CDC shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

CDC shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that the FDA and/or CDC may take appropriate measures including filing a motion with the court or an appeal.

CDC has agreed, by this letter or e-mail and by a signed request letter dated _____, not to publicly disclose the above-described information without prior written permission of FDA. CDC acknowledges that applicable laws and regulations may prohibit the disclosure of such information. *See, e.g.*, 21 U.S.C.331(j); 18 U.S.C. 1905, and 21 CFR parts 20 and 21, 42 CFR parts 5 and 5b, and 42 U.S.C.301(d). CDC also agrees to comply with the principles and procedures set forth in the Memorandum of Understanding between FDA and CDC, *cite*.

[FR Doc. 00–31591 Filed 12–11–00; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; A Nested Case-Control Study of Lung Cancer and Diesel Exhaust Among Non-Metal Miners

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 for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 26, 2000, page 24490, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title. A Nested Case-Control Study of Lung Cancer and Diesel Exhaust Among Non-Metal Miners. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This nested case-control study will examine lung cancer in non-metal miners and its association, if any, with diesel exhaust exposure. The study will involve approximately 160 deaths from lung cancer (the actual number will depend on the number of deaths occurring, but based on national rates we expect 160), and four controls matched to each death, identified from the cohort. Controls will be matched on miners, gender, race/ethnicity and year of birth (within 5 years). Detailed information regarding exposure to diesel exhaust will be obtained from employment records and measurements of diesel exhaust surrogates. Information on potential confounders will be obtained by interview and from environmental measurements. This information will be used in a study by the National Cancer Institute and the National Institute for Occupational Safety and Health to examine risk of mortality from lung cancer for various measures of diesel exhaust exposure, adjusted for smoking and other potential confounders. *Frequency of Response:* Single-time study. *Affected Public:* Individuals. *Type of Respondents:* Workers or next of kin of workers. The annual reporting burden is as follows: Estimated number of Respondents: 227; Estimated Number of Responses per Respondent: One; Average Burden Hours per Response: 1.0; and Estimated Total Annual Burden Hours Requested: 227. There are no Capital Costs, Operating Costs, and/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.

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. Debra Silverman, NCI Project Director, National Cancer Institute, Executive Plaza South, Room 8108, Rockville, Maryland 20892–7240, or call non-toll-free number (301) 435–4716, or FAX your request to (301) 402–1819, or E-mail your request, including your address, to Silvermd@exhange.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before January 11, 2001.

Dated: December 1, 2000.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 00–31522 Filed 12–11–00; 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 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 contacting Peter A. Soukas, 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. 268; fax: 301/402–0220; e-mail: *soukasp@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Antibodies and Other Ligands Directed Against KIR2DL4 Receptor for Production of Interferon-Gamma

Eric Long, Sumati Rajagopalan (NIAID)
DHHS Reference No. E–255–00/0 filed 23 Oct 2000

Interferon-gamma is a potent antiviral and antimicrobial substance produced by natural killer (NK) white blood cells. NK cells are activated during infections by viruses and by other intracellular pathogens, such as parasites and bacteria. Soluble substances, such as interleukins, produced by infected cells activate NK cells to secrete interferon-gamma. Injection of interleukins into patients to stimulate NK cells to secrete interferon-gamma has not been a successful therapeutic approach because of the toxicity involved. The invention is based on the discovery by the inventors that activation of the KIR2DL4 receptor expressed by all NK cells stimulates them to produce interferon-gamma. The invention claims monoclonal antibodies and derivatives thereof, as well as natural and synthetic ligands of KIR2DL4 that can be utilized to stimulate interferon-gamma production by NK cells without any other stimulus. The possibility of inducing interferon-gamma production by NK cells without the toxic side effects of interleukins could be an effective therapy for various types of infections and of cancers. Also claimed in the invention are methods of treating various cancers and viral infections, methods of treating autoimmune disease, and methods of administration of the antibody or derivatives thereof.

Ixodes scapularis Tissue Factor Pathway Inhibitor

Ivo Francischetti, Jesus Valenzuela, Jose Ribeiro (NIAID)
DHHS Reference No. E–208–00/0 filed 05 Oct 2000

Ixodes scapularis is a blood-sucking tick and the principal vector of Lyme disease, a spirochetal illness caused by Borrelia burgdorferi and now the most common vector-borne infection in the United States; more than 50,000 cases have been reported during the last ten years. The salivary gland of I. scapularis has a number of pharmacologically active molecules that help the tick to successfully feed on blood, such as inhibitors of complement system, in addition to coagulation and platelet aggregation inhibitors. This invention describes Ixolaris, a protein that inhibits the initiation of blood coagulation by inhibition of components of the extrinsic pathway. Accordingly, Ixolaris blocks Factor X activation by Factor VIIa/TissueFactor, it attenuates Factor Xa production by the prothrombinase, and inhibits fibrin formation in a diluted prothrombin time. Ixolaris is highly specific since it does not inhibit other serine proteases. Because Ixolaris has anticoagulant properties, it could be used to ameliorate a number of clinical conditions such as disseminated intravascular coagulation, and hypercoagulation states. In addition, Ixolaris may be useful as a vaccine candidate for Lyme disease because inactivation of Ixolaris by antibodies may make transmission of Borrelia burgdorferi more difficult. In addition to the composition of Ixolaris, the invention claims vaccines utilizing Ixolaris, methods of stimulating an immune response, and methods of treatment of restenosis, arterial thrombosis, and stroke.

Ixodes Salivary Anticomplement Protein

Jose Ribeiro (NIAID), Jesus Valenzuela (NIAID), Rosane Charlab (NIAID), Thomas Mather (EM)
DHHS Reference No. E–207–00/0 filed 28 Sep 2000

This invention describes Isac, a novel anticomplement protein that can be isolated and purified from I. scapularis (tick) saliva that may be useful as a peptide vaccine against Lyme disease. Because inactivation of Isac by antibodies will make transmission of Borrelia burgdorferi to humans more difficult, Isac is an ideal candidate for a Lyme disease vaccine. Isac disrupts the alternative complement pathway by inhibiting factors Bb and/or C3b, preventing cell lysis and anaphylatoxin production. The inventors have found no similarity to any protein in GenBank for Isac. Isac may also be used in situations where alternative complement activation is implicated such as in rheumatoid conditions such as lupus erythematosus or juvenile arthritis. The invention is further described in Ribeiro et al., ''Purification, cloning, and expression of a novel salivary anticomplement protein from the tick, Ixodes scapularis,'' J Biol. Chem. 2000 Jun 23; 275(25):18717–23.

LL–37 Is an Immunostimulant

Oleg Chertov (NCI), Joost Oppenheim (NCI), De Yang (NCI), Qian Chen (NCI), Ji Wang (NCI), Mark Anderson (EM), Joseph Wooters (EM)
DHHS Reference No. E–285–00/0 filed 21 Sep 2000

This invention relates to use of an antimicrobial peptide as a vaccine adjuvant. LL–37 is the cleaved antimicrobial 37-residue C-terminal peptide of hCAP18, the only identified