and develop new and innovative approaches to reduce welfare dependency, as well as the Tribal Temporary Assistance for Needy Families (TANF) and Job Opportunities and Basic Skills Training (JOBS) programs.

2. KG.10 Organization. Delete this section in its entirety and replace it with the following:

KG.10 Organization. The Office of Community Services is headed by a Director who reports directly to the Assistant Secretary for Children and Families and consists of:

Office of the Director (KGA)

Division of State Assistance (KGB)

Division of Community Discretionary Programs (KGC)

Division of Community Demonstration Programs (KGD)

Division of Energy Assistance (KGE)

Division of Tribal Services (KGF)

3. KG.20 Functions. Add the following Paragraph F:

F. Division of Tribal Services is responsible for assisting in implementation and coordination of ongoing consultation with tribal governments and, where appropriate, state and federal agencies regarding issues relating to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, P.L. 104–193 (the Act) and related legislation. It is also responsible for development of regulations and guidelines and for providing leadership, policy direction, technical assistance and coordination of tribal services programs. Performs inter and intra-agency liaison functions in all areas such as Child Support Enforcement, Child Care, Child Welfare, Foster Care, Low Income Home Energy Assistance, and Family Violence to promote family stability, economic security, responsibility and self-support for Native Americans. It is responsible for conducting program reviews to ensure compliance with the Act, regulations and policy directives. It is responsible for activities related to tribal data collection reporting requirements relating to the programs.

Dated: February 21, 1997.

Olivia A. Golden,

Principal Deputy Assistant Secretary for Children and Families.

[FR Doc. 97–4758 Filed 2–25–97; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the meeting of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's), establishment license applications (ELA's), and biologics license applications (BLA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meeting will be held on April 8, 1997.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee continues CBER's effort to promote the timely, efficient, and consistent review of PLA's, ELA's, and BLA's.

FDA regulations on filing PLA's, ELA's, and BLA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings will ordinarily be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions. If there are no RTF decisions to review, however, the meeting may be cancelled. Publication of any meeting cancellation will be made only as time permits.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all such confidential commercial information omitted, 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. If, following the committee's review, an RTF decision changes, the appropriate division within CBER will notify the sponsor.

Dated: February 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4731 Filed 2–25–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–855]

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

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals 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:* 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