The burden is based on the number of applications received in the last 3 years.

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14267 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Allergenic 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 13, 2006 from 12 noon to approximately 3:45 p.m.

Location: National Institutes of Health, Bldg. 29B, Conference Rooms A and B, Bethesda, MD.

Contact Person: Gail Dapolito or Jane Brown, 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 3014512388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 13, 2006, the committee will discuss a proposed strategy for the reclassification of Category IIIA allergenic products. The committee will also receive an update of the research program of the Laboratory of Immunobiochemistry, Division of Bacterial, Parasitic and Allergenic Products, Center for Biologics Evaluation and Research.

Procedure: On September 13, 2006, from 12 noon to approximately 3:15 pm, the meeting is open to the public. 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 6, 2006. Oral presentations from the public will be scheduled between approximately 1:45 pm and 2:45 pm. Time allotted for each presentation may be limited. 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 September 6, 2006.

Closed Committee Deliberations: On September 13, 2006 from approximately 3:15 pm to 3:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss individual research programs in the Office of Vaccines Research and Review.

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 Gail Dapolito at least 7 days in advance of the meeting.

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

Dated: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14295 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cardiovascular and Renal Drugs Advisory Committee. This meeting was originally announced in the **Federal Register** of August 1, 2006 (71 FR 43487). The amendment is being made to reflect changes in the *Agenda* portion of the document. The word ''TRASYOL'' should read ''TRASYLOL''. In the same paragraph, the word ''apportioning'' should read ''aprotinin''. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Cathy Groupe, 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: 301–827–6778, e-mail: *Cathy.Groupe@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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 1, 2006, FDA announced that the Cardiovascular and Renal Drugs Advisory Committee would meet on September 21, 2006, from 8 a.m. to 5 p.m., and the committee would discuss clinical data for aprotinin injection (trade name, TRASYLOL), an approved product, new drug application (NDA) 020–304, Bayer Pharmaceuticals). On page 43487, in the third column, the *Agenda* portion of the document is amended to read as follows:

Agenda: The committee will discuss clinical data for aprotinin injection (trade name, TRASYLOL), an approved product, new drug application (NDA) 020–304, Bayer Pharmaceuticals) with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery. This discussion follows a February 8, 2006, FDA Public Health Advisory for the use of aprotinin injection (*www.fda.gov/cder/drug/advisory/aprotinin.htm*).

The background material for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Cardiovascular and Renal Drugs Advisory Committee'' (Click on the year 2006 and scroll down to the above named committee meeting.)

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: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14294 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S