DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Pediatric Advisory Committee; Formation of a Pediatric Ethics Subcommittee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee of the Pediatric Advisory Committee. This subcommittee has been established to address pediatric ethical issues, as well as IRB referrals related to clinical investigations involving children as subjects and IRB referrals that involve both FDA regulated products and research involving children as subjects that is conducted or supported by the Department of Health and Human Services. The subcommittee's preliminary recommendations will be presented to the FDA Pediatric Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Jan Johannessen, Office of Science and Health Coordination (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687.

SUPPLEMENTARY INFORMATION: FDA is announcing the formation of a subcommittee of the Pediatric Advisory Committee. This subcommittee has been established to address pediatric ethical issues, as well as IRB referrals related to clinical investigations involving children as subjects as specified in § 50.54 (21 CFR 50.54) and IRB referrals that involve both FDA regulated products under § 50.54 and research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

The subcommittee's preliminary recommendations will be presented to the FDA Pediatric Advisory Committee. The subcommittee will meet approximately two times a year. Meetings of the subcommittee will be open to the public. All meetings will be announced in the **Federal Register** at least 15 days prior to each scheduled public meeting.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 27, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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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 2005

AGENCY: Food and Drug Administration

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) 2005. 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 2005 fee rates are provided in this document. For all applications submitted on or after October 1, 2004, and through September 30, 2005, fees must be paid at the FY 2005 rates at the time that applications are submitted to FDA. The later of the date that the application is received by FDA or the date that the check is received governs the fee that must be paid. This document provides details on how fees for FY 2005 were determined and payment procedures for medical device applications subject to user fees.

FOR FURTHER INFORMATION CONTACT:

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

For questions relating to this document: Frank Claunts, Office of Management (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 certain medical device applications and supplements. Under statutorily defined conditions, FDA may waive or reduce fees (21 U.S.C. 379j(d) and (e)).

For FY 2003 through 2007, MDUFMA (Public Law 107–250) establishes base revenue amounts for the aggregate of all application fee revenues. Base revenue amounts established for each year 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 document establishes fee rates for FY 2005. These fees are effective on October 1, 2004, and will remain in effect through September 30, 2005.

II. Revenue Amount for FY 2005, 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 2005 is $29,785,000, 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 fiscal year after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of the following factors: (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 (21 U.S.C. 379j(c)(1)).

The inflation adjustment for FY 2004 was 4.27 percent. This was the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees were 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).

The inflation increase for FY 2005 is 4.42 percent. This is the greater of the CPI increase for the 12-month period ending June 30, 2004, (3.27 percent) or the increase in pay for FY 2004 for Federal employees stationed in the Washington, DC metropolitan area (4.42 percent).

Compounding these amounts (1.0427 times 1.0442) yields a total compounded inflation adjustment of 8.88 percent for FY 2005.

The inflation-adjusted revenue amount for FY 2005 is the statutory fee amount ($29,785,000) increased by 8.88 percent, the inflation adjuster for FY

2005. The FY 2005 inflation-adjusted revenue amount is $32,429,908.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each fiscal year 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 is developing a methodology to determine the extent of workload changes for the device program, but has not completed the data gathering and analysis necessary to accurately account for differences in how the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health (CBER and CDRH) define and manage their device review processes. Until FDA develops a sound methodology, we will not invoke the workload adjustment to further increase inflation-adjusted MDUFMA fees and will not be applying a workload adjustment to the FY 2005 inflation-adjusted revenue amount of $32,429,908. The need for workload adjustment will be assessed anew next year when FY 2006 fees are established.

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

For each fiscal year 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. This was the fee revenue amount stated in the statute (see 21 U.S.C. 379j(b)). As of June 30, 2003, just before fees for FY 2004 had to be published, for the first 9 months of the fiscal year, total fee collections were only $14,360,304. If fee collections in the last 3 months had remained proportional to collections in the first 9 months, FDA would have collected another $4,786,768 million—for a total of about $19,647,000 million for the year—still $5,478,000 million less than the statutory revenue amount for FY 2003. Accordingly, FDA used this amount ($5,478,000) as the compensating adjustment when fees for FY 2004 were set a year ago. However, collections in the final quarter were higher than expected, and the compensating adjustment should only have been $3,235,211.

Because experience has shown that it is difficult to predict the amount by which revenues may fall short of the revenue target before the end of the fiscal year, FDA has decided not to assess a compensating adjustment in setting fees for FY 2005. However a year from now when fees for FY 2006 are set, FDA will know with certainty the extent to which fees for FY 2004 fell short of the revised FY 2004 revenue target of $31,654,000. The shortfall, if any, will be applied, in part or in total, as the compensating adjuster in FY 2006.

III. Fee Calculations for FY 2005

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 2005, FDA must first estimate the number of applications that will pay each type of fee. 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 application over the 5-year period, FY 1997 through 2001. Those estimates took into account FDA's estimates of the number of applications that would qualify for a small business reduction or exemption. The original FY 2003 estimates are shown in the ''Original Estimate'' column of table 1 of this document.

The reason that MDUFMA fee revenues fell short of the revenue target in FY 2003 by $3,235,211 is that FDA collected fewer full fees than projected for original premarket approval applications (PMAs) and biologic license applications (BLAs) and their full-fee supplements, and fewer fees for 180-day supplements, as shown in the ''2003 Actuals'' column of table 1 of this document.

FDA is expecting that the numbers of fee-paying applications that will be received in FY 2004 will again be less than the amounts expected when MDUFMA was enacted. The ''2004 Estimate'' column of table 1 of this document shows the current estimate of each type of application that will pay fees, based on all fees received through June 30, 2004, the first 9 months of the fiscal year, and assuming that fee-paying applications for the remaining 3 months of the fiscal year will come in at the same rate as they were received in the first 9 months.

There are several reasons for last year's shortfall and the expected shortfall in FY 2004. The number of original PMA applications that did not pay a fee in FY 2003 because they were the first applications from a qualifying small business was much higher than expected. In addition, the number of applications submitted as 180-day supplements (paying about 3 times the fee of a real-time supplement) has been declining markedly since the enactment of MDUFMA, and the number of supplements submitted as real-time supplements has been increasing correspondingly. While the workload has remained about the same for the two categories combined, the result is substantially less fee revenue. Finally, a number of the applications in each category have been ''bundled'' and did not have to pay separate fees.

Because of the receipt of fewer than expected fee-paying applications in FY 2003, FDA considered basing fees for FY 2004 on lower estimates of the number of full PMA/BLA fees and 180-day supplement fees. The agency did not revise the 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. A year ago, however, the agency stated its intention to reassess whether it should adjust its original estimates of the number of each type of fee-paying application when it sets fees for FY 2005, when the agency would have almost 2 years of data to determine whether its original estimates for annual numbers of applications were too high.

FDA has determined that it needs to revise the numbers of fee-paying applications it expects to receive each year based on the experience of FY 2003 and the first 9 months of FY 2004. The last column of table 1 of this document provides the more realistic estimates of numbers of fee-paying applications upon which FDA will base its fee calculations for FY 2005. Recognizing that industry also needs predictability in fee assessments, the agency is committing to using these same estimates of numbers of each type of fee-paying application when fees are set for FY 2006 and 2007.

TABLE 1.—NUMBERS OF FEE-PAYING DEVICE APPLICATIONS

Type of Fee-Paying Application	Original Estimate	FY 2003 Actuals	FY 2004 Estimates	FY 2005 Projection
Original premarket applications (PMAs), product development protocols (PDPs), premarket reports (PMRs), and biologic license applications (BLAs) and supplements paying full fees	58	46	42	51
PMAs, PDPs, PMRs, BLAs and full fee supplements paying reduced small business (SB) fees	10	6	5	6
180-Day PMA/PDP supplements paying full fees	171	118	80	86
180-Day PMA/PDP supplements paying reduced SB fees	24	22	11	9
Real time PMA supplements paying full fees	86	136	152	160
Real time PMA supplements paying reduced SB fees	14	19	19	15
Premarket notifications (510(k)s) paying full fees			2,855	3,060
Premarket notifications (510(k)s) paying reduced SB fees			487	540
Premarket notifications (510(k)s—total	4,000	4,001	3,341	3,600

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 $32,429,908 in FY 2005, using the estimates of the numbers of each type of application that will pay a fee at each rate in the column entitled ''FY 2005 Projections'' of table 1 of this document, the rate for a full PMA will be $239,237 for FY 2005. 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 2005 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 2005 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee	FY 2005 Full Fee	FY 2005 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)		$239,237	$90,910
PMR (submitted under section 515(c)(2) of the act)	100%	$239,237	$90,910
Panel track supplement	100%	$239,237	$90,910
Efficacy supplement (to an approved premarket application under section 351 of the PHS Act)	100%	$239,237	$90,910
180-Day supplement	21.5%	$51,436	$19,546
Real time supplement	7.2%	$17,225	$6,546
510(k)	1.42% in aggregate	$3,502	$2,802

Under MDUFMA, the statutory fee revenue levels each year by about 9 percent, and the inflation adjusted increase in revenue levels is estimated at about 13 to 14 percent each year. The fees being established for FY 2005, in aggregate, represent an increase of about 10 percent (the weighted combination of an increase of 0.6 percent for 510(k) premarket notification submissions and about 15.7 percent for premarket application submissions. This combined 10 percent increase is well under the norms that should be expected under the provisions of the MDUFMA statute.

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 2005, since collections to date have been less than the amounts provided in appropriations. If fees assessed in FY 2005 inadvertently result in excess collections, FDA will reduce rates when fees are set for FY 2006 or 2007.

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 PMAs, PMRs, supplements, and 510(k)s.

Even if a firm qualified under MDUFMA as a small business in FY 2004, it must obtain a new small business certification and decision number for FY 2005 and for each subsequent fiscal year. This can be initiated any time after the publication of this document. For FY 2005, firms that have not received an FY 2005 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 at least 60 days before they intend to submit their application and fee.

To qualify, you are required to submit the following:

(1) Certified copies of your Federal Income Tax Return for the most recent taxable year (2003 or later), including certified copies of the income tax returns of your affiliates, partners, and parent firms.

(2) 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, 2004, through September 30, 2005, is subject to the FY 2005 fee rate. The later of the date that the application is received in the reviewing center's document room or the date that the check is received by the US Bank determines whether the fee rates for FY 2004 or 2005 apply. 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 in the following paragraphs 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 2005 Fee Rates Will be Available on the Cover Sheet Web Site Beginning on August 25, 2004

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 chose the correct application submission date range. (Two choices will be offered from August 25 until the middle of October 2004. One choice is for applications that will be received on or before September 30, 2004, which will be subject to FY 2004 fee rates. A second choice is for applications that will be received on or after October 1, 2004, which will be subject to FY 2005 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 instructions on the screen. Since electronic transmission is possible, applicants are 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 St. 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, St. 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, MO 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 receives the payment. 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 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17440 Filed 7–30–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.