be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Provider/Supplier Enrollment Application; *Form No.:* HCFA–855; *Use:* This information is needed to enroll providers/suppliers by identifying them, verifying their qualifications and eligibility to participate in Medicare, and to price and pay their claims; *Frequency:* Other (Initial Application/recertification); *Affected Public:* Business or other for profit, not for profit institutions, and federal government; *Number of Respondents:* 165,000; *Total Annual Responses:* 165,000; *Total Annual Hours:* 370,000.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly 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, DC 20503.

Dated: February 21, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–4759 Filed 2–25–97; 8:45 am]

BILLING CODE 4126–03–P

National Institutes of Health

National Cancer Institute and the Food and Drug Administration: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Soluble Tat Peptide Analogs for the Inhibition of HIV Transcription and Viral Replication

AGENCY: National Institutes of Health and the Food and Drug Administration, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) and the Food and Drug Administration (FDA), wherein the participation of the FDA is contingent on resolution of any apparent conflict of interest issues, seek a company that can collaboratively pursue the pre-clinical and clinical development of Soluble Tat Peptide Analogs for the Inhibition of HIV Transcription and Viral Replication. The National Cancer Institute, Laboratory of Molecular Virology (LMV) and the Food and Drug Administration, Center for Biologics, Laboratory of Immunochemistry, have established that particular Soluble Tat Peptide Analogs can inhibit the transcription and replication of the Human Immunodeficiency Virus in vitro. The selected sponsor will be selected as a CRADA partner for the co-development of this agent with the National Cancer Institute and the Food and Drug Administration for the co-development of this agent with the NCI and with the FDA, wherein the participation of the FDA is contingent on resolution of any apparent conflict of interest issues.

ADDRESSES: 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. The Government has filed a patent application related to this CRADA opportunity. For further information on licensing this patent application (DHHS ref. no. E–059–96/0) contact Cindy Fuchs, J.D., NIH Office of Technology Transfer, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, Phone: (301) 496–7735 (ext. 232); Facsimile: (301) 402–0220.

DATES: In view of the important priority of developing new agents for the treatment of infectious disease and related malignancies, interested parties should notify this office in writing no later than April 28, 1997. Respondents will then be provided an additional 30 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION: ''Cooperative Research and 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. 133) 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 Inhibition of HIV Transcription and Viral Replication Using Soluble Tat Peptide Analogs. Licenses to intellectual property rights related to this opportunity are available from the National Institutes of Health, Office of Technology Transfer and may be necessary to continue development of the technology.

The tat gene encodes an 86 amino acid protein with a number of identified domains including an N-terminus, a cysteine rich, a core domain and a basic domain. Tat, through the core region, has been shown to interact with and stabilize the TFIID basal transcription factor and TFIIA preinitiation complex. Mutations within the core domain of Tat significantly decrease both gene expression and viral replication. National Cancer Institute (''NCI'') and Food and Drug Administration (''FDA'') studies have been directed at synthesis of Tat peptide analogs to compete with wild-type Tat in vivo. The NCI and FDA synthesized soluble peptide analogs of the HIV–1 Tat protein. These peptide analogs inhibit transactivation of HIV, viral replication and formation of viral particles. The peptide analogs compete with Tat in down-regulating Tat transactivation and induce a ninety percent reduction of viral particles from infected cells in vitro. The inhibitory peptide analogs are not toxic in vitro.

The Laboratory of Molecular Virology, Division of Basic Sciences, NCI and the Laboratory of Immunochemistry, Division of Transfusion and Transmitted Diseases, FDA are interested in establishing a CRADA with a company to assist in the continuing development of these peptide analogs, wherein the participation of the FDA is contingent on resolution of any apparent conflict of interest issues. 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 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 and Food and Drug

Administration, wherein the participation of the FDA is contingent on resolution of any apparent conflict of interest issues, includes the following:

1. Determine the stability, half-life, and distribution of the Tat peptides upon delivery into cells.
2. Determine the mechanism of the Tat peptide inhibition.
3. Determine the inhibitory effect of peptides on human ''primary'' T-lymphocytic and monocytic cells infected with various HIV–1 clades (subtypes A, G, O, M).
4. Determine the inhibitory effect of peptide derivatives on Kaposi's sarcoma primary cells.
5. Determine the effective dose of Tat peptide analogs in combination with other anti-retroviral drugs.
6. Conduct in vivo testing of appropriate compounds and/or peptide analogs.
7. Evaluate in vivo test results.
8. Prepare manuscripts for publication.

The role of the collaborator, includes the following:

1. Synthesize soluble organic compounds using peptide mimetics to mimic the inhibitory activity of the soluble analogs.
2. Determine the mechanism of the Tat peptide inhibition.
3. Establish a suitable non-invasive peptide delivery system for the preclinical and animal model studies.
4. Determine the effective dose of Tat peptide analogs in combination with other anti-retroviral drugs.
5. Determine the stability, half-life, and distribution of the Tat peptides upon delivery into cells.
6. Conduct in vivo testing of appropriate compounds and/or peptide analogs.
7. Evaluate in vivo test results.
8. Develop vehicle for delivery of compounds to patients.
9. Conduct pre-clinical and clinical trials of appropriate candidate compounds and/or peptide analogs.
10. Prepare manuscripts for publication.

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

1. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.
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 and FDA in the collection, evaluation, publication and maintaining of data from pre-clinical studies and clinical trials regarding the subject compounds.
7. Provision of 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. Scientific expertise in and demonstrated commitment to the treatment of HIV infection and related disorders.
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: February 7, 1997.

Thomas D. Mays,

Director, Office of Technology Development, OD, NCI.

[FR Doc. 97–4742 Filed 2–25–97; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of Health (NIH)

Notice of a Meeting of the Office of AIDS Research Advisory Council

Pursuant to Public Law 92–463, notice is hereby given of the Fourth meeting of the Office of AIDS Research Advisory Council (OARAC) on Friday, March 14, 1997, at the National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, Sixth Floor, Conference Room 6. The meeting will be open to the public from 8:30 am to 3:30 pm.

The Office of AIDS Research is responsible for the planning, coordination, and evaluation of the NIH AIDS research program. The OARAC was established to advise the Director of the OAR regarding these activities.

The agenda of the open meeting will include: The FY 1998 budget request for NIH AIDS research; presentation of the NIH Implementation Plan in response to the Report of the NIH AIDS Research Program Evaluation Task Force; an update on the NIH Panel to Define Principles of Therapy of HIV Infection; an update on the Prevention Science Working Group; and presentations regarding the new initiatives in AIDS vaccine research.

In accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C. and section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, the meeting will be closed to the public from 3:45 p.m. until adjournment for discussions of which the premature disclosure could impede implementation of recommendations.

Copies of the meeting agenda and the roster of council members will be furnished upon request by Jeannette R. De Lawter, Program Analyst, Office of AIDS Research, National Institutes of Health, Building 31, Room 4B54, 9000 Rockville Pike, Bethesda, MD 20892, Phone (301) 402–3357, Fax (301) 402–3360. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mrs. De Lawter no later than March 6.

Dated: February 21, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–4735 Filed 2–25–97; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2) notice is hereby given of advisory committee meetings of the National Cancer Institute.

The meetings will be open to the public as indicated below, with attendance by the public limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Cynthia Morgan, Committee Management Specialist, at (301) 496–5708 in advance of the meetings.

A portion of the meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), 552b(c)(6), and 552(c)(9)(B), Title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual programs and for discussion of issues pertaining to programmatic areas and/or NCI personnel. These discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning the individuals associated with the programs, including consideration of personnel