V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Revised comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 16, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–31214 Filed 12–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Blood Products Advisory Committee; Notice of Meeting; Amendment

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the Blood Products Advisory Committee. This meeting was announced in the **Federal Register** of December 9, 2008 (73 FR 74725). The amendment is being made to reflect a change in the *Agenda* portion of the document.

FOR FURTHER INFORMATION CONTACT: *Contact Person:* William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 9, 2008, FDA announced that a meeting of the Blood Products Advisory Committee would be held on January 9, 2009. On page 74725, in the first column, in the 13th line of the *Agenda* portion of the document, after the phrase ''Acid Constructs'' the following has been added:

''Included in the update will be an overview of the Center of Veterinary Medicine's review of the new animal drug application pertaining to the genetically engineered animals producing milk that contains recombinant Antithrombin III and of the environmental assessment for that application.''

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: December 24, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–31187 Filed 12–29–08; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Cardiovascular and Renal 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: Cardiovascular and Renal 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 February 3, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Elaine Ferguson, 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, email: *elaine.ferguson@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. 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: The committee will discuss new drug application (NDA) 22–307, prasugrel hydrochloride film coated oral tablets, 5 milligrams (mg) and 10 mg, Eli Lilly and Company, for the proposed indication for use in acute coronary syndrome.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 January 16, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. to 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 January 9, 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 January 12, 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 Elaine Ferguson 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/oc/advisory/default.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: December 19, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–31217 Filed 12–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Advisory Committee on Organ Transplantation (ACOT). The ACOT was established by the Amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR Part 121) and, in accordance with Public Law 92–463, was chartered on September 1, 2000.

DATES: The agency must receive nominations on or before February 2, 2009.

ADDRESSES: All nominations should be submitted to the Executive Secretary, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12–105, 5600 Fishers Lane, Rockville, Maryland 20857. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Secretary, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, at the above address.

FOR FURTHER INFORMATION CONTACT: Remy Aronoff, Executive Secretary, Advisory Committee on Organ Transplantation, at (301) 443–3300 or e-mail *Remy.Aronoff@hrsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: As provided by 42 CFR 121.12 (64 FR 56661), the Secretary established the Advisory Committee on Organ Transplantation. The Committee is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The ACOT advises the Secretary, acting through the Administrator, HRSA, on all aspects of organ procurement, allocation, and transplantation, and on other such matters that the Secretary determines. One of its principal functions is to advise the Secretary on ways to maximize Federal efforts to increase living and deceased organ donation nationally. Other matters that recently have been reviewed by the ACOT include:

- Accreditation of all establishments required to be registered with the FDA as manufacturers of human cells, tissues, and cellular- and tissue-based products;
- Concerns about U.S. citizens traveling abroad in order to receive organ transplants (also known as transplant tourism);
- Collection of data on the long-term health status of living donors;
- Organ Procurement and Transplantation Network development and distribution within the transplant community of a set of practice guidelines to be followed with respect to public solicitation of organ donors, both living and deceased; and
- Standards of coverage for living donors relating to future adverse events.

The ACOT consists of up to 25 members, including the Chair. Members and Chair shall be selected by the Secretary from individuals knowledgeable in such fields as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members. To the extent practicable, Committee members should represent the minority, gender and geographic diversity of transplant candidates, transplant recipients, organ donors and family members served by the OPTN. In addition, the Director, Centers for Disease Control and Prevention; the Administrator, Centers for Medicare and Medicaid Services; the Commissioner, Food and Drug Administration; the Director, National Institutes of Health; and the Director, Agency for Healthcare Research and Quality (or the designees of such officials) serve as non-voting ex-officio members.

Specifically, HRSA is requesting nominations for voting members of the ACOT representing: Health care public policy; transplantation medicine and surgery, including pediatric and heart/lung transplantation; critical care medicine; nursing; epidemiology and applied statistics; immunology; law and bioethics; behavioral sciences; economics and econometrics; organ procurement organizations; transplant candidates/recipients; transplant/donor family members; and living donors. Nominees will be invited to serve a 4-year term beginning after July 2009.

HHS will consider nominations of all qualified individuals with a view to ensuring that the Advisory Committee includes the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the ACOT. Nominations shall state that the nominee is willing to serve as a member of the ACOT and appears to have no conflict of interest that would preclude the ACOT membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the Committee to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would