DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Cellular, Tissue and Gene Therapies 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: Cellular, Tissue and Gene Therapies 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 October 22, 2013, from 8 a.m. to 5:30 p.m. and October 23, 2013, 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. 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: Gail Dapolito or Rosanna Harvey, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, HFM–71, Rockville, MD 20852, 301–827–1289 or 301–827–1297, email: *Gail.Dapolito@fda.hhs.gov* or *Rosanna.Harvey@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: On October 22, 2013, from 8 a.m. to 5:30 p.m., and on October 23, 2013, from 8 a.m. to approximately 11:15 a.m., the Committee will discuss oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of infertility. On October 23, 2013, from approximately 11:15 a.m. to 11:30 a.m., the Committee will hear updates on guidance documents issued from the Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research (CBER), FDA. On October 23, 2013, from 12:30 p.m. to approximately 5 p.m. the Committee will discuss considerations for the design of early-phase clinical trials of cellular and gene therapy products. CBER is planning to publish guidance on this topic during calendar year 2013.

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 15, 2013. Oral presentations from the public will be scheduled between approximately 2:15 p.m. and 3:15 p.m. on October 22, 2013, and between approximately 1:15 p.m. and 1:45 p.m. on October 23, 2013. 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 Gail Dapolito (*gail.dapolito@fda.hhs.gov*) 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 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17600 Filed 7–22–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Agency Information Collection Activities; Proposed Collection; Comment Request: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, National Institute of Neurological Disorders and Stroke (NINDS)

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the National Institute of Neurological Disorders (NINDS) has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.).

DATES: Comments must be submitted within 30 days after publication in the **Federal Register**.

ADDRESSES: Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by Email to *OIRA_submission@omb.eop.gov,* or by fax to 202–395–6974.