ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Estimated annual number of respondents	Estimated number of responses per response	Average burden hours per response	Estimated total annual burden hours requested
Reporting:				
Section 52b.9(b)	1	1	.50	.50
Section 52b.10(f)	60	1	1	60
Section 52b.10(g)	60	12	1	720
Section 52b.11(b)	100	1	1	100
Recordkeeping:				
Section 52b.10(g)	60	260	1	15,600
Total	381			16,480.5

The annualized cost to the public, based on an average of 60 active grants in the construction phase, is estimated at: $576,818. 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 should address one or more of the following points: (1) Evaluate whether the proposed collection of information and recordkeeping are 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 and recordkeeping, including the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected and the recordkeeping information to be maintained; 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 and recordkeeping techniques of other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Contact Jerry Moore, NIH Regulations Officer, Office of Management Assessment, Division of Management Support, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, Maryland 20852; call 301–496–4607 (this is not a toll-free number) or Email your request to jm40z@nih.gov.

Comments Due Date: Comments regarding this information collection and recordkeeping are best assured of having full effect if received on or before October 9, 2001.

Dated: July 30, 2001.

Jerry Moore,

Regulations Officer, National Institutes of Health.

[FR Doc. 01–19639 Filed 8–6–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): Opportunity for Cooperative Research and Development Agreements (CRADAs) to Implement a Multicenter, Clinical Trial to Study Viral Resistance to Pegylated Interferon Therapy in Combination with Ribavirin in Patients Who Have Chronic Hepatitis C, Genotype 1, Specifically Focusing Upon African Americans

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

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) is seeking proposals in the form of capability statements from companies for a Cooperative Research and Development Agreement (CRADA) to provide active agent(s) to study important issues surrounding viral resistance to interferon in hepatitis C, particularly in African Americans.

Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to provide active agent(s) to study important issues surrounding viral resistance to interferon in hepatitis C. The potential Collaborator(s) capability statement should provide proof of expertise in the design and implementation of pegylated interferon and ribavirin therapies for hepatitis C and should include the scientific rationale for the study proposed, proposed dosing regimes, possible strategies for assessing compliance, proposed methods for assessing interferon levels, pharmacokinetics, and drug distribution methodology.

DATES: Only written CRADA capability statements received by the NIDDK on or before August 24, 2001 will be considered. Applicants meeting the criteria as set forth in this announcement will be invited to discuss their plans, capabilities, and research findings pertinent to pegylated interferon and ribavirin with the study's Steering Committee on September 23–24, 2001. This will be at the Collaborator's expense. The Institute may issue an additional notice of CRADA opportunity. This notice is directed toward companies with resources to support collaborations.

FOR ADDITIONAL INFORMATION AND QUESTIONS: Capability statements should be submitted to Dr. Michael W. Edwards, Office of Technology Development, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, BSA Building, Suite 350 MSC 2690, 9190 Rockville Pike, Bethesda, MD 20814–3800; Tel: 301/496–7778, Fax: 301/402–0535; Email: mels@nih.gov.

SUPPLEMENTARY INFORMATION: A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the

procurement of goods/services. The NIDDK is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NIDDK can contribute facilities, staff, materials, and expertise to the effort. The collaborator typically contributes facilities, staff, materials, expertise, and funding to the collaboration. The CRADA collaborator receives an exclusive option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a pre-determined field of use and may qualify as a co-inventor of new technology developed under the CRADA.

Study Goal: The goal of this study is to plan and implement a multicenter clinical investigation into combination antiviral therapy of patients with chronic hepatitis C infected with HCV genotype 1.

Applicants must include a description of investigators and staff with experience and expertise to collaborate in multicenter clinical studies to assess combination antiviral therapy of patients with chronic hepatitis C infected with HCV genotype 1. Applicants must give evidence of their ability and experience to conduct multicenter clinical trials, with patients with chronic hepatitis C. If applicants have particular expertise and accomplishments in recruiting individuals from minority groups, these should be described.

Applicants should provide a detailed description of the pharmacokinetics of the proposed drugs to be used including how and when the drugs should be taken. The process for biologic sample collection, storage and handling needs must be included. A description of the laboratory tests that are needed including assays to determine interferon levels along with appropriate methods for performing them should be provided, as well as other core facilities and interactions with core facilities that are needed. Also included should be the methods that would be used to assure privacy and maintain confidentiality of data. How the drug will be sent to each participating center as well as packaging, storing, and accountability issues must be presented.

Capability Statements: A Selection Committee will utilize the information provided in the ''Collaborator Capability Statements'' received in response to this announcement to help in its deliberations. It is the intention of the NIDDK that all qualified Collaborators have the opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

1. The statement should provide specific details of the methods to be utilized in the investigation of combination antiviral therapy of patients with chronic hepatitis C infected with HCV genotype 1 and clearly describe important issues surrounding viral resistance to interferon in hepatitis C.

2. The statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the therapeutic medication agents in a timely manner for the duration of the study.

3. The statement should may include outcome measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to viral resistance to interferon in hepatitis C, specific funding commitment to support the advancement of scientific research, personnel, services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.

4. The statement must address willingness to promptly publish research results and ability to be bound by PHS intellectual property policies (see CRADA: *http://ott.od.nih.gov/newpages/crada.pdf).*

Dated: July 27, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer Office of Technology Transfer.

[FR Doc. 01–19640 Filed 8–6–01; 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 contacting Matthew Kiser at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7735 ext. 224; fax: 301/402–0220; e-mail: *kiserm@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Anticancer Effects of Novel Vitamin D Receptor Antagonists

Julianna Barsony (NIDDK); DHHS Reference No. E–213–01/0 filed 20 Jun 2001

The present invention relates to cancer therapeutics. Specifically, this invention relates to novel selective vitamin D receptor modulators (SEDM), also known as vitamin D receptor antagonists. Methods of treatment resulting in inhibition of cell growth, inducement of cell differentiation, inhibition of breast cancer growth, and inhibition of parathyroid hormone secretion in mice are disclosed.

Vitamin D does not have significant biological activity. Rather, it must be metabolized within the body to its hormonally active form, calcitriol. Calcitriol acts through the vitamin D receptor (VDR) to regulate important functions, such as calcium homeostasis, cell proliferation and differentiation, and immune functions. Many cancers contain VDR and, therefore respond to calcitriol. In such cancers, low concentrations of calcitriol stimulate growth and high concentrations inhibit growth. High doses of calcitriol and calcitriol analogues, however, cause hypercalcemia, limiting the use of this hormone for cancer treatment.

The present invention relates to derivatives of calcitriol that have been synthesized in a manner similar to the principles developed to create estrogen receptor modulators (SERM). These vitamin D receptor modulators bind well to VDR, inhibit their ability to stimulate cancer cell growth and increase their ability to induce cell differentiation. In mice, SEDM inhibited human breast cancer growth without causing hypercalcemia. The technology disclosed herein may also be used for the prevention of breast cancer, treatment and/or prevention of other types of conditions or diseases, such as, but not limited to, prostate, colorectal, and lung cancers, leukemia, primary or metastatic melanoma, glyoma, and parathyroid diseases.