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

(arthropod-borne viruses), by transfusion, infusion, implantation, or transplantation in the United States. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on December 14, 2009, from 8:30 a.m. to 5:30 p.m. and December 15, 2009, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Natcher Conference Center, Main Auditorium, Bldg. 45, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 550N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the *Contact Person* by November 20, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

Requests for Presentations of Data: Interested persons are invited to present data related to technologies for the detection or inactivation of arboviruses in blood products, organs, or tissues. If you are interested in presenting, submit a brief statement of the general nature of the presentation to the *Contact Person* by November 20, 2009 (see section II of this document for additional information).

SUPPLEMENTARY INFORMATION:

I. Background

Arboviruses are a large group of viruses that are spread by certain invertebrate animals, most commonly blood-sucking insects. Arboviruses are found throughout the world, including the United States. Arboviruses, such as Dengue virus, Japanese Encephalitis virus (JE), tick-borne encephalitis virus (TBE), and West Nile virus (WNV), are becoming increasingly widespread. Transmission of WNV and Dengue virus through blood transfusion has been well documented. Transfusion transmission of the Colorado tick fever (CTF) virus, a tick-borne agent present in the United States, also has been reported. Other arboviruses, including JE, TBE, and St. Louis Encephalitis are of concern to blood, cell, tissue, and organ safety because of the possibility of viremia in asymptomatic human infections. Dengue outbreaks have recently occurred in Texas, Hawaii, Puerto Rico, and the U.S. Virgin Islands. Dengue virus, as well as TBE, and JE, have the potential to become endemic in certain regions of the United States. Therefore, proactive discussions among the Department of Health and Human Services public health agencies, including the FDA, National Institutes of Health, and the Centers for Disease Control and Prevention, academia, industry, blood establishments, cell and tissue establishments, and other stakeholders are necessary to address blood, cell, tissue, and organ safety in response to the emerging arboviruses.

The public workshop will facilitate a scientific discussion on approaches to reduce the risk of transmission of arboviruses by transfusion, infusion, implantation, or transplantation in the United States. Topics to be discussed include: (1) Biology and pathogenesis of arboviruses; (2) epidemiology and prevention of arbovirus vectors and hosts in the United States; (3) laboratory detection and prevention of arbovirus infection in humans; (4) transfusion, infusion, implantation or transplantation transmission of arboviruses in the United States; and (5) potential approaches, including donor testing and pathogen inactivation, to reduce the risk of transfusion transmission of arboviruses.

II. Requests for Presentations of Data

Interested persons are invited to present data related to technologies for the detection or inactivation of arboviruses in blood products, organs, or tissues. Those desiring to make presentations at the workshop should notify the *Contact Person* and submit a brief statement of the general nature of the presentation before November 20, 2009. Presentations will be scheduled on the afternoon of December 15, 2009. Time allotted for each presentation will be limited depending on the number of individuals requesting to speak.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.*

Dated: October 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25802 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–2004–N–0063] (formerly Docket No. 2004N–0346)

Saccharomyces boulardii Eligibility for Consideration To Be Added to the Over-the-Counter Drug Monograph for Antidiarrheal Drug Products; Request for Safety and Effectiveness Data; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of notice of eligibility and request for data and information.

SUMMARY: We (Food and Drug Administration (FDA)) are withdrawing a notice of eligibility and call-for-data for safety and effectiveness information. The original notice published in the **Federal Register** of August 23, 2004 (69 FR 51852). In that notice, we announced that *Saccharomyces boulardii* (*S. boulardii*) was eligible for consideration to be added to the over-the-counter (OTC) monograph for antidiarrheal drug products.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION: In 2004, we published a notice of eligibility for consideration of the yeast *S. boulardii* in the OTC drug monograph system. We announced our intention to evaluate *S. boulardii* for inclusion in the monograph for OTC antidiarrheal drug products (21 CFR part 335). The notice also requested submission of data and information on the safety and effectiveness of *S. boulardii* for us to determine whether it could be generally recognized as safe and effective (GRAS/E) and not misbranded for its proposed OTC drug use.

S. boulardii for antidiarrheal use meets the definition of a drug in the Federal Food, Drug, and Cosmetic Act.