• The date U.S. Bank receives the payment. U.S. Bank is required to notify FDA within 1 working day, using the PIN described previously in this document.

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.

V. Procedures for Paying Annual Establishment Fees

If you are required to pay an annual establishment registration fee, you must pay for each establishment prior to registration. Payment must be submitted by first creating a Device Facility Use Fee (DFUF) order through the User Fee Web site at *https://fdasfinapp8.fda.gov/OA_HTML/fdaCAcdLogin.jsp*. You will be issued a PIN once you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2009 until it has completed the steps in this section to register and pay any applicable fee (see 21 U.S.C. 379j(f)(2)).

A. Step One—Submit a Device Facility User Fee Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF order, you must create or have previously created a user account and password for the User Fee Web site listed in this section. After creating a user name and password, log onto the Annual Facility User Fee 2009 store. Complete the DFUF order by entering the number of establishments you are registering. Once you are satisfied that the data on the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Step Two—Pay for Your DFUF Order

Unless paying by credit card, all payments must be in U. S. currency and drawn on a U.S. bank. The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic checks. Follow the instructions provided to make an electronic payment. If you prefer not to pay online, you may pay by a check, in U.S. dollars and drawn on a U.S. bank, mailed to: Food and Drug Administration, P.O. Box 70961, Charlotte, NC 28272–0961. (Note: This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check to: Wachovia Bank, Attn: Food and Drug Administration—Lockbox 70961, rm. NC0810, 1525 West WT Harris Blvd., Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only; do not send mail to this address.)

Please make sure that both of the following numbers are written on your check: (1) The FDA post office box number (P.O. Box 70961), and (2) the PIN that is printed on your order. A copy of your printed order should also be mailed along with your check. FDA's tax identification number is 53–0196965.

Wire transfers may also be used to pay annual establishment fees. For wire transfer information, please contact the user fee helpdesk at 301–827–9539 or *userfees@fda.gov*.

C. Step Three—Complete the Information Online to Update Your Establishment's Annual Registration for FY 2009, or to Register a New Establishment for FY 2009

Go to CDRH's Web site at *http://www.fda.gov/cdrh/reglistpage.html* and click the ''Electronic Registration and Listing System (FURLS)'' link on the left of the page. This opens up a new page with important information about FURLS. After reading this information click on the link at the bottom of the page. That takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2008.

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, there will be a button that you will click to go to the Device Registration and Listing Module (DRLM) of FURLS. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. Once you choose to register or update your annual registration the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, e-mail *reglist@cdrh.fda.gov* or call 240–276–0111 for assistance. (Note: This e-mail address and phone number are for assistance with establishment registration only, and not for any other aspects of medical device user fees.)

D. Step Four—Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. Fees are only required for those establishments defined in section I of this document.

Dated: July 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17739 Filed 7–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0427]

Prescription Drug User Fee Rates for Fiscal Year 2009

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) 2009. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Prescription Drug User Fee Amendments of 2007 (PDUFA IV) (Title 1 of the Food and Drug Administration Amendments Act of 2007 (FDAAA)), 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 to be generated from PDUFA fees were established by PDUFA IV, with provisions for certain adjustments. Fee revenue amounts for applications, establishments, and products are to be established each year by FDA so that

one-third of the PDUFA fee revenues FDA collects each year will be generated from each of these categories. This notice establishes fee rates for FY 2009 for application fees for an application requiring clinical data ($1,247,200), for an application not requiring clinical data or a supplement requiring clinical data ($623,600), for establishment fees ($425,600), and for product fees ($71,520). These fees are effective on October 1, 2008, and will remain in effect through September 30, 2009. For applications and supplements that are submitted on or after October 1, 2008, the new fee schedule must be used. Invoices for establishment and product fees for FY 2009 will be issued in August 2008, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3917.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the act (21 U.S.C. 379g and 379h), establish 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 (section 736(a) of the act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the act).

For FY 2008 through FY 2012, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA IV. The base revenue amount for FY 2008 is to be adjusted for workload, and that adjusted amount becomes the base amount for the remaining 4 fiscal years. That adjusted base revenue amount is increased for drug safety enhancements by $10,000,000 in each of the subsequent 4 fiscal years, and the increased total is further adjusted each year 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 provide one-third of the total revenue to be collected each year.

This notice uses the fee base revenue amount for FY 2008 published on October 12, 2007 (72 FR 58103), adjusts it for the 2009 drug safety increase (see section 736(b)(4) of the act), for inflation, and for workload, and then establishes the application, establishment, and product fees for FY 2009. These fees are effective on October 1, 2008, and will remain in effect through September 30, 2009.

II. Fee Revenue Amount for FY 2009

The total fee revenue amount for FY 2009 is $510,665,000, based on the fee revenue amount specified in the statute, including additional fee funding for drug safety and adjustments for inflation and changes in workload. The statutory amount and a one-time base adjustment are described in section II.A and II.B of this document. The adjustment for inflation is described in section II.C, and the adjustment for changes in workload in section II.D.

A. FY 2009 Statutory Fee Revenue Amounts Before Adjustments

PDUFA IV specifies that the fee revenue amount before adjustments for FY 2009 for all fees is $427,783,000 ($392,783,000 specified in section 736(b)(1) of the act, plus an additional $35,000,000 for drug safety in FY 2009 specified in section 736(b)(4) of the act).

B. Base Adjustment to Statutory Fee Revenue Amount

The statute also specifies that $354,893,000 of the base amount is to be further adjusted for workload increases through FY 2007 (see section 736(b)(1)(B) of the act). The adjustment on this amount is to be made in accordance with the workload adjustment provisions that were in effect for FY 2007, except that the adjustment for investigational new drug (IND) workload is based on the number of INDs with a submission in the previous 12 months, rather than on the number of new commercial INDs submitted in the same 12-month period.

For each fiscal year beginning in FY 2004, the Prescription Drug User Fee Amendments of 2002 (PDUFA III) provided that fee revenue amounts, after they had been adjusted for inflation, should be further adjusted to reflect changes in workload for the process for the review of human drug applications (see section 736(c)(2) of the act). 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 submissions specified in the workload adjustment provision (human drug applications, commercial INDs, 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, 2007. PDUFA IV directs that this same method be used in making the workload adjustment apply to the 2008 statutory revenue amount, except that for this calculation the number of commercial INDs with a submission in the previous 12 months is used for each 12-month period rather than the number of new commercial INDs submitted (see section 736(b) of the act, as amended by PDUFA IV).

The results of these calculations are presented in Columns 1 and 2 of Table 1 of this document. Column 3 reflects the 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 of this document 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 11.73 percent when compared to the base years.

TABLE 1—SUMMARY WORKLOAD ADJUSTER CALCULATION TO BE APPLIED TO FY 2009 STATUTORY BASE

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 % Change
New drug applications (NDAs)/biologics license applications (BLAs)	119.6	123.8	3.5%	35.2%	1.24%
Active INDs	4751.8	5528.2	16.3%	44.2%	7.22%

TABLE 1—SUMMARY WORKLOAD ADJUSTER CALCULATION TO BE APPLIED TO FY 2009 STATUTORY BASE—Continued

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 % Change
Efficacy supplements	159.2	163.4	2.6%	7.4%	0.20%
Manufacturing supplements	2100.6	2589.2	23.3%	13.2%	3.07%
FY 2008 workload adjuster to be applied to the statutory base					11.73%

Increasing the PDUFA IV statutorily specified amount of $354,893,000 by the specified workload adjuster (11.73 percent) results in an increase of $41,629,000, rounded to the nearest thousand dollars. Adding this amount to the $427,783,000 statutorily specified amount from section II.A of this document, results in a total adjusted PDUFA IV base revenue amount of $469,412,000, before further adjustment for inflation and changes in workload after FY 2007.

C. Inflation Adjustment to FY 2009 Fee Revenue Amount

PDUFA IV provides that fee revenue amounts for each fiscal year after 2008 shall be adjusted for inflation. The adjustment must reflect the greater of: (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 fiscal year for which fees are being set; (2) the total percentage pay change for the previous fiscal year for Federal employees stationed in the Washington, DC metropolitan area; or (3) the average annual change in cost, per full time equivalent (FTE) FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years. PDUFA IV provides for this annual adjustment to be cumulative and compounded annually after FY 2008 (see section 736(c)(1) of the act).

The first factor is the CPI increase for the 12-month period ending in June 2008. The CPI for June 2008 was 218.815, and the CPI for June 2007 was 208.352. (These CPI figures are available on the Bureau of Labor statistics Web site, *http://data.bls.gov/cgi-bin/surveymost?bls* by checking the first box under ''Price Indexes'' and then clicking ''Retrieve Data'' at the bottom of the page.) The CPI for June 2008 is 5.05 percent higher than the CPI for the previous 12-month period.

The second factor is the increase in pay for the previous fiscal year (FY 2008 in this case) for Federal employees stationed in the Washington, DC metropolitan area. This figure is published by the Office of Personnel Management, and found on their Web site, *http://www.opm.gov/oca/08tables/html/dcb.asp*, above the salary table. For FY 2008 it was 4.49 percent.

The third factor is the average change in FDA cost for compensation and benefits per FTE over the previous 5 of the most recent 6 fiscal years (FY 2002 through FY 2007). The data on total compensation paid and number of FTEs paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees. Table 2 of this document summarizes that actual cost and FTE use data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the most 5 recent fiscal years, which is 5.64 percent.

TABLE 2—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE ($000)

Fiscal Year	2003	2004	2005	2006	2007	Annual Average Increase for Latest 5 Years
Total PC&B	$971,255	$1,042,749	$1,077,604	$1,114,704	$1,144,369	
Total FTEs	10257	10141	9910	9698	9569	
PC&B per FTE	$94.692	$102.825	$108.739	$114,942	$119.591	
% Change from Previous Year	4.09%	8.59%	5.75%	5.70%	4.05%	5.64%

Because the average change in pay per FTE (5.64 percent) is the highest of the three factors, it becomes the inflation adjustment for total fee revenue for FY 2009. Increasing the FY 2009 fee revenue base of $469,412,000 by 5.64 percent yields an inflation-adjusted fee revenue amount for FY 2009 of $495,887,000, rounded to the nearest thousand dollars, before addition of the FY 2009 workload adjustment.

D. Workload Adjustment to the FY 2009 Inflation Adjusted Fee Revenue Amount

For each fiscal year beginning in FY 2009, PDUFA IV 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 section 736(c)(2) of the act). PDUFA IV continues the PDUFA III workload adjustment with modifications, and provides for a new additional adjustment for changes in review activity. PDUFA IV also specifies that for FY 2009 the additional adjustment for changes in review activity may not result in a total workload adjustment that is more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review workload (see section 736(c)(2)(B) of the act).

Therefore, FDA will first calculate the FY 2009 workload adjustment without the PDUFA IV adjustment for changes in review activity. Then FDA will apply

the adjustment for changes in review activity, to determine if the total workload adjustment is no more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activity.

In calculating the FY 2009 workload adjustment without the PDUFA IV adjustment for changes in review activity, FDA will follow the guidance provided in the conference report accompanying the Prescription Drug User Fee Amendments of 2002, House of Representatives Report number 107–481, using active commercial INDs rather than newly submitted commercial INDs as the surrogate for IND workload, as specified by PDUFA IV.

FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision: (1) Human drug applications, (2) active commercial investigational new drug applications (applications that have at least one submission during the previous 12 months), (3) efficacy supplements, and (4) manufacturing supplements received over the 5-year period that ended on June 30, 2007 (base years), and the average number of each of these types of applications over the most recent 5-year period that ended June 30, 2008.

The calculations are summarized in Table 3 of this document. The 5-year averages for each application category are provided in Column 1 (5-Year Average Base Years 2002–2007) and Column 2 (Latest 5-Year Average 2003–2008). Column 3 reflects the percent change in workload from Column 1 to Column 2. 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 Table 3 of this document is the sum of the values in Column 5 that are added, reflecting an increase in workload of 2.98 percent for FY 2009 when compared to the base years, but before taking into account the impact of change in review activity.

TABLE 3—PRELIMINARY WORKLOAD ADJUSTER CALCULATION FOR FY 2009 WITHOUT ADJUSTMENT FOR CHANGES IN REVIEW ACTIVITY

Application Type	Column 1 5-Year Average Base Years 2002–2007	Column 2 Latest 5-Year Average 2003–2008	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted % Change
NDAs/BLAs	123.8	128.4	3.7%	33.3%	1.24%
Active commercial INDs	5755.8	5897.6	2.5%	45.2%	1.11%
Efficacy supplements	163.4	173.0	5.9%	8.3%	0.49%
Manufacturing supplements	2589.2	2616.2	1.0%	13.2%	0.14%
FY 2009 workload adjuster without adjustment changes for review activity					2.98%

PDUFA IV specifies that FDA make additional adjustments for changes in review activities to the first two categories (human drug applications and active commercial INDs). These adjustments, specified under PDUFA IV, are summarized in the new Columns 2b and 2c in Table 4 of this document. The number in the NDAs/BLAs line of Column 2b of Table 4 of this document is the percent by which the average workload for meetings, annual reports, and labeling supplements for NDAs and BLAs has changed from the 5-year period 2002 through 2007 to the 5-year period 2003 through 2008. Likewise, the number in the active commercial INDs line of Column 2b of Table 4 of this document is the percent by which the workload for meetings and special protocol assessments for active commercial INDs has changed from the 5-year period 2002 through 2007 to the 5-year period 2003 through 2008. There is no entry in the last two lines of column 2b because the adjustment for changes in review workload does not apply to the workload for efficacy supplements and manufacturing supplements.

TABLE 4—FINAL WORKLOAD ADJUSTER CALCULATION FOR FY 2009 WITH ADJUSTMENT FOR CHANGES IN REVIEW ACTIVITY[1]

Application Type	Column 1 5-Year Average Base Years 2002–2007	Column 2a Latest 5-Year Average 2003–2008	Column 2b Adjustment for Changes in Review Activity	Column 2c is Column 2a Adjusted by Column 2b	Column 3 % Change (Column 1 to Column 2c or 2a)	Column 4 Weighting Factor	Column 5 Weighted % Change
NDAs/BLAs	123.8	128.4	-0.55%	127.7	3.1%	33.3%	1.05
Active commercial INDs	5755.8	5897.6	+0.39%	5920.6	2.9%	45.2%	1.31
Efficacy supplements	163.4	173.0	NA	173.3	5.9%	8.3%	0.49%
Manufacturing supplements	2589.2	2516.2	NA	2616.2	1.0%	13.2%	0.14%

TABLE 4—FINAL WORKLOAD ADJUSTER CALCULATION FOR FY 2009 WITH ADJUSTMENT FOR CHANGES IN REVIEW ACTIVITY[1]—Continued

Application Type	Column 1 5-Year Average Base Years 2002–2007	Column 2a Latest 5-Year Average 2003–2008	Column 2b Adjustment for Changes in Review Activity	Column 2c is Column 2a Adjusted by Column 2b	Column 3 % Change (Column 1 to Column 2c or 2a)	Column 4 Weighting Factor	Column 5 Weighted % Change
FY 2009 workload adjuster with adjustment changes for review activity							2.98%

[1] Numbers may not add due to rounding.

The 2009 workload adjuster with adjustment for changes in review activity at the bottom of Table 4 of this document is 2.98 percent exactly the same as the workload adjuster without those changes at the bottom of Table 3 of this document. Therefore the inflation-adjusted revenue amount of $495,887,000 from section II.B of this document will be multiplied by the 2009 workload adjuster of 2.98 percent, resulting in a total adjusted revenue amount in FY 2009 of $510,665,000, rounded to the nearest thousand dollars.

PDUFA specifies that one-third of the total fee revenue is to be derived from application fees, one-third from establishment fees, and one-third from product fees (see section 736(b)(2) of the act). Accordingly, one-third of the total revenue amount, or $ 170,222,000, rounded to the nearest thousand dollars, is the total amount of fee revenue that will be derived from each of these fee categories.

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate one-third of the total fee revenue amount, or $170,222,000, rounded to the nearest thousand dollars, in FY 2009, as calculated in section II.D of this document.

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

For FY 2008 through FY 2012, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive the next fiscal year by averaging the number of fee-paying FAEs received in the 5 most recent fiscal years. This use of the rolling average of the 5 most recent fiscal years is the same method that has applied for the last 6 years.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2009, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FY 2004 through FY 2008. For FY 2008, 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, as we have done for the past 6 years.

Table 5 of this document shows, in Column 1, the total number of each type of FAE received in the first 9 months of FY 2008, 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, 2008. Column 4 estimates the 12-month total fee-paying FAEs for FY 2008 based on the applications received through June 30, 2008. 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 the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

TABLE 5—FY 2008 FULL APPLICATION EQUIVALENTS RECEIVED THROUGH JUNE 30, 2008, AND PROJECTED THROUGH SEPTEMBER 30, 2008

Application or Action	Column 1 Total Received Through 6/30/2008	Column 2 Fee Exempt or Waived Through 6/30/2008	Column 3 Total Fee Paying Through 6/30/2008	Column 4 12-Month Fee-Paying Projection
Applications requiring clinical data	102.3	40.3	62.0	82.7
Applications not requiring clinical data	11.1	4.1	7.0	9.3
Supplements requiring clinical data	45.0	6.0	39.0	52.0
Withdrawn or refused to file	0.5	0	0.5	0.7
Total	158.9	50.4	108.5	144.7

In the first 9 months of FY 2008, FDA received 158.9 FAEs, of which 108.5 were fee-paying. Based on data from the last 9 fiscal years, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 108.5 by 3 and multiplying by 4 extrapolates the amount to the full 12 months of the fiscal year and projects the number of fee-paying FAEs in FY 2008 at 144.7.

As Table 6 of this document shows, the average number of fee-paying FAEs received annually in the most recent 5-year period, and including our estimate for FY 2008, is 136.5 FAEs. FDA will set fees for FY 2009 based on this estimate as the number of FAEs that will pay fees.

TABLE 6—FEE-PAYING FULL APPLICATION EQUIVALENT—5-YEAR AVERAGE

Fiscal Year	2004	2005	2006	2007	2008	5-Year Average
Fee-Paying FAEs	145.1	121.5	136.7	134.4	144.7	136.5

The FY 2009 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 136.5, into the fee revenue amount to be derived from application fees in FY 2009, $170,222,000. The result, rounded to the nearest $100, is a fee of $1,247,200 per full application requiring clinical data, and $623,600 per application not requiring clinical data or per supplement requiring clinical data.

IV. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2008, the establishment fee was based on an estimate that 390 establishments would be subject to, and would pay, fees. By the end of FY 2008, FDA estimates that 435 establishments will have been billed for 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 2008. In addition, FDA estimates that another 10 full establishment fees will be exempted this year based on the orphan drug exemption in the Food and Drug Administration Amendments Act of 2007 (FDAAA) (see section 736(k) of the act). Subtracting 35 establishments (25 plus the estimated 10 establishments under the orphan exemption) from 435 leaves a net of 400 fee-paying establishments. FDA will use 400 for its FY 2009 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 ($170,222,000) by the estimated 400 establishments, for an establishment fee rate for FY 2009 of $425,600 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2008, the product fee was based on an estimate that 2,355 products would be subject to, and would pay, product fees. By the end of FY 2008, FDA estimates that 2,450 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. FDA assumes that there will be about 40 waivers and reductions granted, the same amount estimated last year. In addition, FDA estimates that another 30 product fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the act). FDA estimates that 2,380 products will qualify for product fees in FY 2008, after allowing for waivers and reductions, including the orphan drug products eligible under the FDAAA exemption, and will use this number for its FY 2009 estimate. Accordingly, the FY 2009 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($170,222,000) by the estimated 2,380 products for a FY 2009 product fee of $71,520 (rounded to the nearest $10).

V. Fee Schedule for FY 2009

The fee rates for FY 2009 are set out in Table 7 of this document.

TABLE 7

Fee Category	Fee Rates for FY 2009
APPLICATIONS	
Requiring clinical data	$1,247,200
Not requiring clinical data	$623,600
Supplements requiring clinical data	$623,600
ESTABLISHMENTS	$425,600
PRODUCTS	$71,520

VI. 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, 2008. 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 70963, Charlotte, NC 28272–0963.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., rm. NC0810, Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 70963) is written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payment may also be used. The routing and transit number is 021030004 and the account number is 75060099.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2009 under the new fee schedule in August 2008. Payment will be due on October 1, 2008. FDA will issue invoices in November 2009 for any products and establishments subject to fees for FY 2009 that qualify for fees after the August 2008 billing.

Dated: July 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17738 Filed 7–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,