

103^D CONGRESS
2^D SESSION

S. 2276

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

IN THE SENATE OF THE UNITED STATES

JULY 12 (legislative day, JULY 11), 1994

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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 of 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 re-
24 view of device applications and related activi-
25 ties.

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 re-
2 ductions.

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 APPLICATIONS OR SUPPLEMENT.—If a device
22 application 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 SUBMISSION.—
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 person exist 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 of such fiscal
18 year) are equal to or greater than the amount of ap-
19 propriations for the salaries and expenses of the
20 Food and Drug Administration for fiscal year 1994
21 (excluding the amount of fees appropriated under
22 chapter 7, chapter 97 of title 31, United States
23 Code, or other authority for such fiscal year) multi-
24 plied by the adjustment factor applicable to the fis-
25 cal 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 notice the Food and
2 Drug Administration is not meeting such goals—

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

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

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

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

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