

provided on a space available basis beginning at 7:15 a.m. There is no registration fee for the public workshop.

If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, NHLBI, and OPHS are sponsoring a public workshop entitled "Update on Leukocyte Reduction of Blood and Blood Components." The workshop will include the following topics:

- Leukoreduction in targeted and non-targeted recipients;
- Current data on the potential advantages and hazards of providing leukocyte-reduced blood and blood components;
- A review of observed clinical adverse events and manufacturing failures associated with leukoreduction procedures;
- FDA's current considerations for regulatory standards for leukocyte-reduced components and approaches to quality control testing; and
- New scientific developments in filtration, including developing technologies for prion removal from blood components.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: June 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-12185 Filed 6-20-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 24, 2005, page 3376 and allowed 60-days for public comment. Three requests for more information were received. Additional information on the proposed collection was sent to each requestor. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements: Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** Notice.

Proposed Collection: Title: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. *Type of Information Collection Request:* Revision, OMB control number 0925-0407, expiration date July 31, 2005. *Need and Use of Information Collection:* This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these

cancers which currently cause an estimated 263,000 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. The total sample size is 154,938. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectum, and ovary). In addition, cancer incidence, stage shift, and case survival are to be monitored to help understand and explain results. Biologic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Basic demographic data, risk factor data for the four cancer sites and screening history data, as collected from all subjects at baseline, will be used to assure comparability between the screening and control groups and make appropriate adjustments in analysis. Further, demographic and risk factor information may be used to analyze the differential effectiveness of screening in high versus low risk individuals.

Frequency of Response: On occasion.

Affected Public: Individuals or households. *Type of Respondents:* Adult men and women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 145,852; *Estimated Number of Responses Per Respondent:* 1.14; *Average Burden Hours Per Response:* 0.14; and *Estimated Total Annual Burden Hours Requested:* 23,278. The annualized cost to respondents is estimated at: \$232,780. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated annual number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults	145,852	1.14	0.14	23,278

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235,

Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3070, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301-496-8544 or e-mail your request, including your address to: Bergc@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: June 10, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05-12128 Filed 6-20-05; 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, DHHS.

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.

Epitopes of Ebola Virus Glycoproteins Useful for Vaccine Development

Carolyn A. Wilson et al. (FDA)

U.S. Provisional Application No. 60/532,677 filed 23 Dec 2003 (DHHS Reference No. E-271-2003/0-US-01);

PCT Patent Application filed 23 Dec 2004 (DHHS Reference No. E-271-2003/1-PCT-01).

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

The current technology relates to the identification of two highly conserved linear domains of Ebola or Marburg envelope glycoprotein (GP) and of amino acid residues within these regions critical for virus infection. The identified domains could provide targets for rational design and development of broadly cross-protective antivirals and vaccines. There are currently no licensed vaccines against Ebola and Marburg. The linear domains (or portions) could potentially be used as immunogens in a vaccine. Mutations containing these epitopes have been identified to result in the formation of non-infectious Ebola viral particles, which could be useful for developing vaccines against Ebola virus, a category A biodefense agent. Vaccines utilizing these non-infectious particles may be safer than vaccines that use other common approaches, *e.g.* live-attenuated virus vaccines. This technology describes the polypeptides that form the non-infectious Ebola viral particles, the polynucleotide sequences encoding the polypeptides, vectors comprising the polynucleotides, host cells transformed with such vectors, vaccines and methods suitable for use in the prevention and/or treatment of hemorrhagic fever due to Ebola or Marburg, and a molecular decoy comprising the polynucleotides. These additional materials could also form the basis of an Ebola vaccine or antiviral therapy. Diagnostic applications involving the aforementioned materials are also described. Development of antiviral compounds and vaccines for treatment and prevention of Ebola and Marburg infections would be of tremendous benefit for biodefense and public health. However, the current Ebola vaccine technologies such as DNA-based vaccines and subunit vaccines either have safety risks or lack broad cross-protectivity. Therefore, the present technology could provide a promising technology to make safe and broad cross-reactive antivirals or vaccines against Ebola and Marburg viruses.

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

Detection and Identification of Mycobacterium Using SecA

Steven H. Fischer and Adrian M. Zelazny (CC)

U.S. Provisional Application No. 60/548,371 filed 27 Feb 2004 (DHHS Ref. No. E-238-2003/0-US-01); PCT Application No. PCT/US05/06609 filed 28 Feb 2005 (DHHS Ref. No. E-238-2003/0-PCT-02).

Licensing Contact: Robert M. Joynes, J.D.; 301/594-6565; joynesr@mail.nih.gov.

This invention relates to a method of detecting a wide variety of Mycobacterium and Nocardia species in a sample. The method involves hybridizing an amplified Mycobacterium/Nocardia genus-specific secA nucleic acid to a Mycobacterium/Nocardia species-specific secA probe oligonucleotide, wherein the amplification utilizes at least two Mycobacterium/Nocardia genus-specific primers, and detecting hybridization of the Mycobacterium/Nocardia-specific secA nucleic acid. The Mycobacterium/Nocardia genus-specific primers bind within a conserved region of the nucleic acid sequence encoding a Mycobacterium/Nocardia bi-genus-specific secA protein, wherein the conserved region is in the 5' half of the Mycobacterium/Nocardia secA gene and includes a substrate specificity domain.

The approach for detection of Mycobacterium/Nocardia species in clinical materials could potentially be used as a universal system for detection of any member of the genus Mycobacterium and the genus Nocardia and identification at the species or complex level. The system currently identifies all mycobacteria tested to date. With a few modifications, we believe it will also detect all Nocardia species of clinical significance. Contrary to commercial methods based on 16S rRNA and ITS, the SecA method will detect both Mycobacterium and Nocardia species. The region targeted has sufficient sequence variation for discrimination at the species or complex level.

Based on the information available to date, the SecA approach could be potentially used to replace acid-fast smears (AFB) and modified acid-fast smears, could provide definitive detection and identification of a large variety of Mycobacterium and Nocardia species present in clinical materials, and could be used as a single confirmation and species identification system for suspected positive Mycobacterium or Nocardia cultures. The invention also contemplates devices, including arrays, and kits for