between cancer and nutritional exposures. This questionnaire adheres to The Public Health Service Act, Section 412 (42 U.S.C. 285a–1) and Section 413 (42 U.S.C. 285a–2), which authorizes the Division of Cancer Epidemiology and Genetics of the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention and treatment. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* U.S. adults (persons aged 50–85). The annual reporting burden is as follows: *Estimated Number of Respondents:* 513,225; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .0668; and *Estimated Total Annual Burden Hours Requested:* 34,283. The annualized cost to respondents is estimated at: $302,158. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondents	Number of respondents	Frequency of response	Average burden hours per response	Annual hour burden	Hourly wage rate	Cost to respond
Senior Adults	513,225	1	.0668 (4 minutes).	34,283	$17.68	$302,158

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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 Arthur Schatzkin, M.D., Dr.P.H, Chief, Nutritional Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, Executive Plaza South, Room 3040, 6120 Executive Blvd., EPS–MSC 7242, Bethesda, MD 20892–7335 or call non-toll-free number 301–594–2931 or e-mail your request, including your address to: *schatzka@mail.nih.gov.*

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

Dated: January 14, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E8–1249 Filed 1–24–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Human Monoclonal Antibodies, Their Fragments and Derivatives as Biotherapeutics for the Treatment of HIV Infections

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 inventions embodied in:

1. U.S. Provisional Patent Application S/N 60/329,709 (E–130–2001/0–US–01). PCT/US02/33165 was filed on October 16, 2002 (E–130–2001/0–PCT–01) and converted into 02773789.9 (E–130–2001/0–EP–03) filed in Europe on May 12, 2004, 2002337885 (E–130–2001/0–AU–02) filed in Australia on March 29, 2004, 10/492,729 (E–130–2001/0–US–05) filed in the U.S. on April 15, 2004, divisional application 11/748,992 (E–130–2001/0–US–07) filed in the U.S. on May 15, 2007, and 2,463,931(E–130–2001/0–CA–04) filed in Canada on April 15, 2004; entitled ''Broadly Cross-Reactive Neutralizing Antibodies Against Human Immunodeficiency Virus Selected By Env-CD4-Co-Receptor Complex.'' Inventor(s): Dimiter S. Dimitrov (NCI), Maxime Moulard (EM), Xiadong Xiao (NCI), Yuuei Shu (NCI), Sanjay K. Phogat (IAVI), Mei–Yun Zhang (NCI), and Dennis Burton (Scripps Inst.)

2. U.S. Provisional Patent Application S/N 60/623,394 (E–251–2004/0–US–01). PCT/US2005/39175 (E–251–2004/0–PCT–02) filed on October 28, 2005 and converted into 2,585,574 (E–251–2004/0–CA–04) filed in Canada on October 28, 2005, 05819487.9 (E–251–2004/0–EP–05) filed in Europe on April 27, 2007, 2005302416 (E–251–2004/0–AU–06) filed in Australia on October 28, 2005, and 11/718,202 (E–251–2004/0–US–03) filed in the U.S. on August 10, 2007; entitled ''Novel Broadly Cross-Reactive HIV Neutralizing Human Monoclonal Antibodies Selected From Phage Display Libraries Using Novel Strategy Based On Competitive Antigen Panning.'' Inventor(s): Dimiter S. Dimitrov (NCI) and Mei-Yun Zhang (SAIC) to Profectus Biosciences, Inc. (hereafter Profectus) having a place of business in Baltimore, Maryland. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before March 25, 2008 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: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *hus@od.nih.gov;* Telephone: (301) 435–5606; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The first invention (E–130–2001/0) provides a

novel anti-HIV human monoclonal antibody named X5. This antibody demonstrates promise over conventional anti-HIV antibodies because the X5 antibody exhibits a unique binding activity compared to its counterparts. It has been established that the initial stage of HIV–1 entry into cells is mediated by a complex between the viral envelope glycoprotein (Env) such as gp120-gp41, a receptor CD4 and a co-receptor CCR5. The X5 antibody binds to an epitope on gp120 that is induced by interaction between gp120 and the receptor CD4 and enhanced by the co-receptor CCR5. The X5 antibody also shows strong activity at very low levels (in the range from 0.0001—0.1 Mg/ml concentration based on the particular isolate). Because it is a human antibody, it can be administered directly into patients so that it is an ideal candidate for clinical trials. It also can be easily produced because it was obtained by screening of phage display libraries and its sequence is known. Finally, since it has neutralized all virus envelope glycoproteins, including those from primary isolates of different clades, the epitope is highly conserved and resistance is unlikely to develop. Therefore, this antibody and/or its derivatives including fusion proteins with CD4 are good candidates for clinical development.

The second invention (E–251–2004/0) provides for pharmaceutical compositions of, and methods of using potent cross-reactive human monoclonal antibodies to HIV. Specifically, the invention describes a competitive antigen panning (CAP) method of isolating antibodies that bind to the gp41 subunit of the HIV–1 envelope glycoprotein. Additionally, the invention includes compositions of the aforementioned antibodies and the epitopes recognized by the antibodies. Methods of using the invention in the development of vaccine immunogens for the treatment and prevention of HIV, as well as the detection of HIV in a mammal are also described. The invention has significant implications in the development of HIV inhibitors, vaccines, and research tools for understanding mechanisms of HIV entry. Further development of the disclosed invention may yield novel therapies and methods in the prevention of mother-to-child transmission of HIV, treatment of accidental exposure to HIV, and chronic infection in patients with resistance to current therapies.

The prospective 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 60 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 field of use may be limited to the development of human monoclonal antibodies for use as a therapeutic or preventative in HIV infection either alone or in combination with other compounds.

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: January 16, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–1258 Filed 1–24–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Flavivirus Technologies

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.