the system. At the second voice prompt press 1 to order a document. Enter the document number 1252 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance at any time. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3020 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

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: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. *Type of Information Collection Request:* EXTENSION, OMB control number 0925–0407, expiration date October 31, 2002. *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 251,000 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 after more than 8 years of recruitment is 154,956. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectal, 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 will 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:* 150,598; *Estimated Number of Responses Per Respondent:* 1.38; *Average Burden Hours Per Response:* 0.19; and *Estimated Total Annual Burden Hours Requested:* 39,597. The annualized cost to respondents is estimated at: $395,970. 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. John Gohagan, Chief, Early Detection Branch, EDCOP, National Cancer institute, NIH, EPN Building, Room 3100, 6130 Executive Boulevard, Bethesda, MD 20892–7346, or call non-toll-free number (301) 496–3982 or e-mail your request, including your address to: *jg72p@mail.nih.gov*.

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

Dated: January 28, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02–2904 Filed 2–6–02; 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, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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 application listed below may be obtained by contacting Catherine Joyce, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 258; fax:

301/402–0220; e-mail: *joycec@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

Thymidylate Synthase Peptides that Bind to Thymidylate Synthase Messenger RNA

Drs. Carmen Allegra and Donna Voeller (NCI).

DHHS Reference No. E–311–00/0 filed Mar 07 2001.

Thymidylate synthase (TS) is a folate-dependent enzyme that catalyzes the reductive methylation of 2'-deoxyuridine-5'monphosphate (dUMP) by the reduced folate-5,10-methylene tetrahydrofolate to deoxythymidine 5'-monophosphate (dTMP, thymidylate). Once synthesized, dTMP is phosphorylated to dTDP and then to dTTP, which is the direct precursor for DNA synthesis. Given the direct role of TS in the biosynthesis of dTMP and the finding that inhibition of dTMP synthesis results in prompt cessation of cellular proliferation and growth, TS represents an important target for cancer chemotherapy.

Specific TS peptides have been discovered which bind to TS mRNA. These peptides may be of use in screening assays to identify agents that bind TS mRNA or that inhibit the binding of TS protein to TS mRNA. These peptides are also of use in treating subjects in conjunction with other chemotherapeutic agents, and in identifying molecules and mimetics that bind TS mRNA or bind the bimolecular complex of TS protein and TS mRNA.

The above-mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: January 28, 2002.

Jack Spiegel,

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

[FR Doc. 02–2908 Filed 2–6–02; 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 agencies 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.

Four Chimpanzee Monoclonal Antibodies that Neutralize Hepatitis A Virus

Darren Schofield, Suzanne Emerson, Robert Purcell (NIAID).

DHHS Reference No. E–356–01/0 filed Nov 07 2001.

Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

This invention claims antibodies and/or fragments thereof specific for hepatitis A virus (HAV) and the use of the antibodies in the diagnosis, prevention, and treatment of hepatitis A. Hepatitis A is the most common type of hepatitis reported in the United States, which reports an estimated 134,000 cases annually, and infects at least 1.4 million people worldwide each year. HAV is a positive sense RNA virus that is transmitted via the fecal-oral route, mainly through contaminated water supplies and food sources. HAV is thought to replicate in the oropharynx and epithelial lining of the intestines, where it initiates a transient viremia and subsequently infects the liver. Humoral immunity has been shown to provide an effective defense against Hepatitis A. Prior to the availability of the current inactivated virus vaccines, pooled human immune globulin preparations were routinely used to protect individuals traveling to areas of the world where HAV is endemic. Chimpanzees are susceptible to infection with HAV and can produce antibodies that neutralize the virus. Chimpanzee immunoglobulins are virtually identical to those of humans; thus, they have the same potential as human antibodies for clinical applications. The inventors have shown that the four chimpanzee monoclonal antibodies described in the patent application neutralized HAV strains HM–175, AGM–27, and the HM–175 VP3–070 mutant. Since only a single serotype of HAV has been identified, these antibodies are predicted to neutralize most, if not all, isolates of HAV.

N-Formyl Peptide Receptor Mediation of Platelet Chemotaxis Toward Injured Cells and Activation of Immune Response

Julie Lekstrom-Himes (NIAID), Allan Kirk (NIDDK), David Kleiner (NIAID), Meggan Czapiga (NIAID).

DHHS Reference No. E–282–01/0 filed Oct 05 2001.

Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

Formyl peptides are short peptides generated by bacterial or mitochondrial endopepdidase cleavage of the first few amino acids including the N-formyl-modified methionine group of proteins. They bind to specific receptors on phagocytic cells and platelets, and induce directed migration or chemotaxis. Human phagocytes express two N-formyl peptide receptors, FPR (N-formyl peptide receptor) and FPRL–1 (FPR-like 1), both of which couple to pertussis toxin-sensitive G proteins. FPR binds N-formyl peptides at a 1000 fold higher affinity than FPRL 1 and is attributed with inducing chemotaxis. Based on their chemotactic actions, it has been hypothesized that N-formyl peptides attract phagocytes and platelets to sites of infection and injury and therefore play an important role in microbicidal and other host defense activities. In particular, platelets carry CD154 or CD40 ligand on their surface and can provide induction of dendritic cell maturation and co-stimulatory molecule expression, thus regulating immune versus tolerance responses.

Claimed in the invention are compositions of N-formyl peptides and derivatives of N-formal peptides, use of N-formyl peptides to stimulate an immune or inflammatory response, and methods of using N-formal peptide receptor inhibitors, such as blocking antibodies or other receptor antagonists, for inhibiting inflammation. Also claimed in the invention are methods of mobilizing platelets at an injury site and methods of wound healing at an injury site comprising administering N-formal peptides to the site.

Vaccination Strategies To Provide Protection Against the Ebola Virus

Gary Nabel et al. (VRC/NIAID).

DHHS Reference No. E–241–01/0 filed Oct 01 2001.