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103D CONGRESS
2D SESSION

H. R. 4864

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

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

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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.

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 section 741(3) of the Federal Food, Drug, and Cosmetic Act,

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 and the Committee on Labor and Human Resources of the Senate.

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 device substantial equivalence submission made under section 510(k); 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 following 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) Activities 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 conducted 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) Activities undertaken in connection with the export of a device.

''(J) Activities 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.

''(L) 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) collecting 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

applications 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 the Balanced Budget and Emergency Deficit Control Act of 1985, 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—

''(A) the date of the enactment of the Medical Device User Fee Act of 1994, or

''(B) the date of the enactment of the first appropriation under subsection (g)(4) for fees under this section,

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

''(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) EXCEPTION FOR 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), the fee prescribed by subsection (b) shall be due upon the submission of the application.

''(B) EXCEPTIONS.—

''(i) PENDING.—In the case of a device application for which fees are required under paragraph (1) and which is pending on the later of—

''(I) the date of the enactment of the Medical Device User Fee Act of 1994, or

''(II) 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 later 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.

''(4) REFUND IF APPLICATION OR SUPPLEMENT NOT ACCEPTED FOR FILING.—

''(A) 515(c) AND 351.—The Secretary shall refund 85 percent of the fee paid under paragraph (3) for any application submitted under section 515(c) or section 351 of the Public Health Service Act which is not accepted for filing.

''(B) SUPPLEMENTS.—The Secretary shall refund 85 percent of the fee paid under paragraph (3) for any supplement with required clinical data which is not accepted for filing and shall refund the fee paid under such paragraph for any supplement without required clinical data which is not accepted for filing.

''(C) 510(k).—The Secretary shall refund the fee paid under paragraph (3) for any substantial equivalence submission under section 510(k) which is not accepted for filing.

''(b) FEE AMOUNTS.—

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

''(A) $52,000 for applications submitted under section 515(c) and applications for devices submitted under section 351 of the Public Health Service Act,

''(B) $7,100 for a supplement with required clinical data,

''(C) $4,500 for a supplement without required clinical data, and

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

''(2) SMALL BUSINESS EXCEPTION.—

''(A) APPLICATIONS AND SUBMISSIONS.—Any person employing fewer than 20 employees, including employees of affiliates, and 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 of list of persons making such certification.

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

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

''(ii) directly or indirectly, a third party controls, or has the power to control, 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), the Secretary shall, in a fiscal year beginning after fiscal year 1995, adjust the fees due in the fiscal year following the fiscal year 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 Fed-

eral 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 within the first 60 days of a fiscal 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 by such person 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, 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 the fiscal year 1994 (excluding the amount of fees appropriated under chapter 7, chapter 97 of title 31, United States Code, or other authority for such fiscal year) multi-

plied 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 no 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 in 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 credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(2) 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—

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

''(B) 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 that agency'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 applica-

tions 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) Number of negative decisions for device submissions.

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

(F) Number of deficiency letters for device submissions.

(G) Information for subparagraphs (A) through (F) 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 the

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

(c) COMMITTEES.—The reports described in subsections (a) and (b) 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 which are appropriate for exemption from the requirement of section 510(k) of such Act and exempts such devices from such requirement following their reclassification into class I.

(b) REGULATIONS.—

(1) PROPOSED.—Not later than 30 days after the date of the enactment of this Act, 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 their publication.

(2) FINAL.—Not later than 30 days after the close of the comment period provided under paragraph (1), 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.

(c) 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.

(d) FEES.—An applicant under a 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 (b) 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.

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