

Organ Procurement Organizations (OPO) as well as deficiencies noted during periodic facility and laboratory certification surveys. This information is used to make decisions concerning OPO redesignation, certification/recertification of health care facilities participating in the Medicare/Medicaid Programs, and laboratories regulated by CLIA. *Frequency:* Annually and Biennially; *Affected Public:* State, Local or Tribal Governments, Business or other for-profit, Not-for-profit institutions, Federal Government; *Number of Respondents:* 49,200; *Total Annual Responses:* 98,400; *Total Annual Hours Requested:* 196,800.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent by 5/31/96 to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 22, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96-13519 Filed 5-28-96; 8:45 am]

BILLING CODE 4120-03-P-M

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Hydroxylated Aromatic Protein Cross-Linking Compounds for the Treatment of Hyperproliferative Epithelial Lesions

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a company that can collaboratively pursue the pre-clinical and clinical development of Hydroxylated Aromatic Protein Cross-Linking Compounds for the treatment of hyperproliferative epithelial lesions including skin neoplasia, warts and other hyperproliferative skin disorders. The National Cancer Institute, Laboratory of Cellular Carcinogenesis and Tumor Promotion (LCCTP) has established that this class of compounds (cinnamic acid derivatives) may be effective in treating

hyperproliferative skin disorders. The selected sponsor will be awarded a CRADA for the co-development of this agent with the National Cancer Institute.

ADDRESS: Questions about this opportunity may be addressed to Jeremy A. Cubert, M.S., J.D., Office of Technology Development, NCI, 6120 Executive Blvd., MSC 7182, Bethesda MD 20892-7182, Phone: (301) 496-0477, Facsimile: (301) 402-2117, from whom further information may be obtained.

DATE: In view of the important priority of developing new agents for the treatment or prevention of cancer, interested parties should notify this office in writing no later than July 12, 1996. Respondents will then be provided an additional 30 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION:

"Cooperative Research Development Agreement" or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and amendments (including 104 P.L. 113) and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking a pharmaceutical company which, in accordance with the requirements of the regulations governing the transfer of agents in which the Government has taken an active role in developing (37 CFR 404.8), can further develop the subject compounds through Federal Food and Drug Administration approval and to a commercially available status to meet the needs of the public and with the best terms for the Government. The government has applied for a patent application directed to methods for the treatment for Hyperproliferative Epithelial Lesions by Topical Application of Hydroxylated Aromatic Protein Cross-Linking-Compounds.

Methyl 2,5-dihydroxycinnamate (MC), a cinnamic acid derivative, has been shown to both inhibit cell growth and chemically cross-link proteins. The growth inhibitory and protein cross-linking activity of MC are independent and complementary. The cross-linking effect of the compounds is rapid and leads to programmed cell death for many cell types. At lower concentrations, the compounds inhibit tyrosine kinases and cell growth. The compounds have been shown to be effective in many cell types indicating potential for topical treatment of a wide range of localized hyperproliferative epithelial disorders.

The LCCTP, Division of Basic Sciences, NCI is interested in establishing a CRADA with a company to assist in the continuing development of these compounds. The Government will provide all available expertise and information to date and will jointly pursue pre-clinical and clinical studies as required, giving the company full access to existing data and data developed pursuant to the CRADA. The successful company will provide the necessary scientific, financial and organizational support to establish clinical efficacy and possible commercial status of the subject compounds.

The expected duration of the CRADA will be two (2) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. Selection of appropriate compounds for *in vitro* screening.
2. Selection of appropriate compounds for *in vivo* screening.
3. Conduct *in vitro* screening of appropriate compounds.
4. Identify chemical basis of activity for class of compounds.
5. Conduct *in vivo* testing of appropriate compounds.
6. Evaluation of test results.
7. Preparation of manuscripts for publication.
8. Relevant Government intellectual property rights are available for licensing through the Office of Technology Transfer, National Institutes of Health. For further information contact Allan Kiang, J.D., NIH Office of Technology Transfer, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, Phone: (301) 496-7735 (ext. 270); Facsimile: (301) 402-0220.

The role of the collaborator company, includes the following:

1. Conduct *in vitro* screening of appropriate compounds.
2. Identify chemical basis of activity for class of compounds.
3. Conduct *in vivo* testing of appropriate compounds.
4. Evaluation of test results.
5. Develop vehicle for delivery of compounds to patients.
6. Conduct pre-clinical and clinical trials of appropriate candidate compounds.

Criteria for choosing the company include its demonstrated experience and commitment to the following:

1. Scientific expertise in and demonstrated commitment to the treatment of skin related disorders.
2. Scientific expertise in and demonstrated commitment to the development of drug delivery systems.
3. Experience in preclinical and clinical drug development.
4. Experience and ability to produce, package, market and distribute pharmaceutical products.
5. Experience in the monitoring, evaluation and interpretation of the data from

investigational agent clinical studies under an IND.

6. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from pre-clinical studies and clinical trials regarding the subject compounds.

7. Provide defined financial and personnel support for the CRADA to be mutually agreed upon.

8. An agreement to be bound by the DHHS rules involving human and animal subjects.

9. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

10. Provisions for equitable distribution of patent rights to any CRADA inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government and (2) an option for the collaborator to elect an exclusive or nonexclusive license to Government owned rights under terms that comply with the appropriate licensing statutes and regulations.

Dated: May 1, 1996.

Thomas D. Mays,

Director, Office of Technology Development, OD, NCI.

[FR Doc. 96-13375 Filed 5-28-96; 8:45 am]

BILLING CODE 4140-01-M

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, June 17, 1996, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 9:00 a.m. to adjournment. The topics proposed for discussion include (1) Report from the NIH AIDS Research Program Evaluation Group; (2) Report on Intramural Research Program; (3) Discussion of Misconduct in Science; (4) Discussion of Issues Related to Co-Funding with other Organizations; and (5) Status of Reinvention Activities. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Program Assistant, Office of the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892-0159, telephone (301) 496-0959, fax (301) 496-7451, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than June 12, 1996.

Dated: May 22, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-13364 Filed 5-28-96; 8:45 am]

BILLING CODE 4140-01-M

National Institutes of Health (NIH)

Meeting; Alternative Medicine Program Advisory Council

Pursuant to sec. 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Alternative Medicine Program Advisory Council on June 13, 1996, from 8 a.m. to 5 p.m. and on June 14, 1996, from 8 a.m. to 11 a.m. in Conference Room 6, Building 31C, the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland.

The entire meeting will be open to the public. The purpose of the meeting will be to update the Council on the activities of the Office of Alternative Medicine and to seek the Council's advice on strategic planning for alternative medicine research.

The Council will discuss the priorities voted upon at the February Council meeting and how the Office of Alternative Medicine might implement these activities. Attendance by the public will be limited to space available.

Ms. Beth Clay, Committee Management Officer, Office of Alternative Medicine, NIH, 9000 Rockville Pike, Building 31, Room 5B37 Mail Stop 2182, Bethesda, Maryland 20892, phone (301) 594-1990, fax (301) 402-4741, E-Mail: bethclay@helix.nih.gov, will furnish the meeting agenda, roster of committee members, and substantive program information upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Clay at the above location no later than June 3, 1996.

Dated: May 22, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-13373 Filed 5-28-96; 8:45 am]

BILLING CODE 4140-01-M

Workshop on the Role of Dietary Supplements for Physically Active People

Notice is hereby given of the NIH Workshop on "The Role of Dietary Supplements For Physically Active People," which will be held June 3-4, 1996, in the Natcher Conference Center of the National Institutes of Health, 9000

Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8 a.m. on both days.

Scientific research linking dietary supplements to health over the life span can be viewed as a relatively new area of research. In the early part of this century, nutrition sciences and dietary recommendations were focused on the identification and treatment of nutritional deficiency diseases.

Although the American people have been consuming vitamin and mineral supplements for decades, the direct relationship between diet and health and, therefore, the potential role for nutrients beyond the minimum levels required to avoid deficiencies, has become apparent only within the last 15 years. The possible roles of other food components and derivatives of natural products in promoting health and preventing disease are also now being recognized. The publication of the Surgeon General's Report on Nutrition and Health and the Diet and Health report from the National Academy of Sciences further highlighted the breadth of understanding of the diet-health relationship. Scientific research on the characterization of the potential roles of individual nutrients and compounds as dietary supplements has grown dramatically in the 1990s.

Dietary supplements in the United States are usually defined as comprising plant extracts, enzymes, vitamins, minerals, and hormonal products that are available without prescription and may be consumed in addition to the regular diet. Considerable research on the effects of dietary supplements has been conducted in Asia and Europe, where plant products have a long tradition of use. The overwhelming majority of supplements have not been studied scientifically, and therefore, it is important to conduct research to determine the benefits and risks of the use of promising dietary supplements and to interpret available scientific information so that the public may understand its contents. One strong and continuing public health message to the American people, based on such scientific information, is that moderate exercise should become a part of their daily lives. Physical activity has been shown to reduce the risk of cardiovascular disease through its effects on high blood pressure, high blood cholesterol, diabetes mellitus/insulin resistance, and obesity. Americans should heed the advice of health professionals and adopt a more physically active lifestyle that includes a planned exercise component. This scientific workshop will focus on the role of dietary supplements for