and the Committee on Labor and Human Resources of the  
16 Senate.

17 **SEC. 5. REGULATIONS.**

18       (a) *GENERAL RULE.*—This Act and the amendment  
19 made by section 3 shall not be in effect after June 30, 1995,  
20 unless the Secretary of Health and Human Services,  
21 through the Commissioner of Food and Drugs, approves—

22           (1) *regulations described in subsection (b), and*

23           (2) *regulations which identify devices in class II*  
24 *of the device classes in section 513 of the Federal*  
25 *Food, Drug, and Cosmetic Act that are appropriate*

1       *for exemption from the requirement of section 510(k)*  
2       *of such Act and which exempts such devices from such*  
3       *requirement following their reclassification into class*  
4       *I.*

5       **(b) REGULATIONS.—**

6           **(1) PROPOSED.—***Not later than November 30,*  
7       *1994, the Secretary shall issue proposed regulations*  
8       *that—*

9                   **(A)** *identify all devices in class I of the de-*  
10                   *vice classes in section 513 of the Federal Food,*  
11                   *Drug, and Cosmetic Act which are exempt from*  
12                   *the requirement of section 510(k) of such Act,*  
13                   *and*

14                   **(B)** *identify the criteria for selecting devices*  
15                   *for such exemption.*

16       *The Secretary shall provide an opportunity to com-*  
17       *ment on such proposed regulations for 60 days after*  
18       *publication.*

19           **(2) FINAL.—***Not later than February 28, 1995,*  
20       *the Secretary shall issue final regulations which grant*  
21       *an exemption to the devices identified in the proposed*  
22       *regulations which clearly meet the criteria for exemp-*  
23       *tion from the requirement of such section 510(k) of*  
24       *the Federal Food, Drug, and Cosmetic Act.*

1           (3) *OTHER REGULATIONS.*— Not later than June  
2           30, 1995, the Secretary shall issue final regulations  
3           for the remainder of the devices from the list pub-  
4           lished in the proposed regulations which exempts such  
5           devices from such requirement or which continues the  
6           applicability of such requirement.

7           (c) *FEEES.*—An applicant under a device substantial  
8           equivalence submission under section 510(k) of the Federal  
9           Food, Drug, and Cosmetic Act which the Secretary proposed  
10          to exempt from the requirement of such section under sub-  
11          section (b)(1) shall not be required to pay a fee for such  
12          submission unless the Secretary issues a final regulation re-  
13          quiring such submission. An applicant under a substantial  
14          equivalence submission under such section 510(k) which the  
15          Secretary exempts from the requirement of such section  
16          under subsection (a) shall not be required to pay a fee for  
17          such submission.

18       **SEC. 6. SUNSET.**

19          This Act and the amendment made by section 3 shall  
20          not be in effect after September 30, 1999.

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