TABLE 4.

FEE CATEGORY	FEE RATES FOR FY 2007
APPLICATIONS	
Requiring clinical data	$896,200
Not requiring clinical data	$448,100
Supplements requiring clinical data	$448,100
ESTABLISHMENTS	$313,100
PRODUCTS	$49,750

VIII. Implementation of Adjusted Fee Schedule

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received after September 30, 2006. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee ID number on your check. Your payment can be mailed to: Food and Drug Administration, P.O. Box 360909, Mellon Client Service Center, 500 Ross St., rm. 670, Pittsburgh, PA 15251–6909.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Food and Drug Administration (360909), Mellon Client Service Center, 500 Ross St., rm. 670, Pittsburgh, PA 15262–0001. (Note: This Mellon Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 360909) is written on the check. The tax identification number of the Food and Drug Administration is 530 19 6965.

B. Establishment and Product Fees

By August 31, 2006, FDA will issue invoices for establishment and product fees for FY 2007 under the new fee schedule. Payment will be due on October 1, 2006. FDA will issue invoices in October 2007 for any products and establishments subject to fees for FY 2007 that qualify for fees after the August 2006 billing.

Dated: July 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12397 Filed 8–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Device User Fee Rates for Fiscal Year 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2007. 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 2007 fee rates are provided in this notice. For all applications submitted on or after October 1, 2006, and through September 30, 2007, fees must be paid at the FY 2007 rates at the time the applications are submitted to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your check is received. This notice provides details on how fees for FY 2007 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 U.S.C. 379 j) 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 2007 is $281,600. From this starting point, this notice establishes fee rates for FY 2007. These fees are effective on October 1, 2006, and will remain in effect through September 30, 2007.

II. Fee Calculations for FY 2007

Under the act, all fees are set as a percent 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 $281,600 for FY 2007 (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 2007 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 2007 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of Premarket Application Fee	FY 2007 Full Fee	FY 2007 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)		$281,600	$107,008
Premarket Report (submitted under section 515(c)(2) of the act)	100%	$281,600	$107,008
Panel Track Supplement	100%	$281,600	$107,008
Efficacy Supplement (to an approved premarket application under section 351 of the PHS Act)	100%	$281,600	$107,008
180-Day Supplement	21.5%	$60,544	$23,007
Real Time Supplement	7.2%	$20,275	$7,705
510(k)	1.42% in aggregate	$4,158	$3,326

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 2006, it must obtain a new small business certification and decision number for FY 2007 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 2007 small business qualification decision number from FDA will not be permitted to submit the reduced small business fees for applications submitted during FY 2007. 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 2007 Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, FY 2007 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 (U.S.) Income Tax Return for the most recent taxable year (2005 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*. 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.

IV. Procedures for Paying Application Fees

Any application or supplement subject to fees under MDUFMA that is received on or after October 1, 2006, through September 30, 2007, is subject to the FY 2007 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 2006 or FY 2007 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 2007 fee rates will be available on the Cover Sheet Web Site beginning on September 5, 2007

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 5 until October 1, 2006. One choice is for applications that will be received on or before September 30, 2006, which will be subject to FY 2006 fee rates. A second choice is for applications that will be received on or after October 1, 2006, which will be subject to FY 2007 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, 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 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, Maryland 20852–1448.

Dated: July 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD13–06–034]

Announcement of Public Hearing Regarding the Interstate 5 Bridge Replacement Project Across the Columbia River Between Portland, OR and Vancouver, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of public hearing.

SUMMARY: The Coast Guard will hold a public hearing to receive comments on the Interstate 5 Bridge Replacement Project, also known as the Columbia River Crossing Project, between Portland, Oregon and Vancouver, Washington. The dual vertical lift highway bridges across the Columbia River, mile 106.5, are being examined as candidates for replacement. Comments regarding impacts that the proposed bridge replacement project may have on navigation of the Columbia River and the environment will be of particular relevance to the Coast Guard's bridge permitting responsibilities.

DATES: This hearing will be held on Thursday, September 21, 2006, from 6 p.m. to 9 p.m., or later if necessary. Attendees at the hearing who wish to present testimony and have not previously made a request to do so, will follow those having submitted a request, as time permits. Written material and requests to make oral comment must be received by the Bridge Administrator at the address given under **ADDRESSES** on or before September 14, 2006.

ADDRESSES: The hearing will be held at the Red Lion Hotel on the River—Jantzen Beach, 909 North Hayden Drive, Portland, Oregon. The Timberline Room downstairs from the main lobby has been reserved. Send written material and requests to make oral comment to Mr. Austin Pratt, Bridge Administrator, Commander (dpw), Thirteenth Coast Guard District, 915 Second Avenue, Room 3510, Seattle, WA 98174–1067.

Commander (dpw) maintains the public docket and comments and material received from the public will become part of docket [CGD13–06–034] and will be available for inspection or copying at the above address between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions regarding this notice or the proposed project, call Mr. Austin Pratt, Thirteenth Coast Guard District, Bridge Administrator, telephone (206) 220–7282.

SUPPLEMENTARY INFORMATION:

Proposed Action

The Interstate 5 Bridge Replacement Project under consideration will improve the mobility, reliability, and accessibility for automobile, freight, transit, bicycle, and pedestrian users of the Interstate 5 corridor from State Route 500 in Vancouver to Columbia Boulevard in Portland while meeting the reasonable needs of navigation. The existing Interstate 5 dual vertical lift highway bridges currently provide a 40-foot vertical clearance in the closed position. When raised, the lift spans increase the vertical clearance to 178.9 feet. Critical issues include the determination of the vertical clearance in a fixed span alternative as well as pier placement in the river. In addition to current navigational interests, existing conditions potentially impacting navigational clearances include the surrounding land uses, the Burlington Northern-Santa Fe rail line bridge (approximately one mile downstream), and the glide path requirements for Pearson Airpark in Vancouver and Portland International Airport in Portland. While the main focus of the hearing is to allow interested persons to present comments and information concerning the impact of the proposed bridge project on navigation and air space, comments concerning impacts on the human environment may also be presented and will be included in the public record.

The Federal Highway Administration and Federal Transit Administration are the joint lead Federal agencies for satisfying the requirements of Section 102(2) of the National Environmental Policy Act of 1969 (NEPA), and the preparation of a Draft Environmental Impact Statement (DEIS) has commenced. The Coast Guard is a cooperating agency. This replacement bridge project will require a bridge permit from the Coast Guard (33 U.S.C. 525) and environmental review pursuant to NEPA.

Procedural

All interested parties will have an opportunity to be heard and to present evidence regarding the impacts of the proposed bridge project. Written statements and other exhibits in lieu of,