

*Name of Committee:* Blood Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 20, 2012, from 8 a.m. to 5 p.m. and September 21, 2012, from 8 a.m. to 4 p.m.

*Location:* 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following links: On September 20, 2012, Blood Products Advisory Committee Day 1, <http://fda.yorkcast.com/webcast/Viewer/?peid=27146555dd9347f09571f29589297e0c1d> and on September 21, 2012, Blood Products Advisory Committee Day 2, <http://fda.yorkcast.com/webcast/Viewer/?peid=8effe88a1e834779b4932f882b67e3391d>.

*Contact Person:* Bryan Emery or Pearlina Muckelvine, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1281, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On September 20, 2012, the committee will discuss hepatitis E virus and blood transfusion safety. In the afternoon, the committee will discuss Octapharma's biologics license application for Pooled Plasma (Human, Solvent/Detergent Treated). On September 21, 2012, the committee will discuss considerations for strategies to further reduce the risk of bacterial contamination in Platelets. In the late afternoon the committee will hear the following update: Summary of September 6-7, 2012, public workshop on the risks and benefits of hydroxyethyl starch solutions.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 13, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:15 a.m. and 3:30 p.m. to 4 p.m. on September 20, 2012, and also between approximately 1 p.m. and 2 p.m. on September 21, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 5, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 6, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. The public is encouraged to watch the free Web cast if you are unable to attend this meeting. The link for the Web cast will be available at 8 a.m. each day September 20-21, 2012, located under the *Location* section of this notice.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery, 301-827-1277, or Pearlina Muckelvine, 301-827-1281, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/Advisory>

*Committees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 26, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-18724 Filed 7-31-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0007]

### Prescription Drug User Fee Rates for Fiscal Year 2013

**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) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (Title 1 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, which was signed by the President on July 9, 2012) (PDUFA V)), 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 V, 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 document establishes fee rates for FY 2013 for application fees for an application requiring clinical data (\$1,958,800), for an application not requiring clinical data or a supplement requiring clinical data (\$979,400), for establishment fees (\$526,500), and for product fees (\$98,380). These fees are effective on October 1, 2012, and will remain in effect through September 30, 2013. For applications and supplements that are submitted on or after October 1, 2012, the new fee schedule must be used. Invoices for establishment and product fees for FY 2013 will be issued

in August 2012 using the new fee schedule.

**FOR FURTHER INFORMATION CONTACT:**

David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., PI50, rm. 210J, Rockville, MD 20850, 301-796-7103.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sections 735 and 736 of the FD&C 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 FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013 is to be

adjusted for inflation and workload, and that adjusted FY 2013 amount becomes the base amount for the remaining 4 FYs of PDUFA V. That FY 2013 base revenue amount is further adjusted each year after FY 2013 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.

**II. Fee Revenue Amount for FY 2013**

The statutory fee revenue amount for FY 2013 is \$693,099,000, prior to adjustment for inflation and workload (see section 736(b)(1) of the FD&C Act). Of this amount, \$652,709,000 will be further adjusted for inflation and workload, and \$40,390,000, for new initiatives, will not be adjusted in FY 2013.

*A. FY 2013 Statutory Fee Revenue Adjustments for Inflation*

PDUFA V specifies that \$652,709,000 of the amount for FY 2013 is to be further adjusted for inflation increases for FY 2013 using 2 separate

adjustments—one for payroll costs and one for non-pay costs (see section 736(b)(3)(A) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years multiplied by the proportion of PC&B costs to total FDA costs of the review of human drug applications for the first 3 of the preceding 4 FYs (see section 736(c)(1)(B) of the FD&C Act). The data on total PC&B 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 data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 FYs preceding FY 2013. The 3 year average is 2.17 percent.

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

| Fiscal year                             | 2009            | 2010            | 2011            | 3-Year average |
|---|-----------------|-----------------|-----------------|----------------|
| Total PC&B .....                        | \$1,464,445,000 | \$1,634,108,000 | \$1,761,655,000 | .....          |
| Total FTE .....                         | 11,413          | 12,526          | 13,331          | .....          |
| PC&B per FTE .....                      | \$128,314       | \$130,457       | \$132,143       | .....          |
| Percent Change from Previous Year ..... | 3.56%           | 1.67%           | 1.29%           | 2.17%          |

The statute says that this 2.17 percent should be multiplied by the proportion of PC&B for the review of human drug

applications. Table 2 of this document shows the amount of PC&B and the total amount obligated for the process for the

review of human drug applications for the same 3 FYs.

**TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS**

| Fiscal year        | 2009          | 2010          | 2011          | 3-Year average |
|--------------------|---------------|---------------|---------------|----------------|
| Total PC&B .....   | \$514,874,163 | \$573,603,582 | \$596,627,595 | .....          |
| Total Costs .....  | 855,426,294   | 931,845,581   | 1,025,621,707 | .....          |
| PC&B percent ..... | 60%           | 62%           | 58%           | 60%            |

The payroll adjustment is 2.17 percent multiplied by 60 percent (or 1.30 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2013 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not

seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs of the process for the review of human drug applications other than PC&B (see section 736(c)(1)(C) of the FD&C Act). Table 3 of this document provides the summary data for the percent change in the

specified CPI for the Baltimore-Washington area. The data is published by the Bureau of Labor Statistics and can be found on their Web site at <http://data.bls.gov/cgi-bin/surveymost?cu> by checking the box marked “Washington-Baltimore All Items, November 1996 = 100 – CUURA311SAO” and then clicking on the retrieve data button.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI

| Year                        | 2009    | 2010    | 2011    | 3-Year average |
|-----------------------------|---------|---------|---------|----------------|
| Annual CPI .....            | 140.718 | 142.915 | 146.975 | .....          |
| Annual Percent Change ..... | 0.23%   | 1.72%   | 3.34%   | 1.76%          |

To complete the inflation adjustment for non-pay costs, we multiply the 1.76 percent by the proportion of costs of the process for the review of human drug applications obligated for costs other than PC&B. Since 60 percent was obligated for PC&B as shown in table 2 of this document, 40 percent is the portion of costs other than PC&B (100 percent minus 60 percent equals 40 percent). The non-payroll adjustment is 2.5 percent times 40 percent, or 0.71 percent.

To complete the inflation adjustment, we add the payroll component (1.30 percent) to the non-pay component (0.71 percent), for a total inflation adjustment of 2.01 percent (rounded), and then add one, making 1.0201. We then multiply the amount specified in the statute (\$652,709,000) by 1.0201 percent, yielding an inflation adjusted amount of \$665,828,451.

*B. FY 2013 Statutory Fee Revenue Adjustments for Workload*

PDUFA V specifies that after the \$652,709,000 has been adjusted for inflation, the inflation adjusted amount (\$665,828,451) shall be further adjusted for workload (see section 736(b)(3)(B) of the FD&C Act). For FY 2013 the workload adjustment will be the percentage by which the workload adjustment for FY 2013 exceeds the workload adjuster for FY 2012, if both such adjustments were calculated using the 5 year base period consisting of FYs 2003 through 2007. As published in the

**Federal Register** of August 1, 2011 (76 FR 45831), the FY 2012 workload calculated as directed was 8.12 percent.

To calculate the FY 2013 adjustment factor, 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 (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, 2012.

The calculations are summarized in table 4 of this document. The 5-year averages for each application category are provided in column 1 (“5-Year Average Base Years 2003–2007”) and column 2a (“5-Year Average 2008–2012”).

PDUFA specifies that FDA make additional adjustments for changes in review activities to human drug applications and active commercial INDs. These adjustments, started under PDUFA IV, are summarized in columns 2b and 2c in table 4 of this document. The number in the new drug applications/biologics license applications (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 2003 through 2007, to the 5-year period 2008 through 2012. 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 2003 through 2007, to the 5-year period 2008 through 2012. 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 4 of this document reflects the percent change in workload from column 1 to column 2c. Column 4 of table 4 of this document 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 4 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 4 of this document is the sum of the values in column 5 that are added, reflecting an increase in workload of 9.99 percent for FY 2013 when compared to the base years.

TABLE 4—WORKLOAD ADJUSTER CALCULATIONS FOR FY 2013

| Application type                | Column 1<br>5-Year Average<br>base years<br>2003–2007 | Column 2a<br>5-Year<br>Average<br>2008–2012 | Column 2b<br>Adjustment<br>for changes<br>in review<br>activity | Column 2c<br>Column 2a<br>increased<br>by column<br>2b | Column 3<br>Percent<br>change (col-<br>umn 1 to<br>column 2c) | Column 4<br>Weighting<br>factor | Column 5<br>Weighted<br>percent<br>change |
|---------------------------------|---|---|---|--|---|---------------------------------|---|
| NDAs/BLAs .....                 | 123.8   | 134.4                                       | 0.08%   | 134.5  | 8.6%  | 39.6%                           | 3.42%                                     |
| Active commercial INDs .....    | 5,528.2   | 6724.2                                      | – 3.13%   | 6513.7   | 17.8%   | 40.3%                           | 7.18%                                     |
| Efficacy supplements .....      | 163.4   | 153.8                                       | NA  | 153.8  | – 5.9%  | 9.5%                            | – 0.56%                                   |
| Manufacturing Supplements ..... | 2589.2  | 2575.4                                      | NA  | 2575.4   | – 0.5%  | 10.6%                           | – 0.06%                                   |
| FY 2013 Workload Adjuster ..... | .....   | .....                                       | .....   | .....  | .....   | .....                           | 9.99%                                     |

Since the calculated workload adjustment for 2013 (9.99 percent) is greater than the 8.12 percent that was calculated last year for FY 2012 the difference between the two, 1.87 percent

(9.99 percent minus 8.12 percent), and that is the amount of the workload adjustment for FY 2013 (see section 736(b)(3)(B) of the FD&C Act).

Table 5 of this document shows the calculation of the revenue amount for FY 2013. The \$652,709,000 subject to adjustment on the first line is multiplied by the combined inflation adjustment

factor of 1.0201, resulting in the inflation adjusted amount on the third line. That amount is then multiplied by one plus the workload adjustment of 1.87 percent, resulting in the inflation and workload adjusted amount of \$678,279,443 on the fifth line. Finally the portion of the FY 2013 fees not subject to adjustment (\$40,390,000) is added, resulting in the total FY 2013 fee revenue amount of \$718,669,000 on the last line of table 5 of this document.

**TABLE 5—PDUFA REVENUE AMOUNT FOR FY 2013 AND BASE FOR SUBSEQUENT YEARS**

|  |               |
|--|---------------|
| Portion of FY 2013 Revenues Subject to Adjustments .....   | \$652,709,000 |
| Amount of Inflation Adjustment Factor for FY 2013 .....  | 1.0201        |
| Inflation Adjusted Amount (1 plus 2.01 percent) .....  | \$665,828,451 |
| Workload Adjustment Factor for FY 2013 (1 plus 1.87 percent) .....                               | 1.0187        |
| Inflation and Workload Adjusted Amount .....   | \$678,279,443 |
| Portion of 2013 Revenues Not Subject to Adjustment .....   | \$40,390,000  |
| FY 2013 Revenue Amount and Base for Subsequent Years (Rounded to nearest thousand dollars) ..... | \$718,669,000 |

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 FD&C Act). Accordingly, one third of the total revenue amount (\$718,669,000), or a total of \$239,556,333, is the amount of fee revenue that will be derived from each

of these fee categories: Application Fees, Establishment Fees, and Product Fees.

While the fee revenue amount anticipated in FY 2013 is \$718,669,000, as the previous paragraph shows, FDA assumes that the fee appropriation for FY 2013 will be 5 percent higher, or \$754,602,000, rounded to the nearest thousand dollars. The latest PDUFA 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 real surge in review workload that caused the increased collections—an unexpected increase in the number of applications that FDA must review in accordance with PDUFA goals. For this reason, in most fiscal years since 1993,

actual appropriations have slightly exceeded PDUFA fee revenue estimates made each year.

**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 \$239,556,333 in FY 2013, as calculated previously in this document.

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

For FY 2013 through FY 2017, 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 3 most recently completed fiscal years. This will avoid having FDA try to estimate the number it expects to receive in the current fiscal year.

In estimating the number of fee-paying FAEs, 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.

As Table 6 of this document shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 122.3 FAEs. FDA will set fees for FY 2013 based on this estimate as the number of full application equivalents that will pay fees.

**TABLE 6—FEE-PAYING FAE 3-YEAR AVERAGE**

| Fiscal year           | 2009  | 2010  | 2011   | 3-Year average |
|-----------------------|-------|-------|--------|----------------|
| Fee-Paying FAEs ..... | 140.3 | 118.4 | 108.25 | 122.3          |

The FY 2013 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 122.3, into the fee revenue amount to be derived from application fees in FY 2013, \$239,556,333. The result, rounded to the nearest \$100, is a fee of \$1,958,800 per full application requiring clinical data, and \$979,400 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 2012, the establishment fee was based on an estimate that 450 establishments would be subject to, and would pay, fees. By the end of FY 2012, FDA estimates that 480 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 10 establishment fee waivers

or reductions will be made for FY 2012. In addition, FDA estimates that another 15 full establishment fees will be exempted this year based on the orphan drug exemption in the Food and Drug Administration Amendments Act (FDAAA) (see section 736(k) of the FD&C Act). Subtracting 25 establishments (10 waivers, plus the estimated 15 establishments under the orphan exemption) from 480 leaves a net of 455 fee-paying establishments. FDA will use 455 for its FY 2013 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 (\$239,556,333) by the estimated 455 establishments, for an establishment fee rate for FY 2013 of \$526,500 (rounded to the nearest \$100).

#### B. Product Fees

At the beginning of FY 2012, the product fee was based on an estimate that 2,365 products would be subject to and would pay product fees. By the end of FY 2012, FDA estimates that 2,525 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 50 waivers and reductions granted. In addition, FDA estimates that another 40 product fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the FD&C Act). FDA estimates that 2,435 products will qualify for product fees in FY 2012, after allowing for waivers and reductions, including the orphan drug products eligible under the FDAAA exemption, and will use this number for its FY 2013 estimate. The FY 2013 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$239,556,333) by the estimated 2,435 products for a FY 2013 product fee of \$98,380 (rounded to the nearest \$10).

#### V. Fee Schedule for FY 2013

The fee rates for FY 2013 are set out in Table 7 of this document:

TABLE 7—FEE SCHEDULE FOR FY 2013

| Fee category                              | Fee rates for FY 2013 |
|---|-----------------------|
| Applications:                             |                       |
| Requiring clinical data ...               | \$1,958,800           |
| Not requiring clinical data .....         | 979,400               |
| Supplements requiring clinical data ..... | 979,400               |
| Establishments .....                      | 526,500               |
| Products .....                            | 98,380                |

#### 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, 2012. 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 979107, St. Louis, MO 63197-9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact the U.S. Bank at 314-418-4013 if you have any questions concerning courier delivery.)

Please make sure that the FDA post office box number (P.O. Box 979107) 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 may charge 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, U.S. Department of the 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 2013 under the new fee schedule in August 2012. Payment will be due on October 1, 2012. FDA will issue invoices in November 2013 for any products and establishments subject to fees for FY 2013 that qualify for fee assessments after the August 2012 billing.

Dated: July 24, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-18711 Filed 7-31-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

*Date:* August 16-17, 2012.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, [freundr@csr.nih.gov](mailto:freundr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular Hematology I.

*Date:* August 29, 2012.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435-1210, [chaudhaa@csr.nih.gov](mailto:chaudhaa@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 26, 2012.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-18689 Filed 7-31-12; 8:45 am]

**BILLING CODE 4140-01-P**