93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 20, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–23952 Filed 9–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0268]

Dental Products Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Dental Products Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of June 11, 2010 (75 FR 33315). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Olga I. Claudio, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1553, Silver Spring, MD 20993–0002, 301–796–7608, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512518. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 11, 2010, FDA announced that a meeting of the Dental Products Panel of the Medical Devices Advisory Committee would be held on December 14 and 15, 2010. On page 33316, in the first column, in the *Agenda* portion of the document, in the second full paragraph, in the second sentence, the phrase "(docket numbers FDA–2008–N–0163 and FDA–2009–P–0357)" is changed to read as follows:

"(docket numbers FDA–2008–N–0163, FDA–2009–P–0357, and FDA–2010–P–0056–0001)"

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 21, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–23914 Filed 9–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3240–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—November 17, 2010

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, November 17, 2010. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the currently available evidence regarding the clinical benefits and harms of on-label and off-label use of Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: *Meeting Date:* The public meeting will be held on Wednesday, November 17, 2010 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (EST).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m. EST, October 18, 2010. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., EST on Wednesday, October 18, 2010. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals 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 5 p.m. EST, Wednesday, November 10, 2010. We will be broadcasting the meeting via Webinar. You must register for the Webinar portion of the meeting at *https://webinar.cms.hhs.gov/_a7/txmetaprostatemedcac1117/event/registration.html* by 5 p.m. EST, Wednesday, November 10, 2010.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., EST Friday, November 5, 2010.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to *MedCACpresentations@cms.hhs.gov* or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410–786–0309) or via e-mail at *Maria.Ellis@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 **Federal Register** (63 FR 68780).) This notice announces the November 17, 2010, public meeting of the Committee. During this meeting, the Committee will discuss the currently available evidence regarding the clinical benefits and

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