953877, 1005 Convention Plaza, St. Louis, Missouri 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the US Bank at 314–418–4821. This phone number is only for questions about courier delivery.)

The tax identification number of the Food and Drug Administration is 530 19 6965. (Note: In no case should the check for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the application arrives at FDA's Center for Veterinary Medicine. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's Center for Veterinary Medicine, or the date US Bank notifies FDA that your check in the full amount of the payment due has been received. US Bank is required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the ADUFA website at *http://www.fda.gov/oc/adufa* and, under the ''Forms'' heading, click on the link ''User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process. It may take a day or two to get the organization number and have the user account and password established.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the Cover Sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the Payment for your application as described in section IX.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Place, Rockville, Maryland 20855.

C. Product, Establishment and Sponsor Fees

By December 30, 2006, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2007 using this Fee Schedule. Payment will be due and payable by January 31, 2007. FDA will issue invoices in October 2007 for any products, establishments, and sponsors subject to fees for FY 2007 that qualify for fees after the December 2006 billing.

Dated: July 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12396 Filed 8–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Prescription Drug User Fee Rates for Fiscal Year 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2007. The Federal Food, Drug, and Cosmetic Act, as amended by the Prescription Drug User Fee Amendments of 2002 (Title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PDUFA III)), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Base revenue amounts for application fees, establishment fees, and product fees for FY 2007 were established by PDUFA III. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the revenue levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2007 for application fees for an application requiring clinical data ($896,200), for an application not requiring clinical data or a supplement requiring clinical data ($448,100), for establishment fees ($313,100), and for product fees ($49,750). These fees are effective on October 1, 2006, and will remain in effect through September 30, 2007. For applications and supplements that are submitted on or after October 1, 2006, the new fee schedule must be used. Invoices for establishment and product fees for FY 2007 will be issued in August 2006, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

The FFDCA, sections 735 and 736 (21 U.S.C. 379g and h), establishes three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For FY 2003 through FY 2007, base revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III. Base revenue amounts established for years after FY 2003 are subject to adjustment for inflation and workload. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the revenue levels established in the statute, after those amounts have been first adjusted for inflation and workload. The revenue levels established by PDUFA III continue the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2007 for application, establishment, and product fees. These fees are effective on October 1, 2006, and will remain in effect through September 30, 2007.

II. Revenue Amounts for FY 2007, and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

PDUFA III specifies that the fee revenue amount for FY 2007 for application fees is $86,434,000 and for both product and establishment fees is $86,433,000, for a total of $259,300,000 from all three categories of fees (21 U.S.C. 379h(b), before any adjustments are made.

B. Inflation Adjustment to Fee Revenue Amount

PDUFA III provides that fee revenue amounts for each FY after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of the following amounts: (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. PDUFA III provides for this annual adjustment to be cumulative and compounded annually after FY 2003 (see 21 U.S.C. 379h(c)(1)).

The inflation increase 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 in this case) for Federal employees stationed in the Washington, DC metropolitan area (4.27 percent).

The inflation increase for FY 2005 was 4.42 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, 2004—which was 3.27 percent) or the increase in pay for the previous FY (2004 in this case) for Federal employees stationed in the Washington, DC metropolitan area (4.42 percent).

The inflation adjustment for FY 2006 was 3.71 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2005—which was 2.53 percent) or the increase in pay for FY 2005 for Federal employees stationed in Washington, DC (3.71 percent).

The inflation adjustment for FY 2007 is 4.32 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2006—which is 4.32 percent) or the increase in pay for FY 2006 for Federal employees stationed in Washington, DC (3.44 percent).

Compounding these amounts (1.0427 x 1.0442 x 1.0371 x 1.0432) yields a total compounded inflation adjustment of 17.80 percent for FY 2007.

The inflation adjustment for each category of fees for FY 2007 is the statutory fee amount increased by 17.80 percent, the inflation adjuster for FY 2007. The FY 2007 inflation-adjusted revenue amount for application fees is $101,819,252 ($86,434,000 x 1.1780). For both product and establishment fees the inflation-adjusted revenue amount is $101,818,074 each ($86,433,000 x 1.1780). The total inflation-adjusted fee revenue amount for all three fee categories combined is $305,455,400 in FY 2007.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2004, PDUFA III 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 human drug applications (see 21 U.S.C. 379h(c)(2)).

The conference report accompanying PDUFA III, House of Representatives Report number 107–481, provides guidance on how the workload adjustment provision of PDUFA III is to be implemented. Following that guidance, FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision (human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements) received over the 5-year period that ended on June 30, 2002 (base years), and the average number of each of these types of applications over the most recent 5-year period that ended June 30, 2006.

The results of these calculations are presented in the first two columns of table 1 of this document. Column 3 reflects the average percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, estimating how much of the total FDA drug review workload was accounted for by each type of application in the table during the most recent 5 years. Column 5 of table 1 is the weighted percent change in each category of workload. This was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table the sum of the values in column 5 is added, reflecting a total increase in workload of 6.3 percent for FY 2007 when compared to the base years.

TABLE 1.—SUMMARY WORKLOAD ADJUSTER CALCULATION—FY 2007

Application Type	Column 1 5-Year Average Base Years	Column 2 Latest 5-Year Average	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted Percent Change
NDAs/BLAs	119.6	120.4	0.7%	36.6%	0.25%
Commercial INDs	629.8	676.8	7.5%	44.0%	3.28%
Efficacy supplements	159.2	167.4	5.2%	7.5%	0.38%
Manufacturing supplements	2100.6	2522.4	20.1%	11.9%	2.39%
FY 2007 workload adjuster					6.30%

Increasing the inflation-adjusted revenue amount for application fees of $101,819,252 by the FY 2007 workload adjuster (6.3 percent) results in an increase of $6,414,613, for a total inflation and workload adjusted application fee revenue amount of $108,233,865. Increasing the inflation-adjusted revenue amount for establishment and product fees, each of which is $101,818,074, by the FY 2007 workload adjuster (6.3 percent) results in an increase of $6,414,539, for a total inflation and workload adjusted application fee revenue amount of $108,232,613 for each category. The total FY 2007 inflation and workload adjusted fee revenue target for all three fee categories combined is $324,699,091.

III. Adjustment for Excess Collections in Previous Years

Under the provisions of PDUFA, as amended, if the agency collects more fees than were provided for in appropriations in any year after 1997, FDA is required to reduce its

anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379h(g)(4)).

In FY 1998, Congress appropriated a total of $117,122,000 to FDA in PDUFA fee revenue. As of September 30, 2005, collections for FY 1998 totaled $117,849,016—or $727,016 in excess of the appropriation limit. Also, in FY 2004 Congress appropriated a total of $249,825,000 to FDA in PDUFA fee revenue, and FDA collected a total of $257,055,606 as of September 30, 2005. This is $7,230,906 in excess of appropriations. The total in excess collections for the 2 years is $7,957,922. These are the only fiscal years since 1997 in which FDA has collected more in PDUFA fees than Congress appropriated.

The total of $7,957,922 will be offset against FY 2007 revenue collections, lowering the net amount that would otherwise be collected. One-third of this amount, or $1,985,974, will be subtracted from the FY 2007 adjusted revenue amount for each fee category in the previous section. Thus, after adjustment for prior-year excess collections, the adjusted FY 2007 revenue target for each fee category is as follows:

- Application fee revenue amount: $105,581,224 ($108,233,865 - $2,652,641)
- Establishment fee revenue amount: $105,579,972 ($108,232,613 - $2,652,641)
- Product fee revenue amount: $105,579,973 ($108,232,613 - $2,652,640)

Thus, the adjusted revenue amount from all three categories after this adjustment totals $316,741,167.

IV. Final Year Adjustment

Under the provisions of PDUFA, as amended, the Secretary may, in addition to the inflation and workload adjustments, further increase the fees and fee revenues if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of FY 2008. The rationale for the amount of this increase shall be contained in the annual notice establishing fee revenues and fees for FY 2007 (21 U.S.C. 379h(c)(3)).

As of June 30, 2006, FDA has unallocated cash carryover balances of $42,777,720. In addition, the agency is estimating that application fees over the final 3 months of FY 2006 will add another $18,500,000 to this balance, for an estimated cash carryover of $61,277,720 on September 20, 2006.

In FY 2007, FDA expects to collect a total of $316,741,167 after adjustments, as noted at the end of section III of this document. To sustain current operations in FY 2007, FDA expects to obligate a total of $327 million (compared with anticipated obligations in FY 2006 of about $314,500,000). The anticipated obligations of $327 million will be about $10,259,000 more than anticipated collections. This will reduce the estimated carry-over balance over the course of FY 2007 from $61,278,000 to an estimated $51,019,000 ($61,278,000 - $10,259,000).

To sustain operations supported from user fees for the first 3 months of FY 2008, FDA estimates that it will need one-fourth of the $327 million it expects to spend in FY 2007, or $81,750,000. However, this amount will need to be increased for inflation by an estimated 5.8 percent (the average amount by which FDA's costs per FTE have increased over the past 5 years). The amount needed to sustain operations for the first 3 months of FY 2008 is thus estimated at $86,491,500, while the estimated carry-over balance at the beginning of FY 2008 is estimated at only $51,019,000. Thus, FDA will need an additional $35,472,500 as the final year adjustment to assure sufficient operating reserves for the first 3 months of FY 2008. One-third of this amount, rounded to the nearest thousand, or $11,824,000, will be added to the FY 2007 adjusted revenue amount for each fee category in the previous section. Thus, after the final-year adjustment, the adjusted FY 2007 revenue target for each fee category is as follows:

- Application fee revenue amount: $117,405,224 ($105,581,224 + $11,824,000)
- Establishment fee revenue amount: $117,403,972 ($105,579,972 + $11,824,000)
- Product fee revenue amount: $117,403,973 ($105,579,973 + $11,824,000)

Thus, after the final year adjustment, the adjusted FY 2007 revenue target from all fee types combined totals $352,141,167.

V. Application Fee Calculations

PDUFA III provides that the rates for application, product, and establishment fees be established 60 days before the beginning of each FY (21 U.S.C. 379h(c)(4)). The fees are to be established so that they will generate the fee revenue amounts specified in the statute, as adjusted for inflation and workload.

A. Application Fee Revenues and Application Fees

The application fee revenue amount that PDUFA III established for FY 2007 is $117,381,224, as calculated in the previous section. Application fees will be set to generate this amount.

B. Estimate of Number of Fee-Paying Applications and Establishment of Application Fees

For FY 2003 through FY 2007, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive the next FY by averaging the number of fee-paying FAEs received in the five most recent FYs. This use of the rolling average of the five most recent FYs is the same method that was applied in making the workload adjustment.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2007, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FY 2002 through FY 2006. For FY 2006, FDA is estimating the number of fee-paying FAEs for the full year based on the actual count for the first 9 months and estimating the number for the final 3 months.

Table 2 of this document shows, in column 1, the total number of each type of FAE received in the first 9 months of FY 2006, whether fees were paid or not. Column 2 shows the number of FAEs for which fees were waived or exempted during this period, and column 3 shows the number of fee-paying FAEs received through June 30, 2006. Column 4 estimates the 12-month total fee-paying FAEs for FY 2006 based on the applications received through June 30, 2006. All of the counts are in FAEs. A full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half an FAE, as does a supplement requiring clinical data. An application that is withdrawn, or refused for filing, counts as one-fourth of an FAE if it initially paid a full application fee, or one-eighth of an FAE if it initially paid one-half of the full application fee amount.

TABLE 2.—FY 2006 FULL APPLICATION EQUIVALENTS RECEIVED THROUGH JUNE 30, 2006, AND PROJECTED THROUGH SEPTEMBER 30, 2006

Application or Action	Column 1 Total Received Through June 30, 2006	Column 2 Fee Exempt or Waived Through June 30, 2006	Column 3 Total Fee Paying Through June 30, 2006	Column 4 12-Month Fee-Paying Projection
Applications requiring clinical data	72.25	21.25	51	68
Applications not requiring clinical data	7.5	3.5	4	5.33
Supplements requiring clinical data	60.25	13.75	46.5	62
Withdrawn or refused to file	1	0	1	1.33
Total	141	38.5	102.5	136.7

In the first 9 months of FY 2006, FDA received 141 FAEs, of which 102.5 were fee-paying. Based on data from the last 7 FYs, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 102.5 by 3 and multiplying by 4 extrapolates the amount to the full 12 months of the FY and projects the number of fee-paying FAEs in FY 2006 at 136.7.

All pediatric supplements, which had been exempt from fees prior to January 4, 2002, were required to pay fees effective January 4, 2002. This is the result of section 5 of the Best Pharmaceuticals for Children Act that repealed the fee exemption for pediatric supplements effective January 4, 2002. Thus, in estimating FY 2006 fee-paying receipts we must include in our calculations all the pediatric supplements submitted in the past 5 years that were previously exempt from fees prior to January 4, 2002. The exempted number of FAEs for pediatric supplements for FY 2002 was 4.5. Because fees on these supplements are paid for pediatric applications submitted in FY 2003 and beyond, the number of pediatric supplement FAEs exempted from fees in FY 2002 (the last year in table 3 of this document when fees were exempted) are added to the total of fee-paying FAEs received each year.

As table 3 of this document shows, the average number of fee-paying FAEs received annually in the most recent 5-year period, assuming all pediatric supplements had paid fees, and including our estimate for FY 2006, is 131 FAEs. FDA will set fees for FY 2007 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 3.—FEE-PAYING FULL APPLICATION EQUIVALENT—5-YEAR AVERAGE

Year	2002	2003	2004	2005	2006	5-Year Average
Fee-paying FAEs	127.6	119.5	145.1	121.5	136.7	130.1
Exempt pediatric supplement FAEs	4.5	0	0	0	0	0.9
Total	132.1	119.5	145.1	121.5	136.7	131.0

The FY 2007 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 131, into the fee revenue amount to be derived from application fees in FY 2007, $117,405,224. The result, rounded to the nearest $100, is a fee of $896,200 per full application requiring clinical data, and $448,100 per application not requiring clinical data or per supplement requiring clinical data.

VI. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2006, the establishment fee was based on an estimate that 375 establishments would be subject to, and would pay, fees. By the end of FY 2006, FDA estimates that applicants have been billed for 400 establishment fees, before all decisions on requests for waivers or reductions are made. As in previous years, FDA again estimates that a total of 25 establishment fee waivers or reductions will be made for FY 2006, for a net of 375 fee-paying establishments. FDA will use this same number again, 375, for its FY 2007 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($117,403,972) by the estimated 375 establishments, for an establishment fee rate for FY 2006 of $313,100 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2006, the product fee was based on an estimate that 2,350 products would be subject to and pay product fees. By the end of FY 2006, FDA estimates that 2,400 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. Assuming that there will be about 40 waivers and reductions granted, FDA estimates that 2,360 products will qualify for product fees in FY 2006, after allowing for waivers and reductions, and will use this number for its FY 2007 estimate. Accordingly, the FY 2007 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($117,403,973) by the estimated 2,360 products for a FY 2007 product fee of $49,750 (rounded to the nearest $10).

VII. Fee Schedule for FY 2007

The fee rates for FY 2007 are set out in table 4 of this document:

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.