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. 2013–29933 Filed 12–16–13; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2013–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 January 16, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting. For 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 Kristina Toliver at least 7 days in advance of the meeting.

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 meeting 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 9, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making 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 3, 2014. 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 6, 2014.

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 Kristina Toliver at least 7 days in advance of the meeting.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2013–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 January 14, 2014, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room.
VerDate Mar<15>2010 14:45 Dec 16, 2013 Jkt 232001 PO 00000 Frm 00041 Fmt 4703 Sfmt 4703 E:\FR\FM\17DEN1.SGM 17DEN1

Before the committee. Written
orally or in writing, on issues pending
present data, information, or views,
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
www.fda.gov/AdvisoryCommittees/
default.htm and scroll down to the
appropriate advisory committee
meeting link, or call the advisory committee
information line to learn about possible
modifications before coming to the
meeting.

Agenda: The committee will discuss
new drug application (NDA) 203202,
NORTHERA (droxidopa capsules),
submitted by Chelsea Therapeutics, Inc.,
for the treatment of symptomatic
neuropathic orthostatic hypotension in
patients with primary autonomic failure
(Parkinson’s disease, multiple system
atrophy, or pure autonomic failure),
dopamine beta-hydroxylase deficiency,
and non-diabetic autonomic neuropathy.

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 meeting
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 9, 2014.
Oral presentations from the public will
be scheduled between approximately 1
p.m. and 2 p.m. Those individuals
interested in making 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
3, 2014. 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 6, 2014.

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
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Toliver at least 7 days in advance of the
meeting.

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color 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. 2013–29917 Filed 12–16–13; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Health Resources and Services
Administration

Agency Information Collection
Activities: Proposed Collection: Public
Comment Request

AGENCY: Health Resources and Services
Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the
requirement for opportunity for public
comment on proposed data collection
projects (Section 3506(c)(2)(A) of the
Paperwork Reduction Act of 1995), the
Health Resources and Services
Administration (HRSA) announces
plans to submit an Information
Collection Request (ICR), described
below, to the Office of Management and
Budget (OMB). Prior to submitting the
ICR to OMB, HRSA seeks comments
from the public regarding the burden
estimate, below, or any other aspect of
the ICR.

DATES: Comments on this Information
Collection Request must be received
within 60 days of this notice.

ADDRESSES: Submit your comments to
paperwork@hrsa.gov or mail the HRSA
Information Collection Clearance
Officer, Room 10–29, Parklawn
Building, 5600 Fishers Lane, Rockville,
MD 20857.

FOR FURTHER INFORMATION CONTACT:
To request more information on the
proposed project or to obtain a copy of
the data collection plans and draft
instruments, email paperwork@hrsa.gov
or call the HRSA Information Collection
Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When
submitting comments or requesting
information, please include the
information request collection title for
reference.

Information Collection Request Title:
HRSA AIDS Drug Assistance Program
Quarterly Report OMB No. 0915–0294—
Extension

Abstract: HRSA’s AIDS Drug
Assistance Program (ADAP) is funded
through Part B of Title XXVI of the
Public Health Service Act, as amended
by the Ryan White HIV/AIDS Treatment
Extension Act of 2009 (The Ryan White
HIV/AIDS Program), which provides
grants to states and territories. ADAP
provides medications for the treatment
of HIV disease. Program funds may also
be used to purchase health insurance for
eligible clients or for services that
enhance access, adherence, and
monitoring of drug treatments.

Need and Proposed Use of the
Information: Each of the 50 states, the
District of Columbia, Puerto Rico, the
Virgin Islands, and the Pacific territories
receive ADAP grants. As part of the
funding requirements, ADAP grantees
submit quarterly reports that include
information on patients served,
pharmaceuticals dispensed, pricing,
sources of support to provide HIV/AIDS
medications, eligibility requirements,
cost data, and coordination with

Health Resources and Services
Administration

Agency Information Collection
Activities: Proposed Collection: Public
Comment Request

AGENCY: Health Resources and Services
Administration, HHS.