term. This Committee was created by section 503A(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a(d)(1)). Section 503a(d)(1) specifically directed the Secretary of Health and Human Resources to convene and consult an advisory committee on compounding.

On April 29, 2002, the *United States Supreme Court in Thompson, et al.* v. *Western States Medical Center Pharmacy, et al.*, 122 S.Ct. 1497 (2002), affirmed a decision of the U.S. Court of Appeals for the Ninth Circuit invalidating section 503A of act. Section 503A of the act, enacted as part of the Food and Drug Administration Modernization Act of 1997, exempted drugs compounded by pharmacies from the act's new drug approval, adequate directions for use, and good manufacturing practice requirements if specified conditions, including two restrictions on commercial speech, were met. The Supreme Court held that these two speech related restrictions violate the first amendment to the U.S. Constitution. The Ninth Circuit had also concluded that these unconstitutional speech restrictions may not be severed from the rest of the provisions in section 503A of the act, and that section 503A is invalid in its entirety. Because neither the Government nor the compounding pharmacy plaintiffs sought review of this aspect of the Ninth Circuit's decision, the Supreme Court did not reach the issue. As a result, the Ninth Circuit's invalidation of section 503A of the act in its entirety stands. Because the entire section 503A of the act is invalid, the statutory authorization for an advisory committee on compounding no longer exists.

For the reasons stated previously, the Medical Imaging Drugs Advisory Committee and the Pharmacy Compounding Advisory Committee are terminated.

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

Dated: November 14, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–29573 Filed 11–20–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and Interim Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and interim procedures for medical device user fees for fiscal year (FY) 2003. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), authorizes FDA to collect user fees for certain medical device applications. This notice establishes fee rates for FY 2003. These fees are effective for applications submitted on October 1, 2002, and will remain in effect through September 30, 2003. However, FDA may not begin to collect these fees until enabling appropriations are enacted. FDA will issue invoices for all fees payable for applications submitted between October 1, 2002, and 30 days after the date of the **Federal Register** notice the agency will issue after enactment of enabling appropriations. Those invoices will be due and payable within 30 days of issuance. Subsequently, fees must be submitted to FDA at the time that applications are submitted.

ADDRESSES: Visit the FDA Web site that provides further information on MDUFMA at http://www.fda.gov/cdrh/mdufma/index.html.

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

The act establishes fees in sections 737 and 738 (21 U.S.C. 379i and j) 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 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 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 first been adjusted for inflation, workload, and, if required, revenue shortfalls from previous years.

This notice establishes fee rates for FY 2003. These fees are effective on October 1, 2002, and will remain in effect through September 30, 2003.

II. Inflation, Workload, and Compensating Adjustment Process

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 (all items, U.S. city average) during the 12-month period ending on 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)). No inflation adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

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 changes in workload for the process for the review of medical device applications (21 U.S.C. 379j(c)(2)). No workload adjustment is to made be with respect to fee revenue amounts established in the statute for FY 2003.

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 any shortfall in fee revenue from previous years (21 U.S.C. 379j(c)(3)). No compensating adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

Inflation, workload, and compensating adjustments do not apply to the revenue amounts established in MDUFMA for FY 2003.

III. Fee Calculations for FY 2003

MDUFMA establishes the fee for a premarket application (PMA) at $154,000 in FY 2003. All other fees are set as a percent of this fee. At these rates, the medical device user fees are expected to generate $25,125,000 in FY 2003. The applications subject to fees, the rate of each fee as a percent of a premarket application, and the FY 2003

fee rate are set out in table 1 of this document. For all applications other than premarket notification submissions, the small business rate is 38 percent of the full fee rate. For premarket notification submissions, there is no small business rate in FY 2003. In FY 2004 and subsequent fiscal years, fees for premarket notification submissions will be set so that a small business fee will be 80 percent of a full application fee.

TABLE 1.—FEE TYPES, PERCENT OF PMA FEE, AND FY 2003 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee (percent)	FY 2003 Full Fee (dollars)	FY 2003 Small Business Fee (dollars)
PMA (submitted under section 515(c)(1) or 515(f) of the act or section 351 of the Public Health Service Act (PHS Act))		154,000	58,520
Premarket Report (PMR) (submitted under section 515(c)(2) of the act)	100	154,000	58,520
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	154,000	58,520
Efficacy Supplement (to an approved PMA under section 351 of the PHS Act)	100	154,000	58,520
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	33,110	12,582
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	11,088	4,213
Premarket Notification (submitted under section 510(k) of the act)	1.42	2,187	None in FY 2003

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 2003.

V. Implementation of Fee Collections

A. No Fees May Be Collected Until Enabling Appropriations are Enacted

Under section 738(h) of the act, fees authorized by MDUFMA may neither be collected nor available for obligation unless they are first provided for in appropriation acts. For this reason FDA is not able to accept or deposit any fee revenues until such appropriations are enacted for FY 2003. Therefore, no fees are to be submitted until such appropriations are enacted. After the enactment of enabling appropriations, FDA will publish another notice in the **Federal Register** with detailed payment instructions.

B. Procedures for Firms Seeking to Qualify for Small Business Exemption for First PMA or for Lower Fees for Subsequent Applications.

Firms with gross sales and revenues of $30 million or less, including gross sales and revenues of all affiliate, partner, and parent firms, may qualify for a waiver of the fee for their first PMA, and for lower rates for subsequent PMAs, PMRs, and supplements. Such firms may also qualify for lower rates for premarket notification submissions in FY 2004 and subsequent years. To qualify, these firms will have to submit certified copies of their Federal income tax return for the most recent taxable year, including certified copies of the income tax returns of their affiliate, partner, and parent firms. More detailed procedures for qualifying for small business first-time PMA waiver and lower rates will also be included in the **Federal Register** notice published after the date of enabling appropriations.

C. Subsequent Payment of Fees

Any application or supplement subject to fees under MDUFMA that is submitted after September 30, 2002, is subject to the fee set out in table 1 of this document. FDA will issue invoices for all fees payable for applications submitted between October 1, 2002, and 30 days after the date of the **Federal Register** notice the agency will issue after enactment of enabling appropriations. Those invoices will be due and payable within 30 days of issuance. Subsequently, fees must be submitted to FDA at the time that applications are submitted.

Payment, when due, must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of FDA. More complete payment instructions will be included in the **Federal Register** notice published after the date of enabling appropriations.

Dated: November 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.