

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; *Use:* Historically, the Programs of All-Inclusive Care for the Elderly (PACE) audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocol's information collection request (CMS-10191, OMB 0938-1000). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the PACE burden. Due to PACE audits being substantially different from our MA and Part D audits, we have separated the PACE audit protocols from the MA and Part D protocols and created this information collection request which seeks OMB approval under a new control number.

POs are required to comply with all PACE program requirements. The growth of these PACE organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.

CMS has developed an audit protocol and will post it to the CMS Web site each year for use by POs to prepare for their audit. The data collected for audit is detailed in this protocol and the exact fields are located in the record layouts, at the end of the protocol. In addition, a questionnaire will be distributed as part of our audit. This questionnaire is also included in this package. *Form Number:* CMS-10630 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits institutions); *Number of Respondents:* 72; *Total Annual Responses:* 72; *Total Annual Hours:* 12,960. (For policy questions regarding this collection contact Caroline Zeman at 410-786-0116.)

Dated: August 2, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016-18662 Filed 8-4-16; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Cellular, Tissue, and Gene Therapies 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 Cellular, Tissue, and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public. **DATES:** The meeting will be held on September 7, 2016, from 1 p.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Janie Kim or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 301-796-9016 or 240-402-8158, Janie.kim@fda.hhs.gov or Denise.royster@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. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: <https://collaboration.fda.gov/ctgtac0916/>.

SUPPLEMENTARY INFORMATION:

Agenda: On September 7, 2016, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Gene Transfer and Immunogenicity Branch, Division of Cellular and Gene Therapies, Office of Cellular, Tissue, and Gene Therapies, Center for Biologics Evaluation and Research.

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: On September 7, 2016, from 1 p.m. to 2:20 p.m., the meeting is open to the public. 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 23, 2016. Oral presentations from the public will be scheduled between approximately 2:20 p.m. to 3:20 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, 2016. 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 16, 2016.

Closed Committee Deliberations: On September 7, 2016, from 3:20 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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 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]

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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.

ADDRESSES: 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> (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

Registration: There is a registration fee to attend this public workshop in-person. Seats are limited and registration will be on a first-come, first-served basis. To register, please complete registration online at <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm> (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). There will be no onsite registration. The costs of registration, to attend in-person, for different categories of attendees are as follows:

Category	Cost
Industry Representative	\$50
Nonprofit Organization and Academic Other Than University of Maryland	50
University of Maryland, College Park and Baltimore ...	0
Federal Government	0

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. There is no registration fee for access to the workshop via the Webcast, but registration is still required. Information regarding registration and access to the Webcast link 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.

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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