Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *BRUDAC@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 02BC;s Web site at *https://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.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 208088, oral testosterone undecanoate capsules, submitted by Lipocine Inc. for the proposed indication of testosterone replacement in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

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 02BC;s Web site after the meeting. Background material is available at *https://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. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before December 22, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 December 14, 2017. 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 December 15, 2017.

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 special accommodations due to a disability, please contact Kalyani Bhatt 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 *https://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: November 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24832 Filed 11–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Chimeric Antibodies Against Hepatitis B e-Antigen

Description of Technology: The invention relates to recombinant chimeric rabbit/human monoclonal antibody fragments (Fabs) against hepatitis B Virus e-antigen (HBeAg). Viral hepatitis is the seventh leading cause of death worldwide. Hepatitis B core antigen (HBcAg) forms an icosahedral structure containing the viral genome. Both the HBcAg and the HBeAg of interest here are expressed by two different start codons of the viral C gene. Unlike the related HBcAg which activates type 1 T helper (Th1) cells leading to immune attack, the HBeAg activates Th2 cells which promote immune tolerance. The long-term persistence of HBeAg is associated with the development of hepatocellular carcinoma. Conversely, HBeAg seroconversion (from HBeAg carrier to anti-HBeAg carrier) is a marker for successful therapy of chronically infected patients. The presently phage display engineered antibody has potential for anti-hepatitis B virus therapeutic interventions.

Potential Commercial Applications:

- Hepatitis B therapy.
- Hepatocellular carcinoma prophylaxis.

Development Stage:

- In vitro data available.

Inventors: Paul Winfield, Norman Watts, Alasdair Steven (all of NIAMS).

Intellectual Property: HHS Reference No. E–192–2017/0–US–01.

- U.S. Provisional Patent Application 62/534,603 filed July 19, 2017.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@nih.gov*.

Collaborative Research Opportunity: The National Institute of Environmental Health Sciences seeks statements of capability or nterest from parties interested in collaborative research to

further develop and evaluate, please contact Cecilia Pazman, Ph.D., Technology Development Specialist, Office of Technology Transfer, National Heart, Lung, and Blood Institute, Phone: (301) 594–4273; *pazmance@nhlbi.nih.gov* .

Dated: November 6, 2017.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2017–24773 Filed 11–15–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel, Dysregulation of Immune Cell Regulatory Pathways by MTB in the Context of HIV Infection (R61/R33).

Date: December 11–12, 2017.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G11A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5045, *sundstromj@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Global Infectious Disease Research Administration Development Award For Low-And Middle-Income Country Institutions (G11).

Date: December 13, 2017.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G30, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5058, *rathored@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 9, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–24762 Filed 11–15–17; 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; NCI Cancer Genetics Services Directory Web-Based Application and Update Mailer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

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

ADDRESSES: 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: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Margaret Beckwith, Office of Cancer Content, Office of Communications and Public Liaison (OCPL), 9609 Medical Center Drive, Rockville, MD 20892 or call non-toll-free number 240–276–6600 or email your request, including your address to: *nciocpl@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on September 5, 2017 page 41971 (82 FR 41971) 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.

In compliance with 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 for review and approval of the information collection listed below.

Proposed Collection: NCI Cancer Genetics Services Directory Web-Based Application and Update Mailer, 0925–0639, Exp., date 10/31/2017, Reinstatement without change, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Office of Communications and Public Liaison has created the NCI Cancer Genetics Services Directory on NCI's Web site *Cancer.gov*. This directory is a searchable collection of information about professionals who provide services related to cancer genetics. These services include cancer risk assessment, genetic counseling, and genetic susceptibility testing. The professionals have applied to be in the directory using an online application form and have met basic criteria outlined on the form.

There are currently 552 genetics professionals listed in the directory. Approximately 30–60 new professionals are added to the directory each year. The applicants are nurses, physicians, genetic counselors, and other professionals who provide services related to cancer genetics. The information collected on the application form includes name, professional qualifications, practice locations, and the area of specialization. The information is updated annually using a Web-based update mailer that mirrors the application form.

The NCI Cancer Genetics Services Directory is a unique resource for cancer patients and their families who are