afternoon session, the committee will discuss issues related to the risk of Babesia infection by blood transfusions and the status of laboratory tests. On July 27, 2010, the committee will discuss blood donor hemoglobin/hematocrit qualifications standards, iron status, and interdonation interval.

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 July 19, 2010. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:30 p.m. and between 4 p.m. and 4:45 p.m. on July 26, 2010, and between approximately 10:30 a.m. and 11 a.m. on July 27, 2010. 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 July 9, 2010. 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 July 12, 2010.

Persons planning to attend 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 Bryan Emery 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).


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–15018 Filed 6–21–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Ophthalmic Devices Panel of the Medical Devices 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: Ophthalmic Devices Panel of the Medical Devices 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 July 30, 2010, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: James Engles, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1566, Silver Spring, MD 20993–0002, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512396. 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 July 30, 2010, the committee will discuss, make recommendations, and vote on a premarket approval application for the Glaukos iStent Trabecular Micro-Bypass Stent, Model GTS–100 L/R, sponsored by Glaukos Corp. The device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in subjects with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. For this device, the patients should have normal gonioscopic anatomy and a visually significant cataract eligible for phacoemulsification. The patient’s glaucoma should be considered mild to moderate Primary Open Angle Glaucoma, or the secondary open angle glaucomas, Pigmentary Glaucoma and Pseudoexfoliation Glaucoma. Patients with other causes of secondary open angle glaucoma or angle closure glaucomas are not eligible for use of this device. Patients’ IOP should be controlled on 1–3 glaucoma medications and patients should not previously have had surgery for glaucoma.

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 July 22, 2010. Oral presentations from the public will be scheduled approximately between 1 and 2 p.m. or immediately following lunch. 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 July 14, 2010. 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 July 15, 2010.

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 AnnMarie
Williams, Conference Management
Staff, at 301–796–5966, 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/Advisory
Committees/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).


Jill Hartzler Warner,
Acting Associate Commissioner for Special
Medical Programs.

[FR Doc. 2010–15019 Filed 6–21–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

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 July 29, 2010, from 8 a.m. to 5
p.m.

Location: The Marriott Inn and
Conference Center, University of
Maryland University College, 3501
University Blvd. East, Adelphi, MD. The
conference center telephone number is
301–985–7300.

Contact Person: Elaine Ferguson, c/o
Christine Shipe, Center for Drug
Evaluation and Research, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 31, rm. 2419,
Silver Spring, MD 20993–0002, 301–
796–9001, FAX: 301–847–8532, e-mail:
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: On July 29, 2010, the
committee will discuss Revatio
(sildenafil) for the treatment of pediatric
pulmonary arterial hypertension (PAH)
and whether to amend the clinical trials
section of the written request, issued by
FDA to Pfizer, to include assessment of
a hemodynamic endpoint. An area of
particular interest will be what the
appropriate study endpoint should be in
patients with PAH unable to perform
exercise testing. The discussion will
help the agency determine what studies
to request for products intended to treat
pediatric PAH.

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 July 14, 2010. 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 July 6, 2010. 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 July 7, 2010.

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

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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
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public conduct during advisory
committee meetings.

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


Jill Hartzler Warner,
Acting Associate Commissioner for Special
Medical Programs.

[FR Doc. 2010–15019 Filed 6–21–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and
Prevention

Advisory Board on Radiation and
Worker Health (ABRWH or Advisory
Board), National Institute for
Occupational Safety and Health
(NIOSH)

In accordance with section 10(a)(2) of
the Federal Advisory Committee Act
(Pub. L. 92–463), the Centers for Disease
Control and Prevention (CDC),
announces the following meeting for the
aforementioned committee:

Time and Date: 11 a.m.–3 p.m., July
14, 2010.