click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. Once you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (**Note:** this email address and this telephone number are for assistance with establishment registration only, and not for any other aspects of medical device user fees.) Problems with BERS should be directed to *http://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17902 Filed 7–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–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). At least one portion of the meeting will be closed 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 September 18, 2014, from 1 p.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1506–IR, Silver Spring, MD 20993–0002. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6124, Silver Spring, MD 20993–0002, 240–402–8046, *gail.dapolito@fda.hhs.gov;* or Rosanna Harvey, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6136, Silver Spring, MD 20993–0002, 240–402–8072, *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 September 18, 2014, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Laboratory of Biochemistry, Division of Therapeutic Proteins, the Laboratory of Molecular Oncology and the Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, Office of Biotechnology Products, Office of Pharmaceutical Sciences, Center for Drug Evaluation and Research, FDA.

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 18, 2014, from 1 p.m. to 3:20 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 September 11, 2014. Oral presentations from the public will be scheduled between approximately 2:20 p.m. and 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 September 3, 2014. 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 September 4, 2014.

Closed Committee Deliberations: On September 18, 2014, from approximately 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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito 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 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17890 Filed 7–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The NIH/NCATS GRDR℠ Program; Global Rare Diseases Patient Registry Data Repository (GRDR)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instuments, submit comments in writing, or request more information on the proposed project, contact Yaffa Rubinstein, Ph.D., Office of Rare Diseases Research (ORDR), National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), 6701 Democracy Boulevard, Room 1004, Bethesda, Maryland 20892, or call non-toll free number (301) 402–4338, or Email your request including your address to *yaffa.rubinstein@nih.gov*. Formal requests for additional plans and instuments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The NIH/NCATS GRDR℠ Program, 0925–NEW GRDR, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

Need and Use of Information Collection: The NIH created the GRDR program *https://grdr.ncats.nih.gov* an informatics system and central data repository, housed at the NCATS/NIH Center to support and accelerate research in the cause, diagnosis, and treatment of rare diseases. The GRDR program collects a wide range of data types, including phenotypic, clinical, and genomic, as well as medical images, derived from individuals who participate in rare disease patient registries, regardless of the source of funding. The GRDR program provides the infrastructure to store, search across, retrieve, and analyze these varied types of data. This valuable information will help NIH understand and evaluate the use of repositories/datasets in the research community. The GRDR program will support: (1) Mapping data to standards; (2) increased visibility for participating registries; (3) opportunity for cross-disease research; (4) better and faster RD clinical research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 100.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Request for access	Individuals	1000	1	5/60	83
Request to submit	Individuals	100	1	10/60	17

Dated: July 17, 2014.

Pamela McInnes,

Deputy Director, NCATS, NIH.

[FR Doc. 2014–17952 Filed 7–29–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Ancillary Studies in Clinical Trials.

Date: August 22, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC/Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301–496–2434, *kristen.page@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS).