investigational preventive and therapeutic vaccines for infectious disease indications. The recommendations pertain to the assessment of the developmental toxicity potential of preventive and therapeutic vaccines for infectious diseases indicated for females of childbearing potential and pregnant individuals. This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications,'' dated August 2000.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications,'' dated February 2006. The guidance document provides sponsors with recommendations for the conduct and assessment of developmental toxicity studies for investigational preventive and therapeutic vaccines for infectious diseases indicated for women of childbearing potential and pregnant women.

This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications,'' dated August 2000 (65 FR 54534, September 8, 2000). The guidance was revised based on public comments submitted to the Division of Dockets Management on the draft guidance, and on recommendations made by an expert panel convened at a workshop entitled ''Non-Clinical Safety Evaluation of Preventive Vaccines: Recent Advances and Regulatory Considerations'' held December 2 and 3, 2002, Arlington, VA.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance for 21 CFR 601.2 has been approved under OMB control number 0910–0338.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1998 Filed 2–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request, Fogarty International Center CareerTrac

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 Fogarty International Center, 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: Fogarty International Center CareerTrac.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: This data collection system is being developed to track, evaluate and report short and long-term output, outcomes and impacts of international trainees involved in health research training programs—specifically tracking this for at least ten years following training. The data collection system provides a streamlined, Web-based application permitting principal investigators to record career achievement progress by trainee on a voluntary basis. FIC Program Managers will use this data to monitor, evaluate and adjust grants to ensure desired outcomes are achieved, comply with OMB Part requirements for managing grants, respond to congressional inquiries, and as a guide to in future strategic and management decisions regarding the grants training program.

Frequency of Response: Annual and periodic.

Affected Public: none.

Type of Respondents: Principal Investigators funded by Fogarty International Center.

The annual reporting burden is as follows:

Estimated Number of Respondents: 150;

Estimated Number of Responses per Respondent: 15;

Average Burden Hours per Response: .50; and

Estimated Total Annual Burden Hours Requested: 1125.

The annualized cost to respondents is estimated at $87,939. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 Dr. Flora Katz, Fogarty International Center, National Institutes of Health, 31 Center Drive, Building 31, Bethesda, MD 20892–2220 or call non-toll-free number 301–402–9591 or E-mail your request, including your address to: *KatzF@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 the date of this publication.

Dated: February 1, 2006.

Richard Miller,

Executive Officer, FIC, National Institutes of Health.

[FR Doc. E6–2014 Filed 2–13–06; 8:45 am]

BILLING CODE 4140–01–P

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.

Autoantibody Screening for Cancer Diagnosis

Yoon S. Cho-Chung (NCI).

U.S. Provisional Application filed (HHS Reference No. E–057–2006/0-US–01).

Licensing Contact: David A. Lambertson; 301/435–4632; *lambertsond@mail.nih.gov*.

There are a number of specific antigens, such as alpha-fetal protein (AFP), nonmucinous ovarian cancer antigen (CA125), vascular endothelial growth factor (VEGF), prostate-specific antigen (PSA), which are secreted into the serum of patients who have particular cancers. Kits for detecting these antigens are generally used as a means of diagnosing patients as having a specific cancer. However, the current methods suffer from a lack of sensitivity.

The instant technology provides a method for the early diagnosis of different cancers that does not suffer the drawbacks of the current assays. The inventors observed that auto-antibodies against the cancer marker antigens can be detected in the serum of patients with particular cancers. This new technology is designed to screen for the autoantibodies for a spectrum of secreted tumor antigens in a single assay (BBA, in press). This provides a highly sensitive assay for diagnosing cancer at an early stage, or when the tumor is of a very small size. Claims of the instant invention are drawn to methods and kits for performing this analysis as a means of diagnosing cancer.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Therapeutic HIV Vaccine Vectors for Individuals Receiving Antiretroviral Therapy

Barbara K. Felber *et al.* (NCI).

U.S. Provisional Application filed 09 Jul 2004 (HHS Reference No. E–249–2004/0-US–01); PCT Application No. PCT/US2005/024498 filed 11 Jul 2005 (HHS Reference No. E–249–2004/1-PCT–01);

PCT Application No. PCT/US01/45624 filed 01 Nov 2001, which published as WO 02/36806 on 10 May 2002 (HHS Reference No. E–308–2000/0-PCT–02);

National Stage filed in EP, CA, AU, JP, and U.S. (HHS Reference No. E–308–2000/0-US–07).

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov.*

Antiretroviral therapy (ART) against HIV leads to control of viremia, but it does not eradicate the virus. Thus, interruption of ART leads to virus rebound. In addition, prolonged ART is associated with toxicity and development of virus resistance. The technology describes the use of DNA vaccine vectors that produce either secreted or intracellularly degraded antigens for administration to individuals receiving ART. These DNA vectors have recently been shown to work unusually well in controlling viremia when administered as DNA vaccines to SIV-infected monkeys that are undergoing treatment with antiretroviral agents. The current technologies would decrease the drug dependence and assist in clearing or reducing virus burden.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Haplotypes of Human Bitter Taste Receptor Genes

Dennis Drayna and Un-Kyung Kim (NIDCD).

PCT International Application No. PCT/US2004/019489, filed 18 June 2004 (priority date 19 June 2003), International Publication No. WO 2005/007891, Publication Date 27 January 2005 and global IP (HHS Reference Nos. E–222–2003/0 and E–222–2003/1).

Licensing Contact: Susan Carson, D.Phil., 301 435–5020; *carsonsu@mail.nih.gov*.

Bitter taste has evolved in mammals as a crucial, important warning signal against ingestion of poisonous or toxic compounds. However, many beneficial compounds are also bitter, and taste masking of bitter tasting pharmaceutical