applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Eye Institute Special Emphasis Panel; NEI Institutional Training Grant Applications.

*Date:* August 9, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Anne E. Schaffner, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *aes@nei.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Eye Institute Special Emphasis Panel; NEI Clinician Scientist Grant Applications.

*Date:* August 23, 2010.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Natioanl Institutes of Health, NEI Division of Extramural Research, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Anne E. Schaffner, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, *aes@nei.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 28, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory, Committee Policy.*

[FR Doc. 2010–19162 Filed 8–3–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National Human Immunodeficiency Virus (HIV) Behavioral Surveillance, Funding Opportunity Announcement, PS11–001, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

*Times and Dates:*

8 a.m.–5 p.m., September 20, 2010 (Closed).

8 a.m.–5 p.m., September 21, 2010 (Closed).

*Place:* Sheraton Gateway Hotel Atlanta Airport, 1900 Sullivan Road, Atlanta, Georgia 30337, Telephone: (770)997–1100.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters To Be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to "National HIV Behavioral Surveillance System, FOA PS11–001."

*Contact Person for More Information:* Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road, NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 498–2293.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 27, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2010–19157 Filed 8–3–10; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* Advisory Commission on Childhood Vaccines (ACCV).

*Date and Time:* September 2, 2010, 1 p.m. to 5:30 p.m. EDT. September 3, 2010, 9 a.m. to 12:30 p.m. EDT.

*Place:* Parklawn Building (and via audio conference call), Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, September 2 from 1 p.m. to 5:30 p.m. (EDT) and Friday, September 3 from 9 a.m. to 12:30 pm (EDT). The public can join the meeting via audio conference call by dialing 1–800–857–7178 on September 2 and 3 and providing the following information:

*Leader's Name:* Dr. Geoffrey Evans.

*Password:* ACCV.

*Agenda:* The agenda items for the September meeting will include, but are not limited to: updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice (DOJ), National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (*http://www.hrsa.gov/vaccinecompensation/accv.htm*) prior to the meeting. Agenda items are subject to change as priorities dictate.

*Public Comment:* Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: *aherzog@hrsa.gov.* Requests should contain the name, address, telephone number, e-mail address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by e-mail, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. Public participation and ability to comment will be limited to space and time as it permits.

*For Further Information Contact:* Anyone requiring information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593 or e-mail: *aherzog@hrsa.gov.*

Dated: July 29, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010–19120 Filed 8–3–10; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0390]**

### Prescription Drug User Fee Rates for Fiscal Year 2011

**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) 2011. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Prescription Drug User Fee Amendments of 2007 (Title 1 of the Food and Drug Administration

Amendments Act of 2007 (FDAAA)) (PDUFA IV), 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 2011 for application fees for an application requiring clinical data ($1,542,000), for an application not requiring clinical data or a supplement requiring clinical data ($771,000), for establishment fees ($497,200), and for product fees ($86,520). These fees are effective on October 1, 2010, and will remain in effect through September 30, 2011. For applications and supplements that are submitted on or after October 1, 2010, the new fee schedule must be used. Invoices for establishment and product fees for FY 2011 will be issued in August 2010, using the new fee schedule.

**FOR FURTHER INFORMATION CONTACT:** David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Picard Dr., PI50 RM210J, Rockville, MD 20850, 301–796–7103.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Sections 735 and 736 of the act (21 U.S.C. 379g and 379h, respectively), 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 in the **Federal Register** of October 12, 2007 (72 FR 58103), adjusts it for the FY 2010 and FY 2011 drug safety increases (see section 736(b)(4) of the act), for inflation, and for workload, and then establishes the application, establishment, and product fees for FY 2011. These fees are effective on October 1, 2010, and will remain in effect through September 30, 2011.

## II. Fee Revenue Amount for FY 2011

The total fee revenue amount for FY 2011 is $619,070,000, 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 sections II.A and II.B of this document. The adjustment for inflation is described in section II.C of this document, and the adjustment for changes in workload in section II.D of this document.

### *A. FY 2011 Statutory Fee Revenue Amounts Before Adjustments*

PDUFA IV specifies that the fee revenue amount before adjustments for FY 2011 for all fees is $447,783,000 ($392,783,000 specified in section 736(b)(1) of the act plus an additional $55,000,000 for drug safety in FY 2011 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 workload 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. This adjustment was explained in detail in the **Federal Register** of October 12, 2007 (72 FR 58103). Increasing the 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. Adding this amount to the $447,783,000 statutorily specified amount from section II.A of this document, results in a total adjusted PDUFA IV base revenue amount of $489,412,000, before further adjustment for inflation and changes in workload after FY 2007.

### *C. Inflation Adjustment to FY 2011 Fee Revenue Amount*

PDUFA IV provides that fee revenue amounts for each fiscal year after FY 2008 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 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 2010. The CPI for June 2010 was 217.965 and the CPI for June 2009 was 215.693. (These CPI figures are available on the Bureau of Labor Statistics Web site at *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.) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) The CPI for June 2010 is 1.053 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 2010 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 at *http://www.opm.gov/oca/10tables/html/dcb.asp* above the salary table. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) For FY 2010 it was 2.42 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 2004 through 2009). The data on total compensation paid and numbers of FTE

paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees. Table 1 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 4.53 percent.

TABLE 1.—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

| Fiscal Year | 2005 | 2006 | 2007 | 2008 | 2009 | Annual Average Increase for Latest 5 Years |
|---|---|---|---|---|---|---|
| Total PC&B | $1,077,604 | $1,114,704 | $1,144,369 | $1,215,627 | $1,464,445 | |
| Total FTE | 9,910 | 9,698 | 9,569 | 9811 | 11,413 | |
| PC&B per FTE | $108,739 | $114,942 | $119,591 | $123,905 | $128,314 | |
| % Change from Previous Year | 5.75% | 5.70% | 4.05% | 3.61% | 3.56% | 4.53% |

The inflation increase for FY 2011 is 4.53 percent. This is the greater of the CPI change during the 12-month period ending June 30 preceding the fiscal year for which fees are being set (1.053 percent), the increase in pay for the previous fiscal year (FY 2010 in this case) for Federal employees stationed in the Washington, DC metropolitan area (2.42 percent), and the average annual change in cost, per FTE FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years (4.53 percent). Because the average change in pay per FTE (4.53 percent) is the highest of the three factors, it becomes the inflation adjustment for total fee revenue for FY 2011.

The inflation adjustment for FY 2009 was 5.64 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the fiscal year for which fees were being set (June 30, 2008, which was 5.05 percent), the increase in pay for FY 2008 for Federal employees stationed in Washington, DC (4.49 percent), or the average annual change in cost, per FTE FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years (5.64 percent).

The inflation adjustment for FY 2010 was 5.54 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the fiscal year for which fees were being set (June 30, 2009) (negative 1.43 percent), the increase in pay for FY 2009 for Federal employees stationed in Washington, DC (4.78 percent), or the average annual change in cost, per FTE FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years (5.54 percent).

PDUFA IV provides for this inflation adjustment to be cumulative and compounded annually after FY 2008 (see section 736(c)(1) of the act). This factor for FY 2011 (4.53 percent) is compounded by adding one to it and then multiplying it by one plus the inflation adjustment factor for FY 2010 (5.54 percent) and by one plus the inflation adjustment factor for FY 2009 (5.64 percent). The result of this multiplication of the inflation factors for the 3 years since FY 2008 (1.04.53 times 1.0554 times 1.0564 percent) becomes the inflation adjustment for FY 2011. This inflation adjustment for FY 2010 is 16.54 percent.

Increasing the FY 2011 fee revenue base of $489,412,000, by 16.54 percent yields an inflation-adjusted fee revenue amount for FY 2011 of $570,371,000, rounded to the nearest thousand dollars, before the application of the FY 2011 workload adjustment.

*D. Workload Adjustment to the FY 2010 Inflation Adjusted Fee Revenue Amount*

PDUFA IV does not allow FDA to adjust the total revenue amount for workload beginning in FY 2010 unless the independent accounting firm study is complete (see section 736(c)(2)(C) of the act). That study, conducted by Deloitte Touche, LLP, was completed on March 31, 2009, and is available online at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm164339.htm* . The study found that the adjustment methodology used by FDA reasonably captures changes in workload for reviewing human drug applications under PDUFA IV. Accordingly, FDA continues to use the workload adjustment methodology prescribed in PDUFA IV.

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.

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 INDs (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, 2010.

The calculations are summarized in table 2 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 2a ("5 Year Average 2006–2010").

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 columns 2b and 2c in table 2 of this document. The number in the NDAs/BLAs line of column 2b of table 2 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 2006 through 2010. Likewise, the number in the "Active commercial INDs" line of column 2b of table 2 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 2006 through 2010. 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.

Column 3 of table 2 of this document reflects the percent change in workload from column 1 to column 2c. 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 2 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 table 2 of this document is the sum of the values in column 5 that are added, reflecting an increase in workload of 8.54 percent for FY 2011 when compared to the base years.

TABLE 2.—WORKLOAD ADJUSTER CALCULATION FOR FY 2011

| Application Type | Column 1 | Column 2a | Column 2b | Column 2c | Column 3 | Column 4 | Column 5 |
|---|---|---|---|---|---|---|---|
| | 5-Year Average Base Years 2002–2007 | 5-Year Average 2006–2010 | Adjustment for Changes in Review Activity | is Column 2a increased by Column 2b | Percent Change (Column 1 to Column 2c) | Weighting Factor | Weighted Percent Change |
| NDAs/BLAs | 123.8 | 134.8 | -0.49% | 134.1 | 8.4% | 33.9% | 2.83% |
| Active commercial INDs | 5,528.2 | 6320.0 | -1.60% | 6218.7 | 12.5% | 43.7% | 5.46% |
| Efficacy Supplements | 163.4 | 164.4 | NA | 164.4 | 0.6% | 9.6% | 0.06% |
| Manufacturing Supplements | 2589.2 | 2628.6 | NA | 2628.6 | 1.5% | 12.8% | 0.19% |
| FY 2011 Workload Adjuster | | | | | | | 8.54% |

The 2011 workload adjuster reflected in the calculations in table 3 of this document is 8.54 percent. Therefore the inflation-adjusted revenue amount of $570,376,000 from section II.C of this document will be increased by the 2011 workload adjuster of 8.54 percent, resulting in a total adjusted revenue amount in FY 2011 of $619,070,000, rounded to the nearest thousand dollars.

While the fee revenue amount anticipated in FY 2011 is $619,070,000, as the previous paragraph shows, FDA assumes that the fee appropriation for FY 2011 will be 5 percent higher, or $650,024,000, rounded to the nearest thousand dollars. The PDUFA IV 5-Year Financial Plan, (which can be found at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm153456.htm*) states in Assumption 14 (Fee Revenue and Annual Appropriation Amount) that the PDUFA workload adjuster is a lagging adjustment dampened by averages over 5 years and will not help FDA keep up with workload if there are sudden increases in the number of applications to be reviewed in the current fiscal year. Appropriated amounts for PDUFA fee revenue each year are estimated at 5 percent higher than estimated fee revenues for each year, to provide FDA with the ability to cope with surges in application review workload should that occur. If FDA collects less than the fee estimate at the beginning of the year and less than the fee appropriation, then collections rather than appropriations set the upper limit on how much FDA may actually keep and spend. If, however, FDA collects more than fee estimates at the beginning of the year, due to a workload surge, a slightly higher fee appropriation will permit FDA to keep and spend the higher collections in order to respond to a very real surge in review workload that caused the increased collections—an unexpected increase in the number of applications that FDA must review in accord with PDUFA goals. For this reason, in most fiscal years since 1993, actual appropriations have slightly exceeded PDUFA fee revenue estimates made each year.

### *E. Rent and Rent-Related Adjustment to the FY 2011 Adjusted Fee Revenue Amount*

PDUFA specifies that for FY 2010 and each subsequent fiscal year, the revenue amount will be decreased if the actual cost paid for rent and rent-related expenses for preceding fiscal years are less than estimates made for such fiscal years in FY 2006 (see section 736(c)(3) of the act). The only fiscal years which have been completed, and for which FDA has data at this time, are FY 2008 and FY 2009. Table 3 of this document shows the estimates of rent and rent-related costs for FY 2008 and FY 2009 made in 2006 and the actual costs for these two fiscal years.

TABLE 3.—COMPARISON OF ACTUAL AND ESTIMATED RENT AND RENT-RELATED EXPENSES FOR THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) AND THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

| | Estimates Made in 2006 | | | Actual Costs at Fiscal Year End | | |
|---|---|---|---|---|---|---|
| | FY 2008 | FY 2009 | Total | FY 2008 | FY 2009 | Total |
| CDER | $46,732,000 | $40,415,000 | $87,147,000 | $51,619,000 | $64,687,250 | $116,306,250 |
| CBER | $22,295,000 | $23,067,000 | $45,362,000 | $26,715,000 | $26,966,750 | $53,681,750 |
| Total | $69,027,000 | $63,482,000 | $132,509,000 | $78,334,000 | $91,654,000 | $169,988,000 |

Because FY 2008 and FY 2009 costs for rent and rent-related items in total ($69,988,000) exceeded the estimates of these costs made in 2006 ($132,509,000), no decrease in the FY 2011 estimated PDUFA revenues is required under this provision of PDUFA.

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 ($619,070,000), i.e., $206,356,667, 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 $206,356,667, in FY 2011, as calculated previously in 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 7 years.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2011, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FY 2006 through FY 2010. For FY 2010, 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 8 years.

Table 4 of this document shows, in column 1, the total number of each type of FAE received in the first 9 months of FY 2010, 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, 2010. Column 4 estimates the 12-month total fee-paying FAEs for FY 2010 based on the applications received through June 30, 2010. 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 4.—FY 2010 FULL APPLICATION EQUIVALENTS RECEIVED THROUGH JUNE 30, 2010, AND PROJECTED THROUGH SEPTEMBER 30, 2010

| | Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|---|
| | Total Received Through 6/30/2010 | Fees Exempted or Waived Through 6/30/2010 | Total Fee Paying Through 6/30/2010 | 12-Month Fee Paying Projection |
| Applications requiring clinical data | 59 | 17 | 42 | 56 |
| Applications not requiring clinical data | 14 | 5.5 | 8.5 | 11.33 |
| Supplements requiring clinical data | 43.5 | 6.5 | 37 | 49.33 |
| Withdrawn or refused to file | 1.25 | 0.625 | 06.25 | 0.83 |
| Total | 117.75 | 29.625 | 88.125 | 117.5 |

In the first 9 months of FY 2009, FDA received 117.75 FAEs, of which 88.125 were fee-paying. Based on data from the last 10 fiscal years, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 88.125 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 2010 at 117.5.

As table 5 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 2010, is 133.8 FAEs. FDA will set fees for FY 2011 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 5.—FEE-PAYING FAE 5-YEAR AVERAGE

| Fiscal Year | 2006 | 2007 | 2008 | 2009 | 2010 est. | 5-Year Average |
|---|---|---|---|---|---|---|
| Fee-Paying FAEs | 136.7 | 134.4 | 140.0 | 140.3 | 117.5 | 133.8 |

The FY 2011 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 133.8, into the fee revenue amount to be derived from application fees in FY 2011, $206,356,667. The result, rounded to the nearest $100, is a fee of $1,542,000 per full application requiring clinical data, and $771,000 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 2010, the establishment fee was based on an estimate that 415 establishments would be subject to, and would pay, fees. By

the end of FY 2010, FDA estimates that 445 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 15 establishment fee waivers or reductions will be made for FY 2010. In addition, FDA estimates that another 15 full establishment fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the act). Subtracting 30 establishments (15 waivers plus the estimated 15 establishments under the orphan exemption) from 445 leaves a net of 415 fee-paying establishments. FDA will use 415 for its FY 2011 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 ($206,356,667) by the estimated 415 establishments, for an establishment fee rate for FY 2011 of $497,200 (rounded to the nearest $100).

*B. Product Fees*

At the beginning of FY 2010, the product fee was based on an estimate that 2,380 products would be subject to and would pay product fees. By the end of FY 2010, FDA estimates that 2,460 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be about 50 waivers and reductions granted. In addition, FDA estimates that another 25 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 2,385 products will qualify for product fees in FY 2010, after allowing for waivers and reductions, including the orphan drug products eligible under the FDAAA exemption, and will use this number for its FY 2011 estimate. Accordingly, the FY 2011 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($206,356,667) by the estimated 2,385 products for a FY 2011 product fee of $86,520 (rounded to the nearest $10).

## V. Fee Schedule for FY 2011

The fee rates for FY 2011 are set out in table 6 of this document:

TABLE 6—FEE SCHEDULE FOR FY 2011

| Fee Category | Fee Rates for FY 2011 |
|---|---|
| Applications | |
| Requiring clinical data | $1,542,000 |
| Not requiring clinical data | $771,000 |
| Supplements requiring clinical data | $771,000 |
| Establishments | $497,200 |
| Products | $86,520 |

## VI. Fee Payment Options and Procedures

*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, 2010. 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 identification (ID) number on your check, bank draft, or postal money order. 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: Wells Fargo, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., rm. D1113–022, Charlotte, NC 28262. (Note: This Wells Fargo 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, bank draft, or postal money order.

Wire transfer payment may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution usually charges a wire transfer fee between $15.00 and $35.00. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, US Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

The tax identification number of the Food and Drug Administration is 53–0196965.

*B. Establishment and Product Fees*

FDA will issue invoices for establishment and product fees for FY 2011 under the new fee schedule in August 2010. Payment will be due on October 1, 2010. FDA will issue invoices in November 2011 for any products and establishments subject to fees for FY 2011 that qualify for fees after the August 2010 billing.

Dated: July 29, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5376–N–78]**

## Notice of Submission of Proposed Information Collection to OMB Research Plan for an Evaluation of the Section 202 Demonstration Planning Grant (DPG) Program

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

This research is intended to help HUD better understand sponsor perspectives on the effectiveness of the DPG program in assisting Section 202 properties reach initial closing within 18 months of fund reservation. The study will also provided information on sponsor perspectives of the marketing of the DPG program by HUD filed office staff, the DPG application process and the overall administration of the grant program. The respondents are both recipients and non-recipients on the 202 DPG grant.

**DATES:** *Comments Due Date: September 3, 2010.*

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB