product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SPECTRACEF is 1,461 days. Of this time, 851 days occurred during the testing phase of the regulatory review period, while 610 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 31, 1997. The applicant claims August 30, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 31, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 29, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for SPECTRACEF (NDA 21–222) was initially submitted on December 29, 1999.

3. *The date the application was approved*: August 29, 2001. FDA has verified the applicant's claim that NDA 21–222 was approved on August 29, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,032 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by January 29, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 29, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Copies are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 14, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–19621 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Medical Device User Fee Rates for Fiscal Year 2004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2004. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorizes FDA to collect user fees for certain medical device applications. The FY 2004 fee rates are provided in this notice. For all applications submitted on or after October 1, 2003, and through September 30, 2004, fees must be paid at the FY 2004 rates at the time that applications are submitted to FDA. It is the date that the application is received by FDA, not the date that the check is received, that governs the fee that must be paid. This notice provides details on how fees for FY 2004 were determined and payment procedures for those submitting medical device applications subject to user fees.

FOR FURTHER INFORMATION CONTACT:

For further information on MDUFMA: Visit the FDA Web site at *http://www.fda.gov/oc/mdufma*.

For questions relating to this notice: Frank Claunts, Office of Management and Systems (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 U.S.C. 379j), establishes fees for different kinds of medical device applications. Fees are assessed on certain types of medical device applications and supplements. When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379j(d) and (e)).

For FY 2003 through FY 2007, MDUFMA (Public Law 107–250) establishes revenue amounts for the aggregate of all application fee revenues. Revenue amounts established for years after FY 2003 are subject to adjustment for inflation, workload, and compensation for revenue shortfalls from previous years. Fees for applications are to be established each year by FDA so that revenues will approximate the levels established in the statute, after those amounts have been first adjusted for inflation, workload, and, if required, revenue shortfalls from previous years.

This notice establishes fee rates for FY 2004. These fees are effective on October 1, 2003, and will remain in effect through September 30, 2004.

II. Revenue Amount for FY 2004, and Adjustments for Inflation, Workload, and Compensation for Revenue Shortfalls from Previous Fiscal Years

A. Statutory Fee Revenue Amount

MDUFMA specifies that the fee revenue amount for FY 2004 is $27,255,000, before any adjustments are made (21 U.S.C. 379j(b)).

B. Inflation Adjustment to Fee Revenue Amount

MDUFMA provides that fee revenue amounts for each FY after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of: (1) The total percentage change that occurred in the Consumer Price Index (CPI) (all items; U.S. city average) during the 12-month period ending June 30 preceding the FY for which fees are being set, or (2) the total percentage pay change for the previous FY for Federal employees stationed in the Washington, DC metropolitan area. MDUFMA provides for this annual adjustment to be cumulative and compounded annually after 2003 (see 21 U.S.C. 379j(c)(1)).

The inflation adjustment for FY 2004 is 4.27 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2003—which was 2.11 percent) or the increase in pay for the previous FY (2003) for Federal employees stationed in the Washington, DC metropolitan area (4.27 percent). No compounding is applied to this amount because there was no inflation increase applied in FY 2003.

The inflation-adjusted revenue amount for FY 2004 is the statutory fee

amount ($27,255,000) increased by 4.27 percent, the inflation adjuster for FY 2004. The FY 2004 inflation-adjusted revenue amount is $28,418,789.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2004, MDUFMA provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect increases in workload for the process for the review of medical device applications (see 21 U.S.C. 379j(c)(2)). FDA's current assessment reflects that the change in total review workload as defined in MDUFMA has changed by less than 1 percent. Based on this assessment, FDA is not applying a workload adjustment to the FY 2004 inflation-adjusted revenue amount of $28,418,789. The need for workload adjustment will be assessed anew next year when FY 2005 fees are established.

D. Compensating Adjustment to Fee Revenue Amount Once Adjustments for Inflation and Workload Have Been Made

For each FY beginning in FY 2004, MDUFMA provides that fee revenue amounts, after they have been adjusted for inflation and workload, shall be further adjusted, if necessary, to compensate for the cumulative shortfall in fee revenue from previous years (see 21 U.S.C. 379j(c)(3)). In FY 2003, FDA had expected to collect a total of $25,125,000 in MDUFMA fees, the fee revenue amount stated in the statute (see 21 U.S.C. 379j(b)). As of June 30, 2003, for 9 months of the fiscal year, total fee collections were $14,360,304. If fee collections in the last 3 months are proportional to collections in the first 9 months, FDA will collect another $4,786,768 million—for a total of about $19,147,000 million for the year. In addition FDA expects to collect about $500,000 of outstanding accounts receivable, for a FY 2003 estimated total fee collection of $19,647,000. This is $5,478,000 million less than the statutory revenue amount for FY 2003.

In implementing the compensating adjustment provision, FDA will increase the FY 2004 revenue amount by the amount of the revenue shortfall in FY 2003, $5,478,000. Accordingly, adding $5,478,000 to the inflation-adjusted revenue amount of $28,418,789 derived above (see section II.B of this document), provides a final adjusted revenue amount for FY 2004 of $33,896,789. Fees for FY 2004 are being set to generate this amount of revenue.

III. Fee Calculations for FY 2004

A. Estimating Numbers of Applications That Will Pay Fees

Under MDUFMA, the amount of fee revenue collected is a function of two factors—the fee rate for the application and the number of applications that will pay each type of fee.

To set fees for FY 2004, FDA must first estimate the number of applications that will pay each type of fee. For FY 2003, before MDUFMA was enacted, FDA estimated the number of applications that would pay each type of fee. That estimate was based on the average number of each category of applications over the 5-year period before MDUFMA was enacted, FY 1997 through FY 2001. These estimates took into account FDA's estimates of the number of applications that would qualify for a small business reduction or exemption. (It should be noted that the two-tier fee structure for 510(k)'s is to begin in FY 2004.) The original FY 2003 estimates are shown in Table 1 of this document.

TABLE 1.—ORIGINAL ESTIMATES OF NUMBERS OF FEE-PAYING APPLICATIONS

Type of Fee-Paying Application	Full Year Numbers Based on Original Estimates		
	Full Fee	Reduced Fee	Waived
Original Premarket Applications (PMAs)/Product Development Protocols (PDPs)/Premarket Reports (PMRs)/Biologics License Applications (BLAs) and Full Fee Supplements	58	10	10
180-Day PMA/PDP Supplements to PMAs	171	24	
Real Time Supplements to PMAs	86	14	
Premarket Notifications (510(k)s)	880	3,120	

The reason that MDUFMA fee revenues are projected to fall approximately $5,478,000 short of the revenue target in FY 2003 is that FDA collected fewer full fees than projected for Original PMAs and BLAs and their full-fee supplements, and fewer fees for 180-day supplements. The major reasons for this are twofold. A number of the applications were ''bundled,'' using guidance developed after MDUFMA was enacted, and did not have to pay separate fees. In addition, the agency received fewer full PMAs, BLAs and 180-day supplements in the first 9 months of FY 2003 than the 5-year averages estimated. Because of this, FDA considered basing fees for FY 2004 on lower estimates of the number of full PMA/BLA fees and 180-day supplement fees. This would have resulted in even higher fees for FY 2004.

The agency decided against revising estimated numbers of fee-paying applications in setting the FY 2004 fees, however, because such a revision would have been based on data from too brief a period—the 3 months from April 1 through June 30, 2003, during which applications were not accepted for filing unless the fee was paid. Instead, the agency will continue to use its original estimate of the numbers of fee-paying applications (see Table 1 of this document) again in setting fees for FY 2004.

FDA will reassess whether or not it needs to adjust its original estimates of the number of each type of fee-paying application a year from now when it sets fees for FY 2005. At that time the agency will have 15 months of data to use to determine whether its original estimates for annual numbers of applications were too high.

B. Determining The Fee Rates

Under MDUFMA, all fees are set as a percent of the full fee for a PMA (see 21 U.S.C. 379j(a)(1)(A)). In order to generate $33,896,789 in FY 2004, using the above estimates of the numbers of each type of application that will pay a fee at each rate (see Table 1 of this document), the rate for a full PMA will be $206,811 for FY 2004. For all applications other than premarket notification submissions, the small business rate is 38 percent of the full fee rate (see 21 U.S.C. 379j(d)(2)(C)). For premarket notification submissions (510(k)'s), the small business rate is 80

percent of the full rate for premarket notification submissions (see 21 U.S.C. 379j(e)(2)(C)(i)). The FY 2004 fee rates for all application categories are set out in Table 2 of this document.

TABLE 2.—FEE TYPES, PERCENT OF PMA FEE, AND FY 2004 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee	FY 2004 Full Fee	FY 2004 Small Business Fee
PMA (submitted under section 515(c)(1) or 515(f) of the act or section 351 of the Public Health Service (PHS Act)		$206,811	$78,588
PMR (submitted under section 515(c)(2) of the act)	100%	$206,811	$78,588
Panel Track Supplement (to an approved PMA or PMR that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide reasonable assurance of safety and effectiveness)	100%	$206,811	$78,588
Efficacy Supplement (to an approved premarket application under section 351 of the PHS Act)	100%	$206,811	$78,588
180–Day Supplement (to an approved PMA or PMR that is not a panel track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling)	21.5%	$44,464	$16,896
Real Time Supplement (to an approved PMA or PMR that is not a panel track supplement and requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement)	7.2%	$14,890	$5,658
Premarket Notification (submitted under section 510(k) of the act)	1.42% in aggregate	$3,480	$2,784

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of MDUFMA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379j(h)(4)). No adjustments under this provision are required for fees assessed in FY 2004. If fees assessed in FY 2004 should inadvertently result in excess collections in FY 2004, then when fees are set for FY 2005 a reduction in fee rates for FY 2005 will be made for any excess collections that may have occurred in FY 2004.

V. Small Business Qualification for Purposes of MDUFMA Fees

Firms with annual gross sales and revenues of $30 million or less, including gross sales and revenues of all affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA, and for lower rates for subsequent PMA's, premarket reports, supplements, and premarket notification submissions.

Even if a firm qualified under MDUFMA as a small business in FY 2003, it must obtain a new small business certification and decision number for FY 2004 and for each subsequent fiscal year. This can be initiated any time after the publication of this notice. For FY 2004, firms that have not received a FY 2004 small business qualification decision number from FDA will not be permitted to submit the reduced small business fees. FDA urges firms to apply for this qualification 60 days before they intend to submit their application and fee.

To qualify, you are required to submit the following:

- Certified copies of your Federal Income Tax Return for the most recent taxable year (2002 or later), including certified copies of the income tax returns of your affiliates, partners, and parent firms.
- A certified list of all parents, partners, and affiliate firms since October 1, 2002.

You can find information for determining if an applicant qualifies for a small business first-time PMA waiver and lower rates for subsequent applications on the FDA Web site at *http://www.fda.gov/oc/mdufma*. At that Web site, under the heading ''Guidance Documents,'' click on the link ''Qualifying as a Small Business.'' This Web site provides detailed instructions and the address for mailing documentation to support qualification as a small business under MDUFMA.

VI. Procedures for Paying Application Fees

Any application or supplement subject to fees under MDUFMA that is received on or after October 1, 2003, through September 30, 2004, is subject to the FY 2004 fee rate. It is the date that the application is received in the reviewing center's document room that determines whether the fee rates for FY 2003 or FY 2004 apply—not the date that FDA receives the payment. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee. Please pay close attention to these procedures to ensure that FDA links the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)

A. Step One—Secure a Payment Identification Number and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment. Note: FY 2004 Fee Rates Will be Available on the Cover Sheet Beginning on August 25, 2003.

Log onto the MDUFMA Web site at *http://www.fda.gov/oc/mdufma* and, under the forms heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee Cover Sheet. Be sure you choose the correct application submission date range. (Two choices will be offered from August 25, 2003, until the middle of October 2003. One choice is for applications that will be received on or before September 30, 2003, which will be subject to FY 2003 fee rates. A second choice is for applications that will be received on or after October 1, 2003, which will be subject to FY 2004 fee rates.) After completing data entry, print a copy of the Medical Device User Fee Cover Sheet and note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

B. Step Two—Electronically Transmit a Copy of the Printed Cover Sheet with the Payment Identification Number to FDA's Office of Financial Management

Once you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to the instructions on the screen. Since electronic transmission is possible beginning on August 25, 2003, it will no longer be necessary to fax a copy of the sheet to FDA. After August 25, 2003, applicants will be required to set up a user account and use passwords to assure data security in the creation and electronic submission of Cover Sheets.

C. Step Three—Mail Payment and a Copy of the Completed Medical Device User Fee Cover Sheet to the Saint Louis Address Specified Below

• Make the payment in U. S. currency by check, bank draft, or U.S. Postal money order payable to the Food and Drug Administration. (The tax identification number of the Food and Drug Administration is 53–0196965, should your accounting department need this information.)

• Please write your application's unique Payment Identification Number, from the upper right-hand corner of your completed Medical Device User Fee Cover Sheet, on your check, bank draft, or U.S. Postal money order.

• Mail the payment and a copy of the completed Medical Device User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 956733, Saint Louis, MO, 63195–6733.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the checks to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, Missouri 63101.

(Note: This address is for courier delivery only. Contact the US Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records the official application receipt date as the later of the following:

• The date the application was received by FDA.

• The date US Bank notifies FDA that payment has been received. US Bank is required to notify FDA within 1-working day, using the Payment Identification Number described previously.

D. Step Four—Submit your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee Cover Sheet to one of the following addresses:

• Medical device applications should be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center (HFZ–401), 9200 Corporate Blvd., Rockville, MD 20850.

• Biologic applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center (HFM–99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448.

Dated: July 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19655 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2004. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Prescription Drug User Fee Amendments of 2002 (PDUFA III), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Revenue amounts for application fees, establishment fees, and product fees for FY 2004 were established by PDUFA III. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2004 for application fees ($573,500 for an application requiring clinical data, and $286,750 for an application not requiring clinical data or a supplement requiring clinical data), establishment fees ($226,800), and product fees ($36,080). These fees are effective on October 1, 2003, and will remain in effect through September 30, 2004. For applications and supplements that are submitted on or after October 1, 2003, the new fee schedule must be used. Invoices for establishment and product fees for FY 2004 will be issued in August 2003, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the act (21 U.S.C. 379g and h), establish three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (see 21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (see 21 U.S.C. 379h(d)).

For FY 2003 through FY 2007 revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III (the Prescription Drug User Fee Amendments of 2002, title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002). Revenue amounts established for years after FY 2003 are subject to adjustment for inflation and workload. Fees for applications, establishments, and products are to be established each