discussion and consideration. During the first session, the Office of Pharmaceutical Science and the Office of Compliance will discuss with the committee the use of statistical methods for the evaluation of pharmaceutical product quality. The committee will receive presentations from the Agency on the need for objective metrics of product quality and some of the available statistical methods used by other industries in their quality assurance programs. Representatives from the pharmaceutical industry will provide the manufacturers' perspective.

During the second session, the committee will receive an update and status on research activities within the Office of Pharmaceutical Science supporting regulatory decision making. There will be presentations from the Office of Generic Drugs, the Office of Testing and Research, and the Office of Biotechnology Products. This will be an awareness topic and there will not be formal committee discussion or recommendation.

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 October 16, 2013. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 12:15 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 October 7, 2013. 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 October 8, 2013.

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 Kalyani Bhatt 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: September 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–23021 Filed 9–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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 October 31, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., 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: Kalyani Bhatt, 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: *ACPS-CP@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/AdvisoryCcommittees/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: There will be two topics presented to the committee for their discussion and consideration. During the first session, the Office of New Drug Quality Assessment will lead a discussion on the challenges and opportunities of continuous manufacturing for pharmaceutical products. Speakers from the Agency, academia, and industry will provide their thoughts on scientific and regulatory challenges for implementing continuous processes for drug substance and drug product manufacturing.

During the second session, the committee will receive an informational only update from the Office of Generic Drugs on what Agency actions/changes have taken place following previous discussions with the committee pertaining to quality and bioequivalence concerns for narrow therapeutic index drug products. This will be an awareness topic and there will not be formal committee discussion or recommendation.

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 October 16, 2013. Oral presentations from the public will be scheduled between approximately 10:45 a.m. to 11:45 a.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 October 7, 2013. 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 October 8, 2013.

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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: September 16, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–23022 Filed 9–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1073]

Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases.'' This public workshop is organized by the Center for Devices and Radiological Health (CDRH) and the Office of Orphan Products Development (OOPD) and is being held in conjunction with the Center for Drug Evaluation and Research's workshop entitled ''Complex Issues in Developing Drug and Biological Products for Rare Diseases.'' The purpose of the public workshop is to discuss issues related to the following broad topics associated with medical devices for the diagnosis and treatment of pediatric patients affected by rare diseases: Current approaches toward use of medical devices for pediatric clinical practice; Humanitarian Device Exemption (HDE) marketing pathway, including the Humanitarian Use Device (HUD) designation process; Pediatric Specialty-Specific Practice Areas; Clinical Trials and Registries; and Pediatric Needs Assessment and Possible Approaches to Advancing Pediatric Medical Device Development. FDA is seeking input into these topics from academicians, clinical practitioners, patients and advocacy groups, industry, and governmental agencies. The input from this public workshop will help in developing a strategic plan to encourage and accelerate the development of new medical devices and therapies for pediatric patients affected by rare diseases. This is part of an ongoing effort by FDA to address the needs of pediatric patients affected by rare diseases.

Date and Time: The workshop will be held on January 8, 2014, from 8 a.m. to 5 p.m. This public workshop is being held in conjunction with FDA's public workshop entitled ''Complex Issues in Developing Drug and Biological Products for Rare Diseases'' which will be held on January 6, 2014, from 8 a.m. to 5 p.m. and on January 7, 2014, from 8 a.m. to 4:45 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (section A of Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Carol Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3663, Silver Spring, MD 20993–0002, 301–796–3241, *Carol.Krueger@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases public workshop must register online by December 6, 2013, 5 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan (email: *Susan.Monahan@fda.hhs.gov* or phone: 301–796–5661) no later than December 27, 2013.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Carol Krueger to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by December 6, 2013, 5 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to