Dated: August 21, 2007.

John J. McGowan,

Deputy Director for Science Management, NIAID, National Institutes of Health.

[FR Doc. E7–17012 Filed 8–27–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Scientific Management Review Board (SMRB).

The NIH Reform Act of 2006 (Pub. L. 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

Duration of this committee is tow years from the date of Charter is filed.

Dated: August 20, 2007.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. 07–4221 Filed 8–27–07; 8:45 am]

BILLING CODE 4140–01–M

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.

Development of Antigenic Chimeric St. Louis Encephalitis Virus/Dengue Virus Type Four Recombinant Viruses (SLEV/DEN4) as Vaccine Candidates for the Prevention of Disease Caused by SLEV

Description of Invention: St. Louis Encephalitis Virus (SLEV) is a mosquito-borne flavivirus that is endemic in the Americas and causes sporadic outbreaks of disease in humans. SLEV is a member of the Japanese encephalitis virus serocomplex and is closely related to West Nile Virus (WNV). St. Louis encephalitis is found throughout North, Central, and South America, and the Caribbean, but is a major public health problem mainly in the United States. Prior to the outbreak of West Nile virus in 1999, St. Louis encephalitis was the most common human disease caused by mosquitoes in the United States. Since 1964, there have been about 4,440 confirmed cases of St. Louis encephalitis, with an average of 130 cases per year. Up to 3,000 cases have been reported during epidemics in some years. Many more infections occur without symptoms and go undiagnosed. At present, a vaccine or FDA approved antiviral therapy is not available.

The inventors have previously developed a WNV/Dengue4Delta30 antigenic chimeric virus as a live attenuated virus vaccine candidate that contains the WNV premembrane and envelope (prM and E) proteins on a dengue virus type 4 (DEN4) genetic background with a thirty nucleotide deletion (Delta30) in the DEN4 3'-UTR. Using a similar strategy, the inventors have generated an antigenic chimeric virus, SLE/DEN4Delta30. Preclinical testing results indicate that chimerization of SLE with DEN4Delta30 decreased neuroinvasiveness in mice, did not affect neurovirulence in mice, and appeared to overattenuate the virus for non-human primates. Modifications of the SLE/DEN4Delta30 vaccine candidate are underway to improve its immunogenicity.

This application claims live attenuated chimeric SLE/DEN4Delta30 vaccine compositions and bivalent WNV/SLE/DEN4Delta30 vaccine compositions. Also claimed are methods of treating or preventing SLEV infection in a mammalian host, methods of producing a subunit vaccine composition, isolated polynucleotides comprising a nucleotide sequence encoding a SLEV immunogen, methods for detecting SLEV infection in a biological sample and infectious chimeric SLEV.

Application: Immunization against SLEV or SLEV and WNV.

Development Status: Live attenuated vaccine candidates are currently being developed and preclinical studies in mice and monkeys are in progress. Suitable vaccine candidates will then be evaluated in clinical studies.

Inventors: Stephen S. Whitehead, Joseph Blaney, Alexander Pletnev, Brian R. Murphy (NIAID).

Patent Status: U.S. Provisional Application No. 60/934,730 filed 14 Jun 2007 (HHS Reference No. E–240–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize live attenuated virus vaccine candidates for St. Louis encephalitis virus. Please contact Dr. Whitehead at 301–496–7692 for more information.

Monoclonal Antibodies Against Dengue and Other Viruses With Deletion in Fc Region

Description of Invention: The four dengue virus (DENV) serotypes (DENV–1 to DENV–4) are the most important arthropod-borne flaviviruses in terms of morbidity and geographic distribution. Up to 100 million DENV infections occur every year, mostly in tropical and subtropical areas where vector mosquitoes are abundant. Infection with any of the DENV serotypes may be asymptomatic or may lead to classic dengue fever or more severe dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS), which are increasingly common in the dengue endemic areas. Immunity to the same virus serotype (homotypic immunity) is life-long, whereas immunity to different serotypes (heterotypic immunity) lasts

2–3 months so that infection with a different serotype virus is possible. DHF/DSS often occurs in patients with second, heterotypic DENV infections or in infants with maternally transferred dengue immunity. Severe dengue is a major cause of hospitalization, and fatality rates vary from <1% to 5% in children.

Antibody-dependent enhancement (ADE) has been proposed as an underlying pathogenic mechanism of DHF/DSS. ADE occurs because preexisting subneutralizing antibodies and the infecting DENV form complexes that bind to Fc receptor-bearing cells, leading to increased virus uptake and replication. ADE has been repeatedly demonstrated *in vitro* using dengue immune sera or monoclonal antibodies and cells of monocytic and recently, B lymphocytic lineages bearing Fc receptors. ADE of DENV–2 infection has also been demonstrated in monkeys infused with a human dengue immune serum.

We have identified chimpanzee-human chimeric IgG1 mAbs capable of neutralizing or binding to one or more DENV serotypes. Cross-reactive IgG 1A5 neutralizes DENV–1 and DENV–2 more efficiently than DENV–3 and DENV–4, and type-specific IgG 5H2 neutralizes DENV–4 at a high titer. Analysis of antigenic variants has localized the IgG 1A5 binding site to the conserved fusion peptide in E. Thus, IgG 1A5 shares many characteristics with the cross-reactive antibodies detected in flavivirus infections.

This application claims a variant of an antibody comprising a polypeptide in the Fc region, which binds an Fc gamma receptor (FcgammaR) with lower affinity than the parent antibody. The variant polypeptide comprises a deletion of nine amino acids at the N-terminus of the C_H2 domain in the Fc region. Introduction of the Fc variant abrogates the antibody-mediated dengue virus replication enhancing activity. This invention has important implications for the antibody-mediated prevention of dengue virus infection.

Application: Immunization against Dengue and/or flaviviruses.

Developmental Status: Antibody candidates have been synthesized and preclinical studies have been performed.

Inventors: Ana Goncalvez, Robert Purcell, C.J. Lai (NIAID).

Publication: AP Goncalvez *et al.* Monoclonal antibody-mediated enhancement of dengue virus infection in vitro and in vivo and strategies for prevention Proc Natl Acad Sci USA. 2007 May 29;104(22):9422–9427. Epub 2007 May 15.

Patent Status:

U.S. Provisional Application No. 60/922,282 filed 04 Apr 2007 (HHS Reference No. E–159–2007/0–US–01).

U.S. Provisional Application No. 60/927,755 filed 04 May 2007 (HHS Reference No. E–159–2007/1–US–01).

U.S. Provisional Application No. 60/928,405 filed 08 May 2007 (HHS Reference No. E–159–2007/2–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Live Attenuated Virus Vaccines for La Crosse Virus and Other *Bunyaviridae*

Description of Invention: La Crosse virus (LACV), family *Bunyaviridae,* is a mosquito-borne pathogen endemic in the United States. LACV infection results in 70–130 clinical cases a year and is the major cause of pediatric arboviral encephalitis in North America. LACV was first identified as human pathogen in 1960 after its isolation from a 4 year-old girl from Minnesota who suffered meningoencephalitis and later died in La Crosse, Wisconsin. The majority of LACV infections are mild and never reported, however serologic studies estimate annual infection rates of 10–30/100,000 in endemic areas. LACV is a member of the California serogroup of viruses in the genus *Orthobunyavirus.* The serogroup contains members found on five continents that include human pathogens such as La Crosse, Snowshoe hare, and Jamestown Canyon viruses in North America; Guaroa virus in North and South America; Inkoo and Tahyna viruses in Europe; and Lumbo virus in Africa. Children who recover from severe La Crosse encephalitis may have significantly lower IQ scores than expected and a high prevalence (60% of those tested) of attention-deficit-hyperactivity disorder. Seizure disorders are also common in survivors. LACV can also cause encephalitis in immunosuppressed adults. Projected lifelong economic costs associated with neurologic sequelae range from $48,775–3,090,398 per case. At present, a vaccine or FDA-approved antiviral therapy is not available.

This application principally claims live attenuated LACV vaccine compositions, but also includes subunit vaccine compositions including California encephalitis virus (CEV) serogroup immunogens, attenuated and inactivated CEV serogroup and chimeric *Bunyaviridae.* Also claimed are methods of treating or preventing CEV serogroup infection in a mammalian host, methods of producing a subunit vaccine composition, isolated polynucleotides comprising a nucleotide sequence encoding a CEV serogroup immunogen, methods for detecting LACV infection in a biological sample and infectious chimeric *Bunyaviridae.*

Application: Immunization against *Bunyaviridae.*

Developmental Status: Live attenuated vaccine candidates are currently being developed and preclinical studies in mice and monkeys are in progress. Suitable vaccine candidates will then be evaluated in clinical studies.

Inventors: Stephen S. Whitehead, Richard S. Bennett, Brian R. Murphy (NIAID).

Publication: RS Bennett *et al.* Genome sequence analysis of La Crosse virus and in vitro and in vivo phenotypes. Virol J. 2007 May 8;4:41.

Patent Status:

U.S. Provisional Application No. 60/920,691 filed 29 Mar 2007 (HHS Reference No. E–158–2007/0–US–01).

U.S. Provisional Application No. 60/928,406 filed 08 May 2007 (HHS Reference No. E–158–2007/1–US–01).

U.S. Provisional Application filed 29 Jun 2007 (HHS Reference No. E–158–2007/2–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize live attenuated virus vaccine candidates for La Crosse virus and other *Bunyaviridae.* Please contact Dr. Whitehead at 301/496–7692 for more information.

Chlamydia Vaccine

Description of Invention: Chlamydia trachomatis is an obligate intracellular bacterial pathogen that colonizes and infects oculogenital mucosal surfaces. The organism exists as multiple serovariants that infect millions of people worldwide. Ocular infections cause trachoma, a chronic follicular conjunctivitis that results in scarring and blindness. The World Health Organization estimates that 300–500 million people are afflicted by trachoma, making it the most prevalent form of infectious preventable blindness. Urogenital infections are the leading cause of bacterial sexually transmitted disease in both industrialized and developing nations. Moreover, sexually transmitted diseases

are risk factors for infertility, the transmission of HIV, and human papilloma virus-induced cervical neoplasia. Control of *C. trachomatis* infections is an important public health goal. Unexpectedly, however, aggressive infection control measures based on early detection and antibiotic treatment have resulted in an increase in infection rates, most likely by interfering with natural immunity, a concept suggested by studies performed in experimental infection models. Effective management of chlamydial disease will likely require the development of an efficacious vaccine.

This technology claims vaccine compositions that comprise an immunologically effective amount of PmpD protein from *C. trachomatis.* Also claimed in the application are methods of immunizing individuals against *C. trachomatis.* PmpD is an antigenically stable pan-neutralizing target that, in theory, would provide protection against all human strains, thus allowing the development of a univalent vaccine that is efficacious against both blinding trachoma and sexually transmitted disease.

Application: Prophylactics against *C. trachomatis.*

Developmental Status: Preclinical studies have been performed.

Inventors: Harlan Caldwell and Deborah Crane (NIAID).

Publication: DD Crane *et al.* Chlamydia trachomatis polymorphic membrane protein D is a species-common pan-neutralizing antigen. Proc. Natl Acad Sci USA. 2006 Feb 7;103(6):1894–1899. Epub 2006 Jan 30.

Patent Status: PCT Patent Application No. PCT/US2007/001213 filed 16 Jan 2007 (HHS Reference No. E–031–2006/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID, Laboratory of Intracellular Parasites, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize PmpD vaccine development. Please contact Harlan D. Caldwell, at *hcaldwell@niaid.nih.gov* or 406/363–9333 for more information.

Dated: August 21, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–16935 Filed 8–27–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: September 24–25, 2007.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate the Critical Care Medicine Program.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Room 4–2551, Bethesda, MD 20892.

Contact Person: David K. Henderson, MD, Deputy Director for Clinical Care, Office of the Director, Clinical Center, National Institutes of Health, Building 10, Room 6–1480, Bethesda, MD 20892, (301) 496–3515.

Dated: August 20, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4196 Filed 8–27–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), 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 Cancer Advisory Board.

Open: September 17, 2007, 8:30 a.m. to 4:15 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Closed: September 17, 2007, 4:15 p.m. to 5:30 p.m.

Agenda: Review of grant applications.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Open: September 18, 2007, 8 a.m. to 12 p.m.

Agenda: Program reports and presentations; Business of the Board.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.