hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the field of anesthesiology and surgery.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 4, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss labeling for NDA 18–654, Versed® (midazolam HC1), Hoffmann La-Roche, for pediatric sedation.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: November 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–29831 Filed 11–21–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–190, HCFA–R–96]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to 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:* New collection; *Title of Information Collection:* Hospital Standard for Potentially HIV Infectious Blood and Blood Products, 42 CFR 482.27; *Form No.:* HCFA–R–190; *Use:* Hospitals must establish policies/procedures and document patient notification efforts if they have administered potentially HIV infectious blood and blood products.

Frequency: On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 16; *Total Annual Responses:* 16; *Total Annual Hours Requested:* 16.

2. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Emergency and Foreign Hospital Services—Beneficiary Statement In Canadian Travel Claims and Supporting Regulation 42 CFR 424.123; *Form No.:* HCFA–R–96; *Use:* This form is completed by beneficiaries, representative, or assignees to support claims for payments for Medicare covered emergency services provided in Canada. 42 CFR 424.123 is the regulation supporting this collection of information; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 1,100; *Total Annual Responses:* 1,100; *Total Annual Hours:* 275.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov, or to obtain 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 must be mailed

within 30 days of this notice directly to the HCFA Paperwork Clearance 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: November 15, 1996.

Edwin J. Glatzel,

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

[FR Doc. 96–29848 Filed 11–21–96; 8:45 am]

BILLING CODE 4120–03–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) 40002–0220.

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 January 21, 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 Pub. 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 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 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