harms of on-label and off-label use of Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer. Background information about this topic, including panel materials, is available at *http://www.cms.hhs.gov/center/coverage.asp.* We encourage the participation of appropriate organizations with expertise in the use of Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: *http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac.* We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *http://www.cms.gov/mcd/index_list.asp?list_type=mcac,* via e-mail at *MEDCAC_Registration@cms.hhs.gov,* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

You must register for the Webinar portion of the meeting at *https://webinar.cms.hhs.gov/_a7/txmetaprostatemedcac1117/event/registration.html* by the deadline listed in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 8, 2010.

Barry M. Straube

Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–23582 Filed 9–23–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Prevention, Prophylaxis, Cure, Amelioration, and/or Treatment of Infection and/or the Effects Thereof of Chikungunya Infections in Humans

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in Patent Applications USSN 61/118,206, filed on November 26, 2008, and 61/201,118, filed on December 5, 2008; and PCT/US2009/006294, filed November 24, 2009; entitled "Virus Like Particle Compositions and Methods of Use", to Merck Sharp & Dohme Corp. having a place of business in 770 Sumneytown Pike, West Point, PA 19486. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before October 25, 2010 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Cristina Thalhammer-Reyero, PhD , M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *ThalhamC@mail.nih.gov;* Telephone: 301–435–4507; Facsimile: 301–402–0220.

SUPPLEMENTARY INFORMATION: The prospective worldwide exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 30 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The invention relates to compositions and methods of use as vaccines of virus-like particles (VLPs) expressing one or more alphavirus capsid or envelope proteins, and in particular Chikungunya

virus (CHIKV) envelope proteins. The invention also describes DNA, viral or other gene-based vector and VLP vaccines, methods of making and methods of their use in inducing immunity to alphavirus infection. Alphaviruses are RNA-containing viruses that cause a wide variety of mosquito-transmitted diseases, including equine encephalitis. CHIKV, an alphavirus in the family Togaviridae, was first isolated in Tanzania in 1952 and is transmitted to humans by mosquitoes. The disease caused by CHIKV resembles infection by dengue virus, characterized by rash, high fever, and severe, sometimes persistent arthritis.

The field of use may be limited to "Prevention, prophylaxis, cure, amelioration, and/or treatment of infection and/or the effects thereof of Chikungunya infections in humans".

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 20, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–23975 Filed 9–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 57282–57283 dated September 20, 2010).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Bureau of Clinician Recruitment and Service (RU) to reduce fragmentation and overlap and establish an increased emphasis on policy and program development, external communication and outreach, customer service and system and analytical support.

Chapter RU—Bureau of Clinician Recruitment and Service

Section RU–10, Organization

Delete in its entirety and replace with the following:

The Office of the Associate Administrator (RU) is headed by the Associate Administrator, Bureau of Clinician Recruitment and Service (BCRS), who reports directly to the Administrator, Health Resources and Services Administration. BCRS includes the following components:

(1) Office of the Associate Administrator (RU);
(2) Office of Legal and Compliance (RU1);
(3) Division of National Health Service Corps (RU5);
(4) Division of Nursing and Public Health (RU6);
(5) Division of External Affairs (RU7);
(6) Office of Policy and Program Development (RU8);
(7) Division of Program Operations (RU9);
(8) Division of Regional Operations (RU10); and
(9) Office of Business Operations (RU11).

Section RU–20, Functions

(1) Delete the functional statement for the Bureau of Clinician Recruitment and Service (RU) and replace in its entirety.

Office of the Associate Administrator (RU)

Provides overall leadership, direction, coordination, and planning in support of Bureau of Clinician Recruitment and Service (BCRS) programs that are designed to improve the health of the Nation's underserved communities and vulnerable populations by coordinating the recruitment and retention of caring health professionals in the healthcare system and supporting communities' efforts to build more integrated and sustainable systems of care. Specifically: (1) Establishes program goals, objectives and priorities, and provides oversight as to their execution; (2) plans, directs, coordinates and evaluates Bureau-wide management activities; (3) maintains effective relationships within HRSA and with other Department of Health and Human Services (HHS) organizations, other Federal agencies, State and local governments, and other public and private organizations concerned with improving the health status of the Nation's underserved communities and vulnerable populations by recruiting and retaining health care clinicians into service in areas of greatest need; (4) plans, directs and coordinates Bureau-wide administrative management activities, *i.e.,* budget, personnel, procurements, delegations of authority, and has responsibilities related to the awarding of BCRS funds; and (5) oversees the development of BCRS program policies.

Office of Legal and Compliance (RU1)

Serves as the focal point for service obligation issue resolution and quality assurance for the Bureau's programs. Specifically: (1) Analyzes, administers and manages procedures for the BCRS portfolio of scholarship and loan repayment participants who have breached their service obligation, requested a waiver or suspension, and/or are in default and have requested to serve under a Forbearance, Judgment or Settlement Agreement; (2) reviews default recommendations, determines the action of default, and initiates and monitors procedures for default debt collection; (3) provides programmatic information to Agency officials, the Office of the General Counsel, the Office of Inspector General, Program Support Center, and the Department of Justice for default debt collection, trials, bankruptcy hearings, and other activities; (4) reviews requests and makes determinations regarding scholarship and loan repayment participants' eligibility for a suspension or waiver of their service or default debt obligation; (5) implements policies and procedures in conjunction with default reduction activities, including return to service arrangements and other actions to maximize compliance with scholarship and loan repayment service obligations; and (6) serves as the BCRS quality assurance function.

Division of National Health Service Corps (RU5)

Serves as the point of contact for responding to inquiries, disseminating program information, providing technical assistance, and processing applications and awards pertaining to National Health Service Corps (NHSC) scholarship and loan repayment programs and site approvals. Specifically: (1) Reviews, ranks and selects participants for the scholarship and loan repayment programs; (2) verifies and processes loan and lender related payments in prescribed manner and maintains current information on scholarship and loan repayment applications and awards through automated BCRS information systems; (3) provides oversight, processing and coordination of reviews of NHSC site