response for each submission is based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the final rule, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations. FDA estimates 8 hours to develop and revise the labeling to make such changes. The average burden per response for each submission is based on the estimated time to develop and revise the labeling to make such changes.

In the **Federal Register** of February 18, 2014 (79 FR 9219), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from the public. The comment was not responsive to the comment request on the four specified aspects of the collection of information and did not provide any data or explanation that would support a change regarding the information collection requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	24	24
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	8	8
Total					32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 10, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16589 Filed 7–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Food and Drug Administration Third Annual Patient Network Meeting; Under the Microscope: Pediatric Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA), Office of Health and Constituent Affairs (OHCA) is announcing a 1-day meeting to explore challenges related to pediatric product development. The meeting will serve as a forum for FDA's stakeholders (patients, caregivers, patient advocates, healthcare professional groups, the general public, academia, and industry) to learn about regulations that encourage pediatric product development; to discuss ways to advance pediatric product development, how health disparities impact pediatric product development, the importance of transparency in pediatric clinical trials, and how analysis of information from failed pediatric clinical trials might improve future designs for pediatric trials; and to identify ways patient input can benefit clinical trial design for pediatric trials.

The 1-day meeting will also provide an opportunity to participate in panel discussions on the challenges related to development of products used to treat pediatric patients, including pediatric patients with rare diseases and explore ways that patients/caregivers, FDA, and industry may work together to incorporate patient input in future pediatric product development and regulatory decisionmaking.

DATES: The public meeting will be held on September 10, 2014, from 8 a.m. to 4:30 p.m. If you wish to attend the 1-day meeting, visit the Patient Network at *http://patientnetwork.fda.gov/3rd-annual-patient-network.* Please register before September 5, 2014. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend the meeting in person or via the webcast. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. There is no registration fee for this meeting and early registration is suggested because space is limited. We request that non-patient organizations limit the number of representatives to three. For further registration information or problems with the Web site call Steve Morin (see **FOR FURTHER INFORMATION CONTACT**) at 301–796–0161 or email at *patientnetwork@fda.hhs.gov.*

If you need special accommodations due to a disability, please specify those accommodations when registering for this 1-day meeting.

ADDRESSES: The meeting will be held at the Washington Marriott at Metro Center, 775 12th St. NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Steve Morin, Office of Health and Constituent Affairs, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0161, FAX: 301–847–8623, *patientnetwork@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. The FDA Patient Network

This is the third FDA Patient Network Annual Meeting hosted by OHCA, the Agency's primary liaison with patient and health professional communities. This annual meeting is being hosted as part of the larger FDA Patient Network program. The FDA Patient Network is a resource that seeks to:

- Educate and inform patients and patient advocacy organizations about FDA's:
  - Regulatory authorities and processes;
  - Initiatives;
  - Public meetings;
  - Ways to comment on FDA draft guidances; and
- Provide a venue for patient advocacy involvement within the FDA.

In addition to an annual meeting, the FDA Patient Network consists of:

- The FDA Patient Network Web site (*www.patientnetwork.fda.gov*)—a patient-centered Web site that contains:
  - Educational modules and FDA webinars;
  - Centralized agency information for patients;
  - Periodic LiveChat and listening discussions between patient advocates and FDA staff; and
- The biweekly FDA Patient Network News email newsletter informs the community on current FDA-related information on medical product:
  - Medical approvals;
  - Safety labeling changes;
  - Safety warnings;
  - Ways to participate on upcoming public meetings;
  - Ways to comment on proposed regulatory guidances;
  - Information on food safety; and
  - Other information of interest to patient and patient advocates.

To sign up for the FDA Patient Network News, visit *http://www.patientnetwork.fda.gov/get-involved/get-newsletter.*

FDA will post the agenda 5 days before the meeting at *http://patientnetwork.fda.gov/3rd-annual-patient-network.*

Dated: July 11, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16714 Filed 7–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–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 September 10, 2014, from 8:30 a.m. to 4:30 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, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *CRDAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://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 be asked to discuss the potential clinical utility of fixed-combination prescription drugs composed of an anti-hypertensive drug, aspirin, and a statin administered to reduce the risk of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke in patients with a history of cardiovascular disease. The committee will be asked to discuss the patient population that could benefit from such a product, whether that population would be likely to take such a drug long term, and how this could be assured. The committee will also be asked to consider the pros and cons of a treatment that would not be titrated and in a setting where monitoring might not be rigorous.

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 August 25, 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 August 15, 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 August 18, 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.

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).

Dated: July 10, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–16671 Filed 7–15–14; 8:45 am]

BILLING CODE 4164–01–P