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 or 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. Shelia Hoar Zahm, Project Officer, National Cancer Institute, Executive Plaza North, Room 418, Rockville, MD 20892–7364, or call non-toll-free number (301) 496–9093, or FAX your request to (301) 402–1819, or E-mail your request, including your address, to ZahmS@epndce.nci.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before February 7, 1997.

Dated: December 6, 1996.

Nancy L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–334 Filed 1–7–97; 8:45 am]

BILLING CODE 4140–01–M

National Institutes Of Health

National Eye Institute; National Institute of Arthritis and Musculoskeletal and Skin Diseases: Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Use of Antiflammins

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees and/or CRADA partners for the further development and commercialization of its patent portfolio for antiflammins. The inventions claimed in U.S. Patent No. 5,266,562 issued 30 Nov 1993, ''Anti-Inflammatory Agents,'' are available for either exclusive or non-exclusive licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under one or more CRADAs in several clinically important applications as described below in the Supplementary Information.

To speed the research, development and commercialization of this new class of drugs, the National Institutes of Health is seeking one or more license agreements and/or CRADAs with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents. Any proposal to use antiflammins in the treatment of inflammatory disease processes will be considered.

ADDRESSES: CRADA proposals and questions about this opportunity should be addressed to: Ms. Sue Patow, Office of Technology Transfer, National Heart, Lung, and Blood Institute, Building 31, Room 1B30, Bethesda, MD 20892 (301/402–5579). CRADA proposals must be received by the date specified below.

Licensing proposals and questions about this opportunity should be addressed to: Ms. Carol Lavrich, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852 (301/496–7735 ext. 287). Respondees interested in licensing the invention will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA agreement.

DATES: There is no deadline by which license applications must be received. CRADA proposals must be received on or before April 8, 1997.

SUPPLEMENTARY INFORMATION: Antiflammins are biologically active synthetic oligopeptides, derived from the sequence similarity between lipocortin-1 and uteroglobin, an anti-flammatory protein. These peptides have antiphospholipase A_2 and immunomodulatory properties. Because of the great therapeutic potential of specific and potent antiflammin drugs that may be developed, scientists in several Institutes at the National Institutes of Health are examining the use of antiflammins in the treatment of Health are examining the use of antiflammins in the treatment of a variety of inflammatory processes, including acute anterior ocular inflammation (uveitis) and psoriasis.

Dr. Chi-Cho Chan, a clinical investigator at the National Eye Institute (NEI), has an IND for the use of antiflammin 2 in acute anterior uveitis, and seven patients have previously been enrolled in a clinical trial. To date, no toxicity has been observed in patients treated with this drug. Dr. Chan and Dr. Whitcup at the NEI are interested in developing new topical formulations of antiflammins and the initiation of multi-center randomized clinical trials of antiflammins for the treatment of anterior uveitis, post-operative ocular inflammation, and allergic conjunctivitis.

Dr. John DiGiovanna, an investigator in the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), is studying the use of antiflammins to treat psoriasis, a hyperproliferative inflammatory skin disease. Dr. DiGiovanna would like to continue these studies with a collaborator capable of expanding these studies to include other inflammatory skin diseases such as atopic and contact dermatitis, as well as develop animal and *in vitro* models to study the effects of antiflammins on skin.

In addition, Dr. Dimitrios T. Boumpas, also of NIAMS, is studying the use of anti-inflammatory/immunosuppressive compounds to treat psoriatic arthritis, rheumatoid arthritis, and systemic lupus erythematosus. Dr. Boumpas would like to initiate studies with a collaborator to investigate the effects of antiflammins in animal models of these diseases including toxicity studies and its use and toxicity in patients with autoimmune rheumatic diseases.

CRADA aims include the rapid publication of research results and the timely exploitation of commercial opportunities. The CRADA partner(s) will enjoy rights of first negotiation for licensing Government rights to any inventions arising under the agreement and will be expected to advance funds payable upon signing the CRADA to help defray Government expenses for patenting such inventions and other CRADA-related costs.

The role of the NEI and NIAMS in these CRADAs will be as follows:

1. Provide the Collaborator(s) with samples of the subject compounds for pharmaceutical evaluation.

2. Continue the detailed physicochemical characterization of the test compounds as well as research on their mechanism of biological action, and publish these results and provide

all data to the Collaborator as soon as they become available.

3. Conduct controlled clinical trials of antiflammin formulations that have been determined to have therapeutic potential in ocular and skin inflammatory diseases.

The role of the Collaborator(s) will be to:

1. Perform an exhaustive evaluation of these compounds with respect to their biological activities and to develop appropriate vehicles for drug delivery for disease processes covered under the CRADA. The Collaborator(s) will supply data to the NEI and/or NIAMS in a timely fashion.

2. Synthesize and formulate structural variants of these subject compounds to optimize desired effects.

3. Expand the basic toxicological data as needed in preparation for additional clinical studies.

4. Conduct basic studies designed to better understand the potential for antiflammins in the treatment of inflammatory diseases, bioavailability and how to best administer these agents.

5. Support the execution of clinical trials designed to evaluate efficacy and toxicity. This may include providing pharmaceutical grade compound, equipment and supplies, and support personnel.

6. Provide new and improved formulations in appropriate vehicles.

Selection criteria for choosing the CRADA partner(s) will include but not be limited to:

1. Ability to complete the quality pharmacological evaluations required according to an appropriate timetable to be outlined in the Collaborator's proposal. The target commercial application as well as the strategy for evaluating the test agents' potential in that capacity must be clearly delineated therein.

2. The level of financial support the Collaborator will supply for CRADA-related Government activities.

3. A willingness to cooperate with the NEI and NIAMS in publication of research results.

4. An agreement to be bound by the DHHS rules involving human subjects, patent rights, ethical treatment of animals, and randomized clinical trials.

5. Agreement with provisions for equitable distribution of patent rights to any inventions developed under the CRADA(s). Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, non-exclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an option to negotiate an exclusive or non-exclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor).

Dated: December 23, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–333 Filed 1–7–97; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of Health

National Center for Research Resources: Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of Technologies and Applications for Spatial and Temporal Control of Gene Expression Using a Heat Shock Protein Promoter in Combination With Local Heat

AGENCY: National Institutes of Health, PHS, HHS.

ACTION: Notice.

SUMMARY: The National Center for Research Resources (NCRR) and collaborating institutes of the NIH are seeking CRADA partners and/or licensees for the development of different technologies and applications to provide a safe and efficient introduction of exogenous genes under the control of a heat-sensitive promoter and to assess the efficacy of spatial and temporal control of gene expression using MRI guided FUS. This project is with the In Vivo NMR Research Center, NCRR, in a collaborative study with the National Institute on Aging, the National Heart Lung and Blood Institute, and the National Institute of Dental Research of the National Institutes of Health, Bethesda, Maryland

The NCRR has applied for patents claiming this core technology. Non-exclusive and/or exclusive licenses for these patents covering core aspects of this project are available (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) to interested parties.

DATES: There is no deadline by which license applications or CRADA proposals must be received.

ADDRESSES: CRADA capability statements/proposals and questions about this opportunity should be addressed to Mr. Tom Ingalls, Technology Transfer Specialist, NCRR, Bldg. 12A/Room 4057, Bethesda, Maryland 20892–2490; Phone: 301/496–6235.

Licensing applications and licensing inquiries regarding this technology should be addressed to Mr. Larry Tiffany, Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Phone: 301/496–7735, ext. 206; Fax: 301/402–0220.

Information on the patent and patent applications and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA agreement.

SUPPLEMENTARY INFORMATION: In many instances, it is desirable to express exogenous genes only in certain tissues, and/or at will at certain times, and/or only to a certain degree. However, current gene transfer and exogenous gene expression protocols do not provide adequate means of simultaneously controlling which cells in a heterogeneous population are transformed and when, where, and to what degree the transferred genes are expressed. Here, we seek to accomplish the spatial and local control of expression of exogenous genes using a heat-inducible promoter (such as the inducible hsp70 promoter) in combination with local heat, preferably provided by Magnetic Resonance Imaging (MRI) guided Focused Ultrasound (FUS).

The goals of this project are to use the respective strengths of both parties to achieve one or more of the following:

1. Evaluate the feasibility and safety of gene therapy utilizing a range of suitable vectors as a treatment approach to carry out a systemic gene transfer in which the therapeutic gene is under the control of a heat-sensitive promoter showing negligible constitutive expression at normal body temperature.

2. Evaluate the feasibility of controlling the local and temporal induction of gene expression (pharmacokinetics) using local heat provided by Magnetic Resonance Imaging guided Focused Ultrasound.

3. Develop and evaluate gene therapy products for use in experimental animal models and for human use based on the above control of expression.

It is anticipated that the commercial collaborator(s) will participate in ongoing studies on one or more of the research projects involving:

1. The transfer of genes for various lymphokines into experimental animal