

1600 Clifton Road, Mail Stop E-28, Atlanta, GA 30303, telephone: 404/498-0003, fax: 404/498-0059, E-mail: smalcom@cdc.gov. The deadline for notification of attendance is May 2, 2007.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 9, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7-7188 Filed 4-13-07; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Delegation of Authority

Notice is hereby given that I have delegated to the Administrator of the Centers for Medicare and Medicaid Services, the following authority vested in the Secretary of Health and Human Services.

Subpoenas for the Health Insurance Portability and Accountability Act of 1996 (HIPAA): Authority under Section 205(d) of the Social Security Act (42 U.S.C. 405(d)), with authority to redelegate, to issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or compliance review for failure to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards and requirements related at 45 CFR parts 160, 162 and 164 (except to the extent they pertain to the standards for privacy of individually identifiable health information).

Section 1176(a)(2) of the Social Security Act, 42 U.S.C. 1320d-5(a)(2), which provides authority for the imposition of civil money penalties (CMPs) for violations, makes section 1128A of the Social Security Act, 42 U.S.C. 1320a-7a, applicable to the imposition of CMPs for violations of HIPAA administrative simplification standards. Section 1128A(j)(1), 42 U.S.C. 1320a-7a(j)(1), makes section 205(d) and (e) of the Social Security Act, 42 U.S.C. 405(d) and (e), applicable to section 1128A as the subsections are

with respect to Title II of the Social Security Act. Section 205(d) and (e) authorizes the issuance of subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation by the Secretary and the enforcement of such a subpoena in court in event of refusal to comply.

This delegation shall be exercised under the Department's existing delegation of authority on the issuance of regulations and existing policy on the issuance of regulations.

In addition, I hereby affirm and ratify any actions taken by the Administrator of the Centers for Medicare and Medicaid Services, or his subordinates which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

This delegation is effective immediately.

Michael O. Leavitt,

Secretary.

[FR Doc. 07-1871 Filed 4-13-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 May 16, 2007, from 9 a.m. to 4:30 p.m. and on May 17, 2007, from 8 a.m. to 1 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the

Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 16, 2007, in the morning session, the committee will hear presentations and make recommendations on the safety and effectiveness of influenza virus vaccine live (FluMist) in a pediatric population less than 59 months of age, manufactured by MedImmune Vaccines, Inc. In the afternoon, the committee will hear an overview of the function of the Laboratory of Bacterial Polysaccharides and the Laboratory of Enteric & Sexually Transmitted Diseases, Division of Bacterial Parasitic and Allergenic Products, Office of Vaccines Research and Review, CBER and in closed session will discuss the report of the November 29, 2006, laboratory site visit. On May 17, 2007, the committee will hear presentations and make recommendations on the safety and immunogenicity of a live vaccinia virus smallpox vaccine (ACAM2000) manufactured by Acambis, Inc.

FDA intends to make background material available to the public no later than 1 business day 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/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: On May 16, 2007, from 9 a.m. to 3:50 p.m. and on May 17, 2007, from 8 a.m. to 1 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 May 2, 2007. Oral presentations from the public will be scheduled between approximately 11:45 a.m. to 12:15 p.m. and 3:20 p.m. to 3:50 p.m. on May 16, 2007, and between approximately 11:15 a.m. to 11:45 a.m. on May 17, 2007. Those desiring to make 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 April 24, 2007. 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 April 25, 2007.

Closed Committee Deliberations: On May 16, 2007 from 3:50 p.m. to 4:30 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 the review of internal research programs in the Office of Bacterial Parasitic and Allergenic Products, Office of Vaccines Research and Review, CBER.

Person's 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 Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 6, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-7090 Filed 4-13-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. in accordance with 35 U.S.C. 207 to achieve expeditious 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.

ADDRESSES: Licensing information and copies of the U.S. patent applications

listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

New Mouse T Cell Receptors as Potential Therapeutic Agents for the Treatment of Metastatic Cancer

Description of Technology: Adoptive immunotherapy is one of the most promising new therapeutic approaches to treat cancer.

T cell receptors (TCR) are the proteins responsible for the T cell's ability to recognize infected or transformed cells. A TCR consists of two domains, one variable domain that recognizes the antigen and one constant region that helps the TCR anchor to the membrane and transmit the recognition signal by interacting with other proteins.

This invention describes the identification of two mouse TCRs that target a common and highly expressed melanoma antigen, gp100, expressed by human cancers. These TCRs, have superior (100-1000 times) biological function compared to other human tumor-specific TCR that are currently in use in experimental trials using genetically engineered T cells. Therefore, these new TCRs represent potential therapeutic agents that can be used in the treatment of metastatic cancers, especially melanomas.

Applications: New mouse TCRs have been identified that recognize human gp100; The mouse TCRs have 100-1000 times superior biological function compared to their human counterpart in recognizing gp100 when expressed in human lymphocytes; Human T cells genetically engineered to express new TCRs can serve as potential therapeutic agents in the treatment of patients with metastatic cancers; Clinical trials with these novel TCRs are currently being planned.

Development Status: Pre-clinical work has been completed and clinical studies are forthcoming.

Inventors: Nicholas P. Restifo *et al.* (NCI).

Relevant Publications:

1. A manuscript relating to this invention is under preparation and will be available once accepted.

2. RA Morgan *et al.* Cancer regression in patients after transfer of genetically engineered lymphocytes. *Science*. 2006 Oct 6;314(5796):126-129.

Patent Status: U.S. Provisional Application No. 60/884,732 filed 12 Jan

2007 (HHS Reference No. E-059-2007/0-US-01); U.S. Provisional Application No. 60/885,724 filed 19 Jan 2007 (HHS Reference No. E-059-2007/1-US-01).

Licensing Status: This technology is available for licensing under an exclusive or non-exclusive patent license.

Licensing Contact: Michelle Booden, Ph.D.; 301/451-7337; boodenm@mail.nih.gov.

Collaborative Research Opportunity: The Surgery Branch, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this T cell receptor that is specific for human tumors. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

A Novel DNA Vaccine for the Treatment of Malignancies Expressing Immature Laminin Receptor Protein

Description of Technology: This invention describes a new potent chemoattractant-based DNA vaccine to evoke therapeutic anti-tumor responses against tumors. The vaccine targets the antigen presenting cells (APCs) to efficiently present an antigen to MHC class I and class II molecules to induce tumor specific CD4 and CD8 T cell responses.

The antigen tested is a highly conserved oncofetal antigen named immature laminin receptor protein (OFA-iLRP) that is preferentially expressed in malignant tissues. The vaccine construct consists of novel fusion proteins with enhanced binding affinities to augment antigen processing and antitumor responses.

Applications and Modality:

1. *In vivo* laboratory data shows that OFA-iLRP can be used as a potential immunotherapeutic antigen for the treatment of several malignancies including lymphoma, breast, lung, and ovarian.

2. The vaccine construct is a novel fusion protein designed to enhance immunogenicity of OFA-iLRP via delivering it to chemokine receptors expressed on antigen presenting cells.

3. The vaccine formulation will be most effective if used for treatment of cancer patients with minimal residual disease to protect from the disease relapse.

4. The vaccine potentially could be effective as a preventive measure for people with cancer predisposition by eliciting long term anti-OFA-iLRP humoral and cellular memory.

5. Very simple and less invasive vaccine that can be easily delivered to the skin, muscle or other tissues.