

ATTACHMENT 1, SEC. 738, FDC ACT.

SEC. 738. [21 U.S.C. 379j] **AUTHORITY TO ASSESS AND USE DEVICE FEES.** [7](#)

(a) TYPES OF FEES.—

(1) **IN GENERAL.—**Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 [8](#) , the Secretary shall assess and collect fees in accordance with this section.

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE.--

(A) IN GENERAL.--Except as provided in subparagraph (B) and subsections (d) and (e), each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(5) for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 21.5 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7.2 percent of the fee that applies under clause (i).

(vi) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(vii) For a premarket notification submission, a fee equal to 1.42 percent of the fee that applies under clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).

(B) EXCEPTIONS.--

(i) **HUMANITARIAN DEVICE EXEMPTION.--**An application under section 520(m) is not subject to any fee under subparagraph (A).

(ii) **FURTHER MANUFACTURING USE.--**No fee shall be required under subparagraph (A) for the submission of a premarket application under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only.

(iii) **STATE OR FEDERAL GOVERNMENT SPONSORS.--**No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, or premarket notification submission submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) **PREMARKET NOTIFICATIONS BY THIRD PARTIES.--**No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 523.

(v) PEDIATRIC CONDITIONS OF USE.—

(I) IN GENERAL.--No fee shall be required under subparagraph (A) for a premarket application, premarket report, or premarket notification submission if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) SUBSEQUENT PROPOSAL OF ADULT CONDITIONS OF USE.--In the case of a person who submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

(C) PAYMENT.--The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, or premarket notification submission except that invoices for applications submitted between October 1, 2002, and the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 [9](#) shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 under this section shall include all fees payable from October 1, 2002 , through September 30, 2003 .

(D) REFUNDS.—

(i) **APPLICATION REFUSED FOR FILING.--**The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application or supplement that is refused for filing.

(ii) APPLICATION WITHDRAWN BEFORE FILING--The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) APPLICATION WITHDRAWN BEFORE FIRST ACTION.--After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement. The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(b) FEE REVENUE AMOUNTS.--Except as provided in subsections (c), (d), (e), (g), and (h), the fees under subsection (a) shall be established to generate the following revenue amounts: \$25,125,000 in fiscal year 2003; \$27,255,000 in fiscal year 2004; \$29,785,000 in fiscal year 2005; \$32,615,000 in fiscal year 2006, and \$35,000,000 in fiscal year 2007. If legislation is enacted after the date of the enactment of the Medical Device User Fee and Modernization Act of 2002 requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.--The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of--

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or

(B) the total percentage change for the previous 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. The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2003 under this subsection.

(2) WORKLOAD ADJUSTMENT.--After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year to reflect changes in the workload of the Secretary for the process for the review of device applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of premarket applications, investigational new device applications, premarket reports, supplements, and premarket notification submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

(3) COMPENSATING ADJUSTMENT.--After the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2), the fee revenues shall, beginning with fiscal year 2004, be adjusted further each fiscal year, if necessary, to reflect the cumulative amount by which collections for previous fiscal years, beginning with fiscal year 2003, fell below the cumulative revenue amounts for such fiscal years specified in subsection (b), adjusted for such fiscal years for inflation in accordance with paragraph (1), and for workload in accordance with paragraph (2).

(4) FINAL YEAR ADJUSTMENT.--For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fees and fee revenues established in subsection (b) if such adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of device applications for

the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover user fee balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.

(5) ANNUAL FEE SETTING.--The <> Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustment provided under this subsection and subsection (e)(2)(C)(ii), except that the fees established for fiscal year 2003 shall be based on a premarket application fee of \$154,000.

(6) LIMIT.--The total amount of fees charged, as adjusted under this subsection, 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.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.--

(1) IN GENERAL.--The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vi) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PRMARKET APPROVAL FEES.--

(A) DEFINITION.--

(i) IN GENERAL.--For purposes of this subsection, the term `small business' means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.

(ii) ADJUSTMENT.--The Secretary may adjust the \$30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust <> this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.

(B) EVIDENCE OF QUALIFICATION.--An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent firms, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, partners, and parent firms, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

(C) REDUCED FEES.--Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(5) may be paid at a reduced rate of 38 percent of the fee established under such subsection for a premarket application, a premarket report, or a supplement.

(D) REQUEST FOR FEE WAIVER OR REDUCTION.--An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.--

(1) IN GENERAL.--For fiscal year 2004 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(vii) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PRMARKET NOTIFICATION SUBMISSIONS.--

(A) DEFINITION.--For purposes of this subsection, the term `small business' means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.

(B) EVIDENCE OF QUALIFICATION.--An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate. The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent firms, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, partners, and parent firms, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.

(C) REDUCED FEES.--

(i) IN GENERAL.--For fiscal year 2004 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 80 percent of the fee that applies under subsection (a)(2)(A)(vii), as adjusted under clause (ii) and as established under subsection (c)(5).

(ii) ADJUSTMENT PER FEE REVENUE AMOUNT.--For fiscal year 2004 and each subsequent fiscal year, the Secretary, in setting the revenue amount under subsection (c)(5) for premarket notification submissions, shall determine the revenue amount that would apply if all such submissions for the fiscal year involved paid a fee equal to 1.42 percent of the amount that applies under subsection (a)(2)(A)(i) for premarket applications, and shall adjust the fee under subsection (a)(2)(A)(vii) for premarket notification submissions such that the reduced fees collected under clause (i) of this subparagraph, when added to fees for such submissions that are not paid at the reduced rate, will equal such revenue amount for the fiscal year.

(D) REQUEST FOR REDUCTION.--An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) EFFECT OF FAILURE TO PAY FEES.--A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

(g) CONDITIONS.--

(1) PERFORMANCE GOALS THROUGH FISCAL YEAR 2005; TERMINATION OF PROGRAM AFTER FISCAL YEAR 2005.--With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products:

(A)(i) For each of the fiscal years 2003 and 2004, the Secretary is expected to meet all of the goals identified for the fiscal year involved in any letter referred to in section 101(3) of the Medical Device User Fee and Modernization Act of 2002 (referred to in this paragraph as `performance goals') if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than \$205,720,000 multiplied by the adjustment factor applicable to the fiscal year.

(ii) For each of the fiscal years 2003 and 2004, if the amount so appropriated for the fiscal year involved, excluding the amount of fees appropriated for such fiscal year, is less than the amount that applies under clause (i) for such fiscal year, the following applies:

(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for

fiscal year 2005. A report under the preceding sentence shall be submitted to the Congress not later than July 1 of the fiscal year with which the report is concerned.

(B)(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

- (I) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;
- (II) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and
- (III) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.

(ii) For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:

(I) The Secretary is expected to meet such goals to the extent practicable, taking into account the amounts that are available to the Secretary for such purpose, whether from fees under subsection (a) or otherwise.

(II) The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2006. The report under the preceding sentence shall be submitted to the Congress not later than July 1, 2005 .

(C) For fiscal year 2006, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if the total of the amounts so appropriated for fiscal years 2003 through 2006, excluding the amount of fees appropriated for such fiscal years, is less than the sum of--

- (i) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2006; and
- (ii) an amount equal to the sum that applies for purposes of subparagraph (B)(i).

(D) For fiscal year 2007, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if--

(i) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is less than \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2007; or

(ii) pursuant to subparagraph (C), fees were not assessed under subsection (a) for fiscal year 2006.

(2) AUTHORITY.--If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of subparagraph (C) or (D) of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, and premarket notification submissions, and at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(h) CREDITING AND AVAILABILITY OF FEES.--

(1) IN GENERAL.--Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.--

(A) IN GENERAL.--The fees authorized by this section--

- (i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and
- (ii) 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 (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2002 multiplied by the adjustment factor.

(B) Compliance.—

(i) In GENERAL.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

(ii) MORE THAN 5 PERCENT.— To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(3) AUTHORIZATION OF APPROPRIATIONS.--There are authorized to be appropriated for fees under this section--

(A) \$25,125,000 for fiscal year 2003;

(B) \$27,255,000 for fiscal year 2004;

(C) \$29,785,000 for fiscal year 2005;

(D) \$32,615,000 for fiscal year 2006; and

(E) \$35,000,000 for fiscal year 2007,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application fees.

(4) OFFSET.--Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

(i) COLLECTION OF UNPAID FEES.--In <> any case where the Secretary does not receive payment of a fee 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.

(j) WRITTEN REQUESTS FOR REFUNDS.--To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

(k) CONSTRUCTION.--This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.