

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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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