docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: August 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19490 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0447]

Achieving a Future Vision at the 2008 Parenteral Drug Association and the Food and Drug Administration Joint Regulatory Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Achieving a Future Vision at the 2008 Parenteral Drug Association and the Food and Drug Administration Joint Regulatory Conference. The topics to be discussed are: FDA's Pharmaceutical Inspectorate and the Global Harmonization Task Force; Trans Atlantic initiative; Product development; and legacy products; Supply chain; Combination products; and Recall root causes.

Date and Time: The meeting will be held on September 8 through 12, 2008, 7 a.m. to 6.

Location: The meeting will be held at Renaissance Hotel, 999 9th St., NW., Washington, DC 20001.

Contact: Wanda Neal-Ballard, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 200, Bethesda, MD 20814 or by telephone on 301–986–0293, ext. 111.

Registration and Meeting Information: See PDA Web site, *www.pda.org/pdafda2008* or contact Wanda Neal-Ballard on 301–986–0293, ext. 111. From now until August 25, 2008, registration fees are as follows: $1,600.00 for Members, $2,000.00 for Non-members, $615.00 for Government/Health Authority/Academic and $230.00 for Students. After August 25, 2008, registration fees are as follows: $1,800.00 for Members, $2,200.00 for Non-members, $700.00 for Government/Health Authority/Academic and $260.00 for Students.

If you need special accommodations due to a disability, please contact Wanda Neal-Ballard at least 7 days in advance.

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19491 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; California Health Interview Survey Cancer Control Module (CHIS–CCM) 2009 (NCI)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: California Health Interview Survey Cancer Control Module (CHIS–CCM) 2009. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The NCI has sponsored four Cancer Control Modules in the California Health Interview Survey (CHIS), and will be sponsoring a fifth to be administered in 2009. CHIS is a telephone survey that collects population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the state. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults, in 2005 to 43,020 adults, and in 2007 to 48,150 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2009, the fifth bi-annual survey, is planned for administration to 55,000 adult Californians. This study will allow NCI to examine patterns and trends in cancer screening and follow-up, as well as to study other cancer-related topics such as tobacco control, diet, physical activity, and obesity. Additionally, CHIS is designed to be comparable to the National Health Interview Survey (NHIS) data in order to conduct comparative analyses. CHIS provides enhanced estimates for cancer risk factors and screening among racial/ethnic minority populations. *Frequency of Response:* Once. *Affected public:* Individuals or households. *Types of Respondents:* U.S. adults and adolescents (persons 12 years of age and older). The total annual burden hours requested are 3,276.94 (see Table A). The annualized cost to respondents is estimated at: $55,071.88. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2009

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Adults	Adult Pilot	75	1	8/60	10.00
	Adult Survey	24,000.00	1	8/60	3,200.00

TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2009—Continued

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Adolescents	Adolescent Pilot	8	1	2/60	.27
	Adolescent Survey	2,000.00	1	2/60	66.67
Total		26,083			3,276.94

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 proposed 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 Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20852–7344, or call non-toll free number 301–496–8500 or email your request, including your address to: *breenn@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: August 13, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison Office, National Institutes of Health.

[FR Doc. E8–19453 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing and/or Cooperative Research and Development Agreement (CRADA) Opportunities—Enhanced T-cell Activation by Costimulation: A Potentially Novel Approach for the Prevention and/or Therapy of Cancer (Excluding Prostate Diseases and Melanoma) and for Infectious Diseases

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. Cooperative Research and Development Agreement (CRADA) opportunities are also available.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Mojdeh Bahar, J.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville MD 20852; *telephone:* 301/435–2950; *e-mail: baharm@mail.nih.gov*. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications. If interested in a Cooperative Research and Development Agreement (CRADA) Opportunity, please submit a statement of interest and capability to Kevin Brand, J.D., in the NCI Technology Transfer Center, 6120 Executive Boulevard, Suite 450, Rockville MD 20852; *telephone:* 301/451–4566; *e-mail: kb229t@nih.gov*.

SUPPLEMENTARY INFORMATION:

Description of Technology

Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells and not expressed or minimally expressed in normal tissues, are employed to generate a tumor specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that results in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen specific via the peptide/major histocompatibility complex and the second or ''costimulatory'' signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

The present technology describes recombinant poxvirus vectors encoding at least three or more costimulatory molecules and tumor associated antigens (TAAs). The use of three costimulatory molecules such as B7.1, ICAM–1 and LFA–3 (TRICOM®) has been shown to act in synergy with several tumor antigens and antigen epitopes to activate T cells. The effects with TRICOM® were significantly greater than with one or two costimulatory molecules. Laboratory results support the greater effect of TRICOM® to activate both $CD4^+$ and $CD8^+$ T cells. The invention also describes the use of at least one target antigen or immunological epitope as an immunogen or vaccine in conjunction with TRICOM®. The antigens include but are not limited to carcinoembryonic antigen (CEA) and MUC–1. The combination of CEA, MUC–1, and TRICOM® is referred to as PANVAC®.

Availability

The technology is available for exclusive and non-exclusive license in combinations and fields of use. Some potential licensing opportunities involving recombinant poxviral vectors containing transgenes are as follows:

(1) TRICOM® (alone or with a transgene for a tumor antigen and/or an immunostimulatory molecule);