Union Calendar No. 413

103D CONGRESS
2D SESSION

H. R. 4864

[Report No. 103–751]

A BILL

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

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]

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device User Fee Act of 1994''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. FINDINGS.

The Congress finds that—

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

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

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

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

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

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

SEC. 3. FEES RELATING TO DEVICES.

Chapter VII is amended by adding at the end of subchapter C the following:

''PART 3—FEES RELATING TO DEVICES

''SEC. 741. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term—

''(A) 'device application' means an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act, a supplement to such an application, or a submission for a device made under section 510(k) claiming the devise is substantially equivalent as described in section 513(f)(1)(A) (in this part referred to as a 'device substantial equivalence submission'); and

''(B) 'section 351 application' means a device application submitted under section 351 of the Public Health Service Act.

''(2) The term 'supplement' means a request to the Secretary to approve a change in a device application which has been approved under section 515(d) or section 351 of the Public Health Service Act.

''(3) The term 'process for the review of device applications and related activities' means the follow-

ing activities of the Secretary with respect to the review of device applications and related activities:

''(A) The activities necessary for the review of device applications and related activities.

''(B) The issuance of action letters which allow marketing of devices or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The inspection of device establishments and other facilities undertaken as part of the Secretary's review of pending device applications.

''(D) Any activity necessary for the review of applications for licensure of devices subject to section 351 of the Public Health Service Act, for the licensure of establishments where such devices are manufactured, and for the release of lots of such devices.

''(E) Review of device applications for an investigational new drug exemption under section 505(i) and for an investigational device exemption under section 520(g) and activities con-

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

''(F) The development of guidance and policy documents to improve the process for the review of device applications.

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

''(H) The provision of technical assistance to device manufacturers in connection with the submission of a device application.

''(I) Any activity undertaken in connection with the export of a device.

''(J) Any activity undertaken under sections 513 and 515(i) in connection with the initial classification and reclassification of a device and under section 515(b) in connection with any requirement for premarket approval of a device.

''(K) Monitoring of research on devices.

''(L) Any activities undertaken under sections 519(a) and 519(b).

''(M) Postmarket studies required as a condition of an approval of a device application under section 515(d) or section 351 of the Public Health Service Act.

''(N) Postmarket surveillance required under section 522.

''(4) The term 'costs of resources allocated for the process for the review of device applications and related activities' means the expenses incurred in connection with the process for the review of device applications and related activities for—

''(A) officers and employees of the Food and Drug Administration, employees under contract with the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees,

''(B) management of information, and the acquisition, maintenance, and repair of computer resources,

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials, services, and supplies, and

''(D) collection fees under section 742 and accounting for resources allocated for the review of device applications and related activities, including activities related to the review of appli-

cations for fee exceptions, waivers, and reductions.

''(5) The term 'adjustment factor' applicable to a fiscal year is the lower of—

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

''(B) the total budget authority provided for discretionary programs for the immediately preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, required under section 254(d) of the Balanced Budget and Emergency Deficit Control Act of 1985) divided by such budget authority for fiscal year 1994 (as reported in the Office of Management and Budget final sequestration report submitted after the end of the 103d Congress, 2d Session).

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

"SEC. 742. AUTHORITY TO ASSESS AND USE DEVICE USER FEES.

"(a) FEES.—Beginning in fiscal year 1995, the Secretary shall assess and collect fees as follows:

"(1) GENERAL RULE.—Except as provided in paragraph (2), each person that submits, on or after 90 days before the date of the enactment of the first appropriation under subsection (g)(4) for fees under this section, a device application shall be subject, in accordance with paragraph (3), to the fee prescribed by subsection (b). Before April 30, 1995, the Secretary shall establish guidelines for the combination of multiple device applications in those situations where it is appropriate to combine the applications and assess a single fee. A single fee shall be assessed upon an application which is such a combination.

"(2) EXCEPTION.—

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

"(B) PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a device application was—

"(i) submitted by a person that paid the fee for such application,

"(ii) accepted for filing, and

''(iii) not approved or withdrawn (without a waiver under subsection (d)),

the submission of a device application for the identical device by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under paragraph (1).

''(3) PAYMENT SCHEDULE.—

''(A) GENERAL RULE.—Except as provided in subparagraph (B)—

''(i) in the case of an application submitted under section 515(c), an application for a device submitted under section 351 of the Public Health Service Act, or a supplement submitted with required clinical data, 15 percent of the fee prescribed by subsection (b) shall be due upon submission of such application or supplement and the remainder within 30 days of receipt of notice from the Secretary of acceptance of such application or supplement for filing or review, and

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

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

''(B) EXCEPTIONS.—

''(i) PENDING APPLICATIONS.—In the case of a device application for which fees are required under paragraph (1) and which is pending on the date of the enactment of the first appropriation under subsection (g)(4) for fees under this section, the fee required by paragraph (1) shall be due 90 days after such date of enactment.

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

''(b) FEE AMOUNTS.—

''(1) AMOUNT.—Except as provided in paragraph (2) and subject to subsections (c), (d), (f), and (g)(3)(A), the fees required under subsection (a) are as follows:

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

''(B) $7,100 for a supplement for which clinical data are required.

''(C) $4,500 for a supplement for which clinical data are not required.

''(D) $3,200 for a device substantial equivalence submission under section 510(k).

''(2) SMALL BUSINESS EXCEPTION.—

''(A) APPLICATIONS AND SUBMISSIONS.—Any person employing fewer than 20 employees, including employees of affiliates, which does not have a device introduced or delivered for introduction into interstate commerce under a device application—

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

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

after the date of final action by the Secretary on such submission.

''(B) CERTIFICATION.—The Secretary shall require any person who applies to pay a fee in accordance with subparagraph (A) to certify such person's qualification under such subparagraph. The Secretary shall periodically publish in the Federal Register a list of persons making such certification.

''(C) DEFINITION.—For purposes of this paragraph, a person is an affiliate of another person when—

''(i) one person controls, or has the power to control, directly or indirectly, the other person,

''(ii) a third party controls, or has the power to control, directly or indirectly, both persons, or

''(iii) an identity of interest between or among such persons exists such that affiliation may be found.

''(c) ADJUSTMENTS.—

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

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

''(A) the total percentage increase that occurred during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; United States city average) that exceeds 3.5 percent, or

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

The Secretary shall, by notice published in the Federal Register, make an adjustment under this paragraph before December 1 of each year.

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

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

''(1) that such application is a device application for a device which has a humanitarian device exemption under section 520(m), or

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

''(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances.

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

''(f) ASSESSMENT OF FEES.—

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

''(A) appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated under chapter 7 of this Act, chapter 97 of title 31, United States Code, or other authority for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 1994 (excluding the amount of fees appropriated under chapter 7 of this Act, chapter 97 of title 31, United States Code, or other authority for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved, and

''(B) the number of full-time equivalent positions at the Food and Drug Administration for such year, whose salary is not paid for by fees authorized under this section, is equal to or greater than the number of full-time equivalent positions during fiscal year 1994 multiplied by the employee adjustment factor. For purposes of this paragraph, the term 'employee adjustment

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

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary is authorized to assess such fees, the Secretary may assess and collect such fees, without any modification in the rate to account for the time during which the Secretary could not collect such fees.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be deposited in an escrow account established by the Secretary of Health and Human Services and shall be available and credited to the appropriation account for salaries and expenses of the Food and Drug Administration as provided in paragraph (2)(A), and shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(2) USE OF FUNDS.—

''(A) ESCROW.—

''(i) 15 PERCENT.—15 percent of the fee assessed for the submission of an application under section 515(c), an application for a device under section 351 of the Public Health Service Act, or a supplement with required clinical data shall be immediately available upon receipt by the Secretary.

''(ii) 35 PERCENT.—35 percent of the fee assessed on an application or supplement described in clause (i) shall be available upon receipt of the fee after acceptance of such application or supplement for filing.

''(iii) 50 PERCENT.—50 percent of the fee assessed on an application or supplement described in clause (i) shall be available upon completion of a comprehensive substantive review of such application or supplement.

''(iv) OTHER SUPPLEMENTS AND SUBMISSIONS.—50 percent of the fee assessed for the submission of a supplement for which clinical data are not required or a submission under section 510(k) shall be immediately available upon receipt by the Sec-

retary and the remainder of such fee shall be available upon completion of a comprehensive, substantive review of the supplement or submission.

''(v) INTEREST ON ESCROW.—The amount of interest which may accrue on fees in the escrow account established under paragraph (1) shall be paid into the General Fund of the Treasury.

''(B) LIMIT ON AVAILABILITY.—Not more than 5 percent of the projected fee receipts in any fiscal year may be used for activities described in subparagraphs (L) and (N) of section 741(3), except that up to 15 percent of the projected fee receipts in any fiscal year may be used for such activities after the Commissioner of the Food and Drug Administration issues a public notice that the Food and Drug Administration has met the applicable goals referenced in section 2(3) of the Medical Device User Fee Act of 1994. If subsequent to such public notice the Food and Drug Administration is not meeting such goals—

''(i) the Commissioner shall issue a public notice of the Food and Drug Administration's actual performance level, and

''(ii) not more than 5 percent of projected fee receipts may be used for such activities until the Commissioner issues a subsequent notice that the Food and Drug Administration is again meeting such goals.

''(3) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by this section—

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

''(B) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications and related activities (including increases in such costs for an additional number of full-time equivalent employees in the Department of Health and Human Services to be engaged in such process) over such costs for fiscal year 1994 multiplied by the adjustment factor.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

''(A) $23,000,000 for fiscal year 1995,

''(B) $21,300,000 for fiscal year 1996,

''(C) $23,000,000 for fiscal year 1997,

''(D) $24,000,000 for fiscal year 1998, and

''(E) $24,000,000 for fiscal year 1999,

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

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

''(i) POSITIONS.—Any employee whose salary is paid for by fees authorized under this section shall not be included in calculating any limit on full-time equivalent positions or the grade levels for such positions.''.

SEC. 4. ANNUAL REPORTS.

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

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

(1) a specific statement from the Secretary concerning the Food and Drug Administration's actions to reduce the backlog in the review of device applications and meeting statutory review times applicable to submissions for devices, and

(2) the following data from the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research:

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

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

(C) Total time for review of device submissions as calculated by such Center.

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

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

(F) The number of deficiency letters for device submissions.

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

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

(I) The number of major amendments to device applications and the number of device applications subject to post-market requirements established as a condition of approval of a device application.

(J) The number of devices with post-approval problems which resulted in one or more of the following actions: Withdrawal of approval or temporary suspension of an approved application under section 515 of the Federal Food, Drug, and Cosmetic Act, mandatory product recall under section 518 of such Act, seizure under section 304 of such Act, or criminal prosecution under section 303 of such Act.

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

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

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

(1) the closing monthly balance of the escrow account established under section 742(g)(2) of the Federal Food, Drug, and Cosmetic Act,

(2) the monthly receipt of fees insuch account reported for each fee established under section 742(b) of such Act, and

(3) the monthly accrual of interest in such account

(d) COMMITTEES.—The reports described in subsections (a), (b), and (c) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

SEC. 5. REGULATIONS.

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

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

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

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

(b) REGULATIONS.—

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

(A) identify all devices in class I of the device classes in section 513 of the Federal Food, Drug, and Cosmetic Act which are exempt from the requirement of section 510(k) of such Act, and

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

The Secretary shall provide an opportunity to comment on such proposed regulations for 60 days after publication.

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

(3) OTHER REGULATIONS.— Not later than June 30, 1995, the Secretary shall issue final regulations for the remainder of the devices from the list published in the proposed regulations which exempts such devices from such requirement or which continues the applicability of such requirement.

(c) FEES.—An applicant under a device substantial equivalence submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act which the Secretary proposed to exempt from the requirement of such section under subsection (b)(1) shall not be required to pay a fee for such submission unless the Secretary issues a final regulation requiring such submission. An applicant under a substantial equivalence submission under such section 510(k) which the Secretary exempts from the requirement of such section under subsection (a) shall not be required to pay a fee for such submission.

SEC. 6. SUNSET.

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