

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4728

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

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IN THE HOUSE OF REPRESENTATIVES

JULY 12, 1994

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

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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”.

6 (b) REFERENCE.—Whenever in this Act an amend-  
7 ment or repeal is expressed in terms of an amendment  
8 to, or repeal of, a section or other provision, the reference  
9 shall be considered to be made to a section or other provi-  
10 sion of the Federal Food, Drug, and Cosmetic Act.

1 **SEC. 2. FINDINGS.**

2 The Congress finds that—

3 (1) prompt approval and clearance of safe and  
4 effective devices is critical to the improvement of the  
5 public health so that patients may enjoy the benefits  
6 of devices to diagnose, treat, and prevent disease;

7 (2) the public health will be served by furnish-  
8 ing additional funds for the review of devices so that  
9 statutorily mandated deadlines may be met, and

10 (3) the fees authorized by the amendment made  
11 by section 3 will be dedicated—

12 (A) toward expediting the review of device  
13 applications, supplements, and substantial  
14 equivalence submissions, and

15 (B) for related activities as defined in sec-  
16 tion 741(3) of the Federal Food, Drug, and  
17 Cosmetic Act,

18 as set forth in goals identified in the letter of July  
19 8 , 1994, from the Commissioner of Food and Drugs  
20 to the Committee on Energy and Commerce of the  
21 House of Representatives and the Committee on  
22 Labor and Human Resources of the Senate.

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

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

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

2   **“SEC. 741. DEFINITIONS.**

3           “For purposes of this subchapter:

4               “(1) The term—

5                       “(A) ‘device application’ means an applica-  
6                       tion for approval of a device submitted under  
7                       section 515(c) or section 351 of the Public  
8                       Health Service Act, a supplement to such an  
9                       application, or a device substantial equivalence  
10                      submission made under section 510(k); and

11                      “(B) ‘section 351 application’ means a de-  
12                      vice application submitted under section 351 of  
13                      the Public Health Service Act.

14               “(2) The term ‘supplement’ means a request to  
15                      the Secretary to approve a change in a device appli-  
16                      cation which has been approved under section  
17                      515(d) or section 351 of the Public Health Service  
18                      Act.

19               “(3) The term ‘process for the review of device  
20                      applications and related activities’ means the follow-  
21                      ing activities of the Secretary with respect to the re-  
22                      view of device applications and related activities:

23                      “(A) The activities necessary for the  
24                      review of device applications and related  
25                      activities.

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

7           “(C) The inspection of device establish-  
8 ments and other facilities undertaken as part of  
9 the Secretary’s review of pending device appli-  
10 cations.

11           “(D) Activities necessary for the review of  
12 applications for licensure of devices subject to  
13 section 351 of the Public Health Service Act,  
14 for the licensure of establishments where such  
15 devices are manufactured, and for the release of  
16 lots of such devices.

17           “(E) Review of device applications for an  
18 investigational new drug exemption under sec-  
19 tion 505(i) and for an investigational device ex-  
20 emption under section 520(g) and activities  
21 conducted in anticipation of the submission of  
22 an application under sections 505(i) and  
23 520(g).

1           “(F) The development of guidance and pol-  
2           icy documents to improve the process for the  
3           review of device applications.

4           “(G) The development of test methods and  
5           standards in connection with the review of de-  
6           vice applications and related activities.

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

10          “(I) Activities undertaken in connection  
11          with the export of a device.

12          “(J) Activities undertaken under sections  
13          513 and 515(i) in connection with the initial  
14          classification and reclassification of a device  
15          and under section 515(b) in connection with  
16          any requirement for premarket approval of a  
17          device.

18          “(K) Monitoring of research.

19          “(L) Activities undertaken under sections  
20          519(a) and 519(b).

21          “(M) Postmarket studies required as a  
22          condition of an approval of a device application  
23          under section 515(d) or section 351 of the Pub-  
24          lic Health Service Act.

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

3           “(4) The term ‘costs of resources allocated for  
4           the process for the review of device applications and  
5           related activities’ means the expenses incurred in  
6           connection with the process for the review of device  
7           applications and related activities for—

8                   “(A) officers and employees of the Food  
9                   and Drug Administration, employees under con-  
10                  tract with the Food and Drug Administration,  
11                  advisory committees, and costs related to such  
12                  officers, 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  
19                  equipment, and other necessary materials, serv-  
20                  ices, and supplies, and

21                   “(D) collecting fees under section 742 and  
22                  accounting for resources allocated for the re-  
23                  view of device applications and related activi-  
24                  ties, including activities related to the review of

1 applications for fee exceptions, waivers, and  
2 reductions.

3 “(5) The term ‘adjustment factor’ applicable to  
4 a 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  
10 for discretionary programs for the immediately  
11 preceding fiscal year (as reported in the Office  
12 of Management and Budget sequestration pre-  
13 view 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  
19 end of the 103d Congress, 2d Session).

20 The term ‘budget authority’ in subparagraph (B) is  
21 as defined in the Balanced Budget and Emergency  
22 Deficit Control Act of 1985, as in effect as of Janu-  
23 ary 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—

8 “(A) the date of the enactment of the Med-  
9 ical Device User Fee Act of 1994, or

10 “(B) the date of the enactment of the first  
11 appropriation under subsection (g)(4) for fees  
12 under this section,

13 whichever occurs later, a device application shall be  
14 subject to the fee prescribed by subsection (b).

15 “(2) EXCEPTION.—

16 “(A) FURTHER MANUFACTURING USE.—  
17 No fee shall be required for the submission of  
18 a section 351 application for a product licensed  
19 for further manufacturing use only.

20 “(B) EXCEPTION FOR PREVIOUSLY FILED  
21 APPLICATION OR SUPPLEMENT.—If a device ap-  
22 plication was—

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

25 “(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  
6           be subject to a fee under paragraph (1).

7           “(3) PAYMENT SCHEDULE.—

8           “(A) GENERAL RULE.—Except as provided  
9           in subparagraph (B), the fee prescribed by sub-  
10          section (b) shall be due upon the submission of  
11          the application.

12          “(B) EXCEPTIONS.—

13                 “(i) PENDING.—In the case of a de-  
14                 vice application for which fees are required  
15                 under paragraph (1) and which is pending  
16                 on the later of—

17                         “(I) the date of the enactment of  
18                         the Medical Device User Fee Act of  
19                         1994, or

20                         “(II) the date of the enactment  
21                         of the first appropriation under sub-  
22                         section (g)(4) for fees under this sec-  
23                         tion,

1 the fee required by paragraph (1) shall be  
2 due 90 days after such later date of enact-  
3 ment.

4 “(ii) EXCESS OF AUTHORIZATION.—A  
5 fee which is due after an amount of fees  
6 equal to the authorization of appropria-  
7 tions under subsection (g)(4) for the fiscal  
8 year in which the fee is imposed has been  
9 collected shall be due on November 1 in  
10 the following fiscal year.

11 “(4) REFUND IF APPLICATION OR SUPPLEMENT  
12 NOT ACCEPTED FOR FILING.—

13 “(A) 515(c) AND 351.—The Secretary shall  
14 refund 85 percent of the fee paid under para-  
15 graph (3) for any application submitted under  
16 section 515(c) or section 351 of the Public  
17 Health Service Act which is not accepted for fil-  
18 ing.

19 “(B) SUPPLEMENTS.—The Secretary shall  
20 refund 85 percent of the fee paid under para-  
21 graph (3) for any supplement with required  
22 clinical data which is not accepted for filing and  
23 shall refund the fee paid under such paragraph  
24 for any supplement without required clinical  
25 data which is not accepted for filing.

1           “(C) 510(k).—The Secretary shall refund  
2           the fee paid under paragraph (3) for any sub-  
3           stantial equivalence submission under section  
4           510(k) which is not accepted for filing.

5           “(b) FEE AMOUNTS.—

6           “(1) AMOUNT.—Except as provided in para-  
7           graph (2) and subsections (c), (d), (f), and (g), the  
8           fees required under subsection (a) are as follows:

9           “(A) \$52,000 for applications submitted  
10           under section 515(c) and applications for de-  
11           vices submitted under section 351 of the Public  
12           Health Service Act,

13           “(B) \$7,100 for a supplement with re-  
14           quired clinical data,

15           “(C) \$4,500 for a supplement without re-  
16           quired clinical data, and

17           “(D) \$3,200 for a submission under sec-  
18           tion 510(k).

19           “(2) SMALL BUSINESS EXCEPTION.—

20           “(A) APPLICATIONS AND SUBMISSIONS.—

21           Any person employing fewer than 20 employees,  
22           including employees of affiliates, and which  
23           does not have a device introduced or delivered  
24           for introduction into interstate commerce under  
25           a device application—

1           “(i) shall pay one-half the amount of  
2           the fee prescribed by paragraph (1)(A) one  
3           year after the date of final action by the  
4           Secretary on an application of such person  
5           which is subject to such fee, and

6           “(ii) shall pay the fee prescribed by  
7           paragraph (1)(D) for a submission made  
8           by such person under section 510(k) one  
9           year after the date of final action by the  
10          Secretary on such submission.

11          “(B) CERTIFICATION.—The Secretary  
12          shall require any person who applies to pay a  
13          fee in accordance with subparagraph (A) to cer-  
14          tify such person’s qualification under such sub-  
15          paragraph. The Secretary shall periodically  
16          publish in the Federal Register of list of per-  
17          sons making such certification.

18          “(C) DEFINITION.—For purposes of this  
19          paragraph, a person is an affiliate of another  
20          person when—

21                 “(i) directly or indirectly, one person  
22                 controls, or has the power to control, the  
23                 other person,

1           “(ii) directly or indirectly, a third  
2           party controls, or has the power to control,  
3           both persons, or

4           “(iii) an identity of interest between  
5           or among such persons exists such that af-  
6           filiation may be found.

7           “(c) ADJUSTMENTS.—

8           “(1) FEE ADJUSTMENT.—Subject to the  
9           amount appropriated for a fiscal year under sub-  
10          section (g), the Secretary shall, in a fiscal year be-  
11          ginning after fiscal year 1995, adjust the fees due  
12          in the fiscal year following the fiscal year in which  
13          the adjustment is made to reflect the greater of—

14               “(A) the total percentage increase that oc-  
15               curred during the preceding fiscal year in the  
16               Consumer Price Index for all urban consumers  
17               (all items; U.S. city average) that exceeds 3.5  
18               percent, or

19               “(B) the total percentage increase for such  
20               preceding fiscal year in basic pay under the  
21               General Schedule in accordance with section  
22               5332 of title 5, United States Code, as adjusted  
23               by any locality-based comparability payment  
24               pursuant to section 5304 of such title for Fed-

1           eral employees stationed in the District of Co-  
2           lumbia that exceeds 3.5 percent.

3           The Secretary shall, by notice published in the Fed-  
4           eral Register, make an adjustment under this para-  
5           graph within the first 60 days of a fiscal year.

6           “(2) LIMIT.—The total amount of fees charged,  
7           as adjusted under paragraph (1), for a fiscal year  
8           may not exceed the total costs for such fiscal year  
9           for the resources allocated for the process for the re-  
10          view of device applications and related activities.

11          “(d) FEE WAIVER OR REDUCTION.—The Secretary  
12         shall grant a waiver from or a reduction of a fee for a  
13         person under subsection (a) if the person has submitted  
14         an application under section 515(c) or section 351 of the  
15         Public Health Service Act and if the Secretary finds—

16                 “(1) that such application is a device applica-  
17                 tion for a device which has a humanitarian device  
18                 exemption under section 520(m), or

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

21                 “(B) the assessment of the fee would present a  
22                 significant barrier to innovation because of limited  
23                 resources available to such person or other cir-  
24                 cumstances.

1       “(e) EFFECT OF FAILURE TO PAY FEES.—A device  
2 application or supplement submitted by a person subject  
3 to fees under subsection (a) shall be considered incomplete  
4 and shall not be accepted for review by the Secretary until  
5 all fees owed by such person under subsection (a) have  
6 been paid. The Secretary may discontinue review of any  
7 device application submitted by a person if such person  
8 has not paid all fees owed by such person under subsection  
9 (a).

10       “(f) ASSESSMENT OF FEES.—

11           “(1) LIMITATION.—Fees may not be assessed  
12 under subsection (a) for a fiscal year beginning after  
13 fiscal year 1995 unless appropriations for salaries  
14 and expenses of the Food and Drug Administration  
15 for such fiscal year (excluding the amount of fees  
16 appropriated under chapter 7, chapter 97 of title 31,  
17 United States Code, or other authority for such fis-  
18 cal year) are equal to or greater than the amount of  
19 appropriations for the salaries and expenses of the  
20 Food and Drug Administration for the fiscal year  
21 1994 (excluding the amount of fees appropriated  
22 under chapter 7, chapter 97 of title 31, United  
23 States Code, or other authority for such fiscal year)  
24 multiplied by the adjustment factor applicable to the  
25 fiscal year involved.

1           “(2) AUTHORITY.—If the Secretary does not  
2           assess fees under subsection (a) during any portion  
3           of a fiscal year because of paragraph (1) and if at  
4           a later date in such fiscal year the Secretary is au-  
5           thorized to assess such fees, the Secretary may as-  
6           sess and collect such fees, without any modification  
7           in the rate to account for the time in which the Sec-  
8           retary could not collect such fees.

9           “(g) CREDITING AND AVAILABILITY OF FEES.—

10           “(1) IN GENERAL.—Fees collected for a fiscal  
11           year pursuant to subsection (a) shall be credited to  
12           the appropriation account for salaries and expenses  
13           of the Food and Drug Administration and shall be  
14           available in accordance with appropriation Acts until  
15           expended, without fiscal year limitation.

16           “(2) AVAILABILITY.—Not more than 5 percent  
17           of the projected fee receipts in any fiscal year may  
18           be used for activities described in subparagraphs (L)  
19           and (N) of section 741(3), except that up to 15 per-  
20           cent of the projected fee receipts in any fiscal year  
21           may be used for such activities after the Commis-  
22           sioner of the Food and Drug Administration issues  
23           a public notice that the Food and Drug Administra-  
24           tion has met the applicable goals referenced in sec-  
25           tion 2(3) of the Medical Device User Fee Act of

1 1994. If subsequent to such public notice the Food  
2 and Drug Administration is not meeting such  
3 goals—

4 “(A) the Commissioner shall issue a public  
5 notice of the Food and Drug Administration’s  
6 actual performance level, and

7 “(B) not more than 5 percent of projected  
8 fee receipts may be used for such activities until  
9 the Commissioner issues a subsequent notice  
10 that the Food and Drug Administration is  
11 again meeting such goals.

12 “(3) COLLECTIONS AND APPROPRIATION  
13 ACTS.—The fees authorized by this section—

14 “(A) shall be collected in each fiscal year  
15 in an amount equal to the amount specified in  
16 appropriation Acts for such fiscal year, and

17 “(B) shall only be collected and available  
18 to defray increases in the costs of the resources  
19 allocated for the process for the review of device  
20 applications and related activities (including in-  
21 creases in such costs for an additional number  
22 of full-time equivalent employees in the Depart-  
23 ment of Health and Human Services to be en-  
24 gaged in such process) over such costs for fiscal  
25 year 1994 multiplied by the adjustment factor.

1           “(4) AUTHORIZATION OF APPROPRIATIONS.—

2           There are authorized to be appropriated for fees  
3           under this section—

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

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

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

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

8                   and

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

10           as adjusted to reflect the percentage adjustment of  
11           fees authorized under subsection (c)(1).

12           “(h) COLLECTION OF UNPAID FEES.—In any case  
13           where the Secretary does not receive payment of a fee for  
14           a pending application assessed under subsection (a) within  
15           30 days after it is due, such fee shall be treated as a claim  
16           of the United States Government subject to subchapter  
17           II of chapter 37 of title 31, United States Code.

18           “(i) POSITIONS.—

19                   “(1) GENERAL RULE.—The number of full-time  
20                   equivalent employees in the Department of Health  
21                   and Human Services not engaged in the process of  
22                   the review of device applications and related activi-  
23                   ties, may not be reduced by the Secretary to offset  
24                   the number of officers, employees, and advisory com-  
25                   mittees so engaged.

1           “(2) EXECUTIVE ORDER AND OTHER LIMITS.—  
2           The number of full-time equivalent employees en-  
3           gaged in the process of the review of device applica-  
4           tions and related activities are not subject to count-  
5           ing or inclusion in the limits on hiring Civilian Per-  
6           sonnel set out in Executive Order 12839 of Feb-  
7           ruary 10, 1993, any other current limit, or any limit  
8           that may be implemented through September 30,  
9           1999. The full-time equivalent employees not so en-  
10          gaged may not be reduced by the Secretary to offset  
11          the number of full-time equivalent employees exempt  
12          from such limit.”.

13   **SEC. 4. ANNUAL REPORTS.**

14          (a) FIRST REPORT.—Within 90 days after the end  
15          of each fiscal year during which fees are collected under  
16          part 3 of subchapter C of chapter VII of the Federal Food,  
17          Drug, and Cosmetic Act, the Secretary of Health and  
18          Human Services shall submit a report stating the Food  
19          and Drug Administration’s progress in achieving the goals  
20          identified in section 2(3) of this Act during such fiscal  
21          year and that agency’s future plans for meeting such  
22          goals. There shall be included in such report—

23                  (1) a specific statement from the Secretary con-  
24                  cerning the Food and Drug Administration’s actions  
25                  to reduce the backlog in the review of device applica-

1 tions and meeting statutory review times applicable  
2 to submissions for devices, and

3 (2) the following data from the Center for De-  
4 vices and Radiological Health and the Center for  
5 Biologics Evaluation and Research:

6 (A) The number of device submissions  
7 found not fileable.

8 (B) Total elapsed time for review of device  
9 submissions.

10 (C) Total time for review of device submis-  
11 sions as calculated by such Center.

12 (D) Number of negative decisions for de-  
13 vice submissions.

14 (E) Number of non-approveable letters for  
15 device submissions.

16 (F) Number of deficiency letters for device  
17 submissions.

18 (G) Information for subparagraphs (A)  
19 through (F) for fiscal year 1994.

20 (b) SECOND REPORT.—Within 120 days after the  
21 end of each fiscal year during which such fees are col-  
22 lected, the Secretary of Health and Human Services shall  
23 submit a report on the implementation of the authority  
24 for such fees during such fiscal year and on the use the

1 Food and Drug Administration made of the fees collected  
2 during such fiscal year for which the report is made.

3 (c) COMMITTEES.—The reports described in sub-  
4 sections (a) and (b) shall be submitted to the Committee  
5 on Energy and Commerce of the House of Representatives  
6 and the Committee on Labor and Human Resources of  
7 the Senate.

8 **SEC. 5. REGULATIONS.**

9 (a) GENERAL RULE.—This Act and the amendment  
10 made by section 3 shall not be in effect after June 30,  
11 1995, unless the Secretary of Health and Human Services,  
12 through the Commissioner of Food and Drugs, approves—

13 (1) regulations described in subsection (b), and

14 (2) regulations which identify devices in class II  
15 of the device classes in section 513 of the Federal  
16 Food, Drug, and Cosmetic Act which are appro-  
17 priate for exemption from the requirement of section  
18 510(k) of such Act and exempts such devices from  
19 such requirement following their reclassification into  
20 class I.

21 (b) REGULATIONS.—

22 (1) PROPOSED.—Not later than 30 days after  
23 the date of the enactment of this Act, the Secretary  
24 shall issue proposed regulations that—

1           (A) identify all devices in class I of the de-  
2           vice classes in section 513 of the Federal Food,  
3           Drug, and Cosmetic Act which are exempt from  
4           the requirement of section 510(k) of such Act,  
5           and

6           (B) identify the criteria for selecting de-  
7           vices for such exemption.

8           The Secretary shall provide an opportunity to com-  
9           ment on such proposed regulations for 60 days after  
10          their publication.

11          (2) FINAL.—Not later than 30 days after the  
12          close of the comment period provided under para-  
13          graph (1), the Secretary shall issue final regulations  
14          which grant an exemption to the devices identified in  
15          the proposed regulations which clearly meet the cri-  
16          teria for exemption from the requirement of such  
17          section 510(k) of the Federal Food, Drug, and Cos-  
18          metic Act.

19          (c) OTHER REGULATIONS.— Not later than June 30,  
20          1995, the Secretary shall issue final regulations for the  
21          remainder of the devices from the list published in the pro-  
22          posed regulations which exempts such devices from such  
23          requirement or which continues the applicability of such  
24          requirement.

1 (d) FEES.—An applicant under a substantial equiva-  
2 lence submission under section 510(k) of the Federal  
3 Food, Drug, and Cosmetic Act which the Secretary pro-  
4 posed to exempt from the requirement of such section  
5 under subsection (b)(1) shall not be required to pay a fee  
6 for such submission unless the Secretary issues a final  
7 regulation requiring such submission. An applicant under  
8 a substantial equivalence submission under such section  
9 510(k) which the Secretary exempts from the requirement  
10 of such section under subsection (b) shall not be required  
11 to pay a fee for such submission.

12 **SEC. 6. SUNSET.**

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

○

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HR 4728 IH—3