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 disabilities. If you require accommodations due to a disability, please contact Janie Kim 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: August 1, 2016.

Janice M. Soreth,
Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–18560 Filed 8–4–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Pediatric Master Protocols; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop titled, “Pediatric Master Protocols”. The objective of the workshop is to discuss regulatory and scientific concerns related to pediatric master protocols and clinical trial design considerations for these protocols. In addition, applications of pediatric master protocols to specific pediatric therapeutic areas will be presented.

DATES: The public workshop will be held on September 23, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESS: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting 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.

FOR FURTHER INFORMATION CONTACT: Audrey Thomas, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4220, Silver Spring, MD 20993–0002, 301–796–3520, Audrey.Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide an opportunity for relevant stakeholders including: Clinicians and scientists from FDA and other government Agencies, academia, non-profit organizations, and industry to discuss use of pediatric master protocols for development of medical products for children. Specifically, the workshop will present the current status of pediatric protocol development in the United States, considerations for pediatric protocol development internationally, and development of international consortia in this area. Clinical trial design considerations and the preliminary steps needed for development of pediatric master protocols, including the role of in vitro diagnostic tests, will also be discussed. Finally, examples of pediatric master protocol development for medical products with no, partial, and full extrapolation of data from adults to children will be presented. The workshop will include two panel sessions for interaction and discussion among the speakers and attendees.

Agenda: The agenda is available at http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations while at FDA’s White Oak Campus due to a disability, please contact Shari Solomon at Shari.Solomon@fda.hhs.gov at least 7 days in advance.

Dated: August 1, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–18555 Filed 8–4–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the National Mammography Quality Assurance Advisory Committee.

The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory...