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]

BILLING CODE 4160–01–P

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.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact: Paul Scott, Ph.D., Director, Office of Science Policy and Planning, NINDS, 31/8A03 Center Drive, Bethesda, MD 20892–2178, or Email your request, including your address to *scottp@ninds.nih.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

No comments were received in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

Below we provide NINDS's projected average estimates for the next three years:

Current Actions: New collection of information.

Type of Review: New Collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of activities: 6.

Respondents: 14,700.

Annual responses: 24,700.

Frequency of Response: Once per request for 5 activities, twice per request for 1 activity.

Average minutes per response: 57.

Burden hours: 5750.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: July 16, 2013.

Story Landis,

Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

[FR Doc. 2013–17646 Filed 7–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Financial Sustainability of Human Tissue Biobanking (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 7, 2013, Vol. 78, p. 26639 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Jim Vaught, Chief, Biorepositories and Biospecimen Research Branch, Cancer Diagnosis Program, 9609 Medical Center Drive, Rockville, MD 20892 or call non-toll-free number 240–276–5716 or Email your request, including your address to: *vaughtj@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Financial Sustainability of Human Tissue Biobanking, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this web-based survey is to collect information regarding the challenges that human tissue biobanks encounter in achieving financially sustainable operations. The information will be used to assist the National Cancer Institute (NCI) in strategizing program plans to provide increased and tailored support for national and international biobanks. The survey will collect a combination of structured, quantitative, and free-text descriptive data that characterize the type and maturity of respondent biobanks, their sources of funding, and their usage of funding in conducting operations. The survey will also collect information describing the difficulties in maintaining funding sources and establishing new ones. Finally, the survey will elicit descriptions of techniques used to overcome the difficulties.

It is expected that the information generated by this survey will be used to inform published guidance to biobanks regarding the financial hazards to sustained operations and the means by which these hazards can be avoided or overcome.