on the WWW. FDA believes that the transfer will allow CDRH to expand both the amount of information available and the number of users that can access the information.

ADDRESSES: Submit written comments on the electronic docket to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 ext. 124, E-Mail: DSMO@FDAR.CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 27, 1993 (58 FR 40150), FDA announced, among other things, the establishment of a public docket for policy speeches, policy statements, and standard operating procedure guides pertaining to product evaluation and regulatory enforcement for its medical device and radiological health programs. This docket was intended to operate on a 1-year trial basis and serve as a repository for critical policy documents generated by the Center for Devices and Radiological Health (CDRH) and as a public display mechanism for access by representatives of the industry and other interested persons. The public docket contained ''hard copies'' of documents and was maintained through FDA's Dockets Management Branch. This action was intended to serve as an overall communications initiative to endure uniform and timely access to important information. The trial period for this public began July 27, 1993, and was intended to end July 27, 1994.

To further increase industry access to major CDRH documents in a real time and dynamic fashion, a nationwide electronic docket was established concurrently with the public (''hard copy'') docket and contained the same information as the public docket. The electronic docket allowed medical device companies, clinical researchers, manufacturers of radiation-emitting products, and others to electronically access the same documents available in the public docket. The documents could be read directly on the requestor's computer screen, printed at the requestor's terminal, downloaded to the requestor's personal computer, or be requested by mail. The system was menu-driven and included automated searching capabilities.

In the **Federal Register** of February 7, 1995 (60 FR 7204), FDA issued a notice that extended, for an indefinite period of time, this electronic docket. The agency also decided to stop maintaining a public ''hard copy'' docket. During its trial period, the success of the electronic docket as an information dissemination source was clearly demonstrated by the high volume of electronic accessions and transfers. However, demand soon outstripped the ability of the computer bulletin board service, which restricts the numbers of users that can simultaneously access the system. In order to increase the level of service to the public, the computer bulletin board service has been supplanted by the WWW. The technology offered by the WWW has enabled CDRH to logarithmically expand both the amount of information available and the number of users that can access the information. The CDRH web site Home Page is located at TTP://WWW.FDA.GOV/CDRH and is linked to FDA's Home Page. Through FDA's Home Page, the web site Home Pages of many other FDA components, such as Import Operations and Field Activities, can also be accessed.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the discontinuation of the electronic docket. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13819 Filed 5–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for a Cooperative Research and Development Agreement (CRADA) Partner To Develop a Diagnostic System for Identifying Infectious Agents

SUMMARY: The Department of Health and Human Services (DHHS), National Institute of Health Clinical Center (NIHCC) is seeking a Cooperative Research and Development Agreement (CRADA) partner to further develop a collaboration with NIHCC, a diagnostic system for identifying infectious agents.

Investigators at the National Institute of Health, Clinical Center (NIHCC) and University of Maryland have been developing a reliable and easy to use detection system for identifying various infectious agents. The detection system can identify, with high specificity, infectious agents by type and subtype (e.g. HIV, HCV and HIV–1 type A, HIV–2 type B respectively. This technology is based upon enzyme recognition and site-directed cleavage of a DNA oligo probe, whose sequence allows for hybridization with an RNA or DNA target strand. Further development is needed to improve sensitivity for diagnostic use via signal amplification methodologies.

ADDRESSES: For more information, please contact John Gill (Tel# 301–496–0477, Fax # 301–402–2117), Office of Technology Development, National Cancer Institute, 6120 Executive Plaza South, Ste. 450; Bethesda, MD 20892–7182. For hand carry or overnight delivery please substitute ''Rockville, MD 20852'' for ''Bethesda, MD 20892–7182'' in the above address.

DATES: In view of the important priority of developing the diagnostic systems, interested parties should notify this office in writing no later than July 28, 1997.

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement of ''CRADA'' means the anticipated joint agreement to be entered into by NIHCC pursuant to the Federal Technology Transfer Act (''FTTA'') of 1986 and amendments (including 104 P.L. 113) to collaborate on the specific research project described below. As provided by the FTTA, the selected CRADA partner is granted an option to elect an exclusive or non-exclusive license to a field of use for subject invention(s) arising under and within the scope the CRADA research plan.

NIHCC Will—

Provide assay information, protocol(s) and/or method(s) for the detection and subtyping of various infectious agents;

Provide intellectual guidance and assistance for improving assay sensitivity by signal amplification;

Provide facilities and biological materials for evaluation and validation of the assay;

Provide information on nuclei acid sequence and expression of the enzyme;

Provide assistance with subcloning, over-expression and purification of the enzyme;

Provide personnel to support and facilitate completion of the studies.

Collaborator Will—

Identify, through appropriate means, gene(s) encoding a thermostable enzyme;

Perform subcloning and over-expression of gene(e) encoding a thermostable enzyme;

Purify to homogeneity adequate quantities of thermostable enzyme(s) to complete the studies;

Conduct assays to measure enzyme activity at various temperatures and substrate concentrations;

Develop a method for improving assay sensitivity by signal amplification using a thermostable enzyme having certain selected for characteristics.

Selection Criteria

Demonstrated ability in protein engineering and molecular biology. Particular expertise in cloning, over-expression and purification of a thermal stable enzyme;

Scientific expertise and demonstrated commitment to the development of diagnostic systems;

Experience in preclinical and clinical diagnostic development;

Experience and ability to produce, package, market and distribute pharmaceutical products;

Willingness to cooperate with NIHCC in the collection, evaluation, publication and maintenance of data from pre-clinical studies and clinical trials regarding the diagnostic system.

Dated: May 15, 1997.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 97–13831 Filed 5–23–97; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for a Cooperative Research and Development Agreement (CRADA) and Licensing Opportunity for Testosterone Bucyclate

AGENCY: National Institute of Child Health and Human Development, National Institutes of Health, Public Health Service, DHHS; and UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (WHO/HRP).

ACTION: Notice.

SUMMARY: The National Institutes of Health and the World Health Organization are seeking (a) partner(s) for the further development, evaluation and commercialization of testosterone bucyclate and pharmaceutical compositions thereof. The invention claimed in the issued U.S. patent referenced below is available for either exclusive or non-exclusive licensing. Licensing by NIH is subject to 35 U.S.C. 207 and 37 CFR part 404.

Long-Acting Androgenic Compounds and Pharmaceutical Compositions Thereof

Inventors: Sydney Archer, Gabriel Bialy, Richard P. Blye, Pierre Crabbe, Egon R. Diczfalusy, Carl Djerassi, Josef Fried and Hyun K. Kim.

Assignees: National Institutes of Health and the World Health Organization.

Issued: August 14, 1990.

Patent Number: 4,948,790.

To expedite the research, development and commercialization of testosterone bucyclate, the National Institutes of Health and the World Health Organization are seeking one or more CRADA and/or license agreements with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents and WHO's public sector objectives, as outlined below. Any proposal to use or develop these drugs will be considered.

SUPPLEMENTARY INFORMATION:

Androgens are principally employed in therapeutic medicine for replacement or supplementation in androgen deficiency states but also find use in hypopituitarism, menstrual disorders, anemia, promotion of anabolism, suppression of lactation and as a palliative measure in recurrent and metastatic carcinoma of the breast. NIH's and WHO's interest is to develop testosterone bucyclate for use in a hormonal method of male contraception and for androgen replacement in other methods of male contraception which usually compromise the endocrine as well as the gametogenic function of the testis. Long-term androgen therapy is complicated by the side effectes and/or poor bioavailability of oral preparations and the need for frequent injections of parenteral products. Two of the most commonly used injectable androgens, testosterone enanthate and testosterone cypionate, must be administered about every two weeks. There is thus a crucial need for longer-acting injectable androgens.

Testosterone bucyclate emanated, in 1980, from a joint NIH-WHO-sponsored steroid synthesis program in which the preparation of selected steroid esters was contracted by WHO and the resulting compounds screened by the Contraceptive Development Branch (CDB) of the National Institute for Child Health and Human Development at its Biological Testing Facility. Chemically, testosterone bucyclate is Testosterone 17β-(*trans*-4*n*-butyl) cyclohexyl carboxylate. This ester of the natural hormone, testosterone, exhibits prolonged activity when administered intramuscularly as an aqueous crystalline suspension in all species studied, including man. The drug was evaluated, including pharmacokinetics and metabolic studies in both rodents and primates, by CDB. WHO supported studies in primates as well as the first clinical studies in hypogonadal and normal men. The patent is jointly held by NIH and WHO. NIH and WHO intend to continue joint development of testosterone bucyclate.

Although each patentee may proceed with granting a non-exclusive license independently, joint licensing is envisaged. Licensing will include use of testosterone bucyclate as a hormonal method of male contraception, use for androgen replacement in other methods of male contraception, which usually compromise the endocrine as well as the gametogenic function of the testis and use as a therapeutic androgen for patients with androgen deficiency syndromes. A ''Notice of Claimed Investigational Exemption For A New Drug'' (IND) was filed with the FDA in October, 1996.

The National Institute of Child Health and Human Development and the World Health Organization seeks partners for the further development and commercialization of testosterone bucyclate.

The role of the National Institute of Child Health and Human Development and the World Health Organization is expected to be as follows:

1. Provide the commercial partner with all biological data on testosterone bucyclate covered by the agreement.

2. Provide samples of the drug and, upon successful completion of ongoing formulation studies, clinical dosage forms.

3. Provide, upon successful completion of ongoing studies, chemical data on testosterone bucyclate, including routes of synthesis, analytical methods employed, purity, stability and formulation.

4. Provide reports of all safety studies of the drug.

5. Continue studies on the pharmacokinetics and biological activity of testosterone bucyclate and formulations thereof.

6. Conduct appropriate studies to optimize formulations of testosterone bucyclate.