Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; HIV/AIDS Vaccines Study Section.

Date: November 20, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AMCB, AIP and NAED Member Conflicts.

Date: November 23, 2009.

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: Eduardo A. Montalvo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@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: October 19, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–25726 Filed 10–26–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs 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 December 15, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Montgomery Ballroom, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 15, 2009, the subcommittee will consider and discuss: (1) FDA expectations regarding the development of pediatric formulations for cancer drugs, and (2) the development of dosing regimens in infants and toddlers with cancer.

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 link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before December 1, 2009. Oral presentations from the public will be scheduled between approximately 10:45 a.m. to 11:15 a.m., and 3:15 p.m. to 3:45 p.m. Those desiring to make 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 November 20, 2009. 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 November 23, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Diem-Kieu Ngo 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/AdvisoryCommittees/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: October 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25806 Filed 10–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs 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 December 15, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301–977–8900.

Contact Person: Paul Tran, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 15, 2009, the committee will discuss supplemental new drug application (sNDA) 21–366, CRESTOR (rosuvastatin calcium) tablets, AstraZeneca Pharmaceuticals. CRESTOR is a member of the statin drug class which lowers lipids (fats that circulate in the bloodstream, including cholesterol) by inhibiting HMG-CoA reductase, an enzyme involved in producing lipids in the body. The proposed indication (use) of CRESTOR in this application is primary prevention of cardiovascular disease based on the results of JUPITER. JUPITER was a clinical trial that studied individuals who did not have obvious or overt cardiovascular disease, but did have the following characteristics: Low or normal levels of the variety of cholesterol known as low-density lipoprotein, or LDL; elevated levels of C-reactive protein (hsCRP), a marker of inflammation in the body, and at least one of the conventional risk factors for cardiovascular disease. (The ''conventional risk factors'' are smoking, age, high blood pressure, low levels of the good cholesterol, HDL, and family history of heart disease). In these individuals, JUPITER evaluated the reduction of risk with rosuvastatin therapy on the study's combined objectives (known as the study's ''composite endpoint'') which included: Death from heart disease (heart attack) or vascular disease (stroke), heart attack that did not result in death, stroke that did not result in death, unstable angina (when the heart does not get enough blood flow, often a warning of heart attack), and heart or blood vessel disease that necessitates arterial revascularization, commonly known as ''bypass surgery.''

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 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 December 1, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 November 20, 2009. 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 November 23, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Paul Tran 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/AdvisoryCommittees/About AdvisoryCommittees/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: October 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25805 Filed 10–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0339]

Prescription Drug User Fee Rates for Fiscal Year 2010; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of August 3, 2009 (74 FR 38451). The document announced the fiscal year 2010 fee rates for the Prescription Drug User Fee Act. The document was published with errors. This document corrects those errors.

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: In FR Doc. E9–18457, appearing on page 38451, in the **Federal Register** of Monday, August 3, 2009, the following corrections are made:

1. On page 38451, in the first column, in the **SUMMARY** section, the fifth sentence ''This notice establishes fee rates for FY 2010 for application fees for an application requiring clinical data ($1,405,500), for an application not requiring clinical data or a supplement requiring clinical data ($702,750), for establishment fees ($457,200), and for product fees ($77,720).'' is corrected to read ''This notice establishes fee rates for FY 2010 for application fees for an application requiring clinical data ($1,405,500), for an application not requiring clinical data or a supplement requiring clinical data ($702,750), for establishment fees ($457,200), and for product fees ($79,720).''

2. On page 38452, the title of table 2 is corrected to read ''Table 2.—FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Change (Dollars in Thousands)''.

3. On page 38452, in table 2, in the fourth column that begins ''PC&B per FTE'', remove '','' everywhere it appears and replace it with ''.''.

4. On page 38454, footnote 1 to table 3 is corrected to read ''[1] Table 3 published in the **Federal Register** of August 1, 2008 (73 FR 45017), showed the average number of active INDs for the base years of 2002–2007 as 5,755.8. FDA discovered that a small subset of INDs had been double counted in the number reported last year. That error has been corrected in the revised number of 5,528.2 reflected in the table this year. Had the error not been made, the workload adjustment in FY 2009 would have been 3.76 percent rather than the 2.98 percent published in the **Federal Register** last year.''

Dated: October 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25804 Filed 10–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Emerging Arboviruses: Risk Assessment for Blood, Cell, Tissue, and Organ Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Emerging Arboviruses: Risk Assessment for Blood, Cell, Tissue and Organ Safety.'' The purpose of the public workshop is to assess the risk and discuss approaches to minimize the incidence of transmission of arboviruses