into the annual financial and programmatic reports. All indicators need to be drawn from the Emergency Plan.

3. Financial status report, no more than 90 days after the end of the budget period. The financial report must show obligations, disbursements and funds remaining by program activity. Indicators must be developed for each program milestone and incorporated into the periodic financial and programmatic reports. All indicators need to be drawn from The Emergency Plan Indicator Guide.

4. Final performance reports, no more than 90 days after the end of the project period.

Recipients must mail these reports to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2700.

For program technical assistance, contact: Kathy Grooms, Project Officer, Global AIDS Program, HHS/CDC National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, Mailstop E–04, Atlanta, GA 30333. Telephone: 404–639–8394.

For financial, grants management, or budget assistance, contact: Vivian Walker, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2724. E-mail: *vwalker@cdc.gov*.

VIII. Other Information

Applicants can find this and other HHS/CDC funding opportunity announcements on the HHS/CDC web site, Internet address: *http://www.cdc.gov* (Click on ''Funding,'' then ''Grants and Cooperative Agreements''), and on the web site of the HHS Office of Global Health Affairs, Internet address: *http://www.globalhealth.gov*.

Dated: August 5, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. 05–15893 Filed 8–10–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement AA134]

Strengthening HIV/AIDS, TB and STI Prevention, Control and Treatment Activities Within the Police Force of Ethiopia; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to strengthen the activities in the prevention, control, and treatment of HIV/AIDS, Sexually Transmitted Infections (STI) and Tuberculosis (TB) within the Police Force of Ethiopia. The project particularly aims to: (1) Improve HIV/AIDS, STI and TB prevention following the Abstinence, Be Faithful, and Correct and Consistent Condom Use (ABC) strategies, care and treatment services within the Police Force of Ethiopia; (2) strengthen human resource capacity of the police force for HIV/AIDS/STI/TB services; and (3) implement and support targeted monitoring and evaluation. The Catalog of Federal Domestic Assistance number for this program is 93.067.

B. Eligible Applicant

Assistance will be provided only to the FPC of the Federal Democratic Republic of Ethiopia for this project.

The FPC of Ethiopia is the most appropriate and qualified agency to conduct the activities because:

1. FPC's HIV Prevention and Control Office is the only office uniquely positioned in terms of legal authority, ability, and credibility to coordinate and support prevention, care, and treatment activities among members of the police force and their dependents.

2. The FPC administers all the police force health facilities which constitute the only facilities where members of the police force and their dependents receive care.

3. FPC is the umbrella entity that can access the police force and their dependents at the national and regional levels.

4. FPC is mandated by the Federal Government of Ethiopia to work on HIV/AIDS in behalf of the police force and their dependants with international organizations and civil societies in the prevention and control of HIV/AIDS.

5. The Police Hospital is the only referral hospital for the police and their dependants in the country playing a leading role in providing an integrated and comprehensive HIV/AIDS treatment and care and serving also as a major training center for all cadres of health care professionals deployed at the police force health facilities in the country that also integrate training, service and research.

C. Funding

Approximately $140,000 is available in FY 2005 to fund this award on September 15, 2005, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146. Telephone: 770–488–2700.

For technical questions about this program, contact: Tadesse Wuhib, MD, MPH, Country Director, CDC-Ethiopia, P.O. Box 1014, Entoto Road, Addis Ababa. Telephone: (Office) 251–1–66–95–33; (Cell) 251–9–228543. E-mail address: *wuhibt@etcdc.com*.

Dated: August 4, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–15894 Filed 8–10–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Device User Fee Rates for Fiscal Year 2006

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) 2006. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), authorizes FDA to collect user fees for certain medical device applications. The FY 2006 fee rates are provided in this notice. For all applications submitted on or after October 1, 2005, and through September 30, 2006, fees must be paid

at the FY 2006 rates at the time the applications are submitted to FDA. The fee you must pay is the fee that is in effect on the date your application is received by FDA or on the date your check is received, whichever is later. This notice provides details on how fees for FY 2006 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/cdrh/mdufma*.

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

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 USC 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)).

Under MDUFMA, the fee rate for each type of application is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol, or a biologic licensing application). MDUFSA specifies that the standard fee for a premarket application submitted during FY 2006 is $259,600. From this starting point, this notice establishes fee rates for FY 2006. These fees are effective on October 1, 2005, and will remain in effect through September 30, 2006.

II. Fee Calculations for FY 2006

Under the act, all fees are set as a percentage of the full fee for a premarket application (see 21 U.S.C. 379j(a)(1)(A)), and the act sets the standard fee for a premarket application at $259,600 for FY 2006 (see 21 U.S.C. 379j(c)(1); this is referred to as the ''base fee.'' A 180-day supplement is set at 21.5 percent of the base fee; the fee for a real-time supplement is set at 7.2 percent of the base fee (see 21 U.S.C. 379j(a)(1)(A)).

For all applications other than premarket notification submissions (510(k)s), the small business rate is 38 percent of the standard (full fee) rate (see 21 U.S.C. 379j(d)(2)(C)). For 510(k) premarket notification submissions, the fees are to be set so that fees from all 510(k)s would produce revenue as if all were assessed a fee of 1.42 percent of the base fee, but these fee rates are to be adjusted so that the fee paid by a qualifying small business is 80 percent of the full rate for a 510(k) premarket notification submission (see 21 U.S.C. 379j(e)(2)(C)). Based on FDA's estimates, about 19 percent of 510(k) premarket notifications will qualify for the small business fee, and about 81 percent will pay the standard (full) fee. The FY 2006 fee rates for all application categories are set out in table 1 of this document.

TABLE 1.—FEE TYPES, PERCENT OF PMA FEE, AND FY 2006 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of Premarket Application Fee	FY 2006 Full Fee	FY 2006 Small Business Fee
PMA (submitted under section 515(c)(1) or 515(f) of the act or section 351 of the Public Health Service Act)		$259,600	$98,648
Premarket Reporting (submitted under section 515(c)(2) of the act)	100%	$259,600	$98,648
Panel Track Supplement	100%	$259,600	$98,648
Efficacy Supplement (to an approved premarket application under section 351 of the PHS Act)	100%	$259,600	$98,648
180-Day Supplement	21.5%	$55,814	$21,209
Real Time Supplement	7.2%	$18,691	$7,103
510(k)	1.42% in aggregate	$3,833	$3,066

III. Small Business Qualification for Purposes of MDUFMA Fees

Firms with annual gross sales or receipts of $30 million or less, including the gross sales and receipts of all affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA. Firms with annual gross sales or receipts of $100 million or less, including the gross sales and receipts of all affiliates, partners, and parent firms, may qualify for lower rates for all applications that are subject to a fee.

Even if a firm qualified under the act as a small business for MDUFMA fees in FY 2005, it must obtain a new small business certification and decision number for FY 2006 and for each subsequent FY. This can be initiated any time after the publication of this notice. A firm that does not have an FY 2006 small business qualification decision number from FDA will not be permitted to submit the reduced small business fees for applications submitted during FY 2006. 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) A completed FY 2006 Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, FY 2006 MDUFMA Small Business Qualification Worksheet and Certification, available on FDA's Web site at *http://www.fda.gov/cdrh/mdufma*. This form is not available separate from the guidance document.

(2) Certified copies of your Federal Income Tax Return for the most recent taxable year (2004 or later), and certified copies of the income tax returns of your affiliates, partners, and parent firms.

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/cdrh/mdufma*, 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.

IV. Procedures for Paying Application Fees

Any application or supplement subject to fees under MDUFMA that is received on or after October 1, 2005, through September 30, 2006, is subject to the FY 2006 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 US Bank determines whether the fee rates for FY 2005 or FY 2006 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 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 2006 Fee Rates Will be Available on the Cover Sheet Web Site Beginning on September 6, 2005

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 September 6 until October 1, 2005. One choice is for applications that will be received on or before September 30, 2005, which will be subject to FY 2005 fee rates. A second choice is for applications that will be received on or after October 1, 2005, which will be subject to FY 2006 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, DHL, UPS, etc.), the courier may deliver the check 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: August 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15863 Filed 8–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: July 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of July 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
AFSHARIAN, PAYAM SANTA MONICA, CA	8/18/2005
AQUATIC & PHYSICAL THERAPY ASSOCIATES KALAMAZOO, MI	8/18/2005
AWAHMUKALAH, MARGARET AVONDALE, PA	8/18/2005
BERGMAN, BARBARA RHINELANDER, WI	8/18/2005
BILLS, BETTY OPA LOCKA, FL	8/18/2005
BROWN, KELENKA E CHICAGO, IN	8/18/2005
CABALLERO, HERMINIO MIAMI, FL	8/18/2005
CAP PHARMACY, INC DENVER, CO	12/13/2004
CERDA, LOURDES FONTANA, CA	8/18/2005
COCHRAN, JUDITH GUTHRIE, OK	8/18/2005
DANIELS, LANISHA	8/18/2005