

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/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.*

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## 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 ";", wherever it appears and replace it with ".".

4. On page 38454, footnote 1 to table 3 is corrected to read "<sup>1</sup> 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.*

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## 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