SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Merck & Co., West Point, PA 19486, has filed an application requesting approval for the export of the human drug Preservative-Free Intravenous Sodium Edecrin® (ethacrynate sodium) 50 mg ethacrynic acid equivalent/50 mL in 60 mL glass bottle to Germany through the Netherlands for packaging and labeling. This product is used in the treatment of accumulation of fluid in tissues (edema, ascites) due to heart, hepatic, or renal disease as well as edemas of the following origin: Edema or ascites caused by tumor compression, lymphedema, and idiopathic edema. The product is being manufactured by a revised process. The firm has new drug application approval for a product containing a thimerosal preservative. The application was received and filed in the Center for Drug Evaluation and Research on May 17, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 24, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 26, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–17236 Filed 7–12–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Warren Grant Magnuson Clinical Center: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of High Resolution PET Scanner Using Scintillation Cameras

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Nuclear Medicine Department in the Clinical Center at the Warren Grant Magnuson Clinical Center is seeking a collaborator with expertise in imaging equipment. The primary focus of this collaboration will be the development and commercialization of an imaging device that is capable of three distinct types of imaging at high resolution: Single photon planar imaging, single photon emission computed tomography (SPECT), and positron emission tomography (PET). An invention that has set the groundwork for this technology is claimed in U.S. Patent Applications 08/235,310, entitled ''Variable Axial Aperture Positron Emission Tomography Scanner'' (filed April 29, 1994) and (CIP) 08/357,574 (filed December 15, 1994). These patents have been filed for the initial phase of foreign filing (PCT) designating all states. NCI seeks a collaborator that will apply the technology to develop imagers for human subjects and/or for high resolution PET imaging of small animals.

Sponsors will be selected based on their ability to develop and commercialize the new imaging technology. NCI will enter into CRADA negotiations with the chosen sponsor with the intention of awarding a CRADA.

The term of the CRADA(s) is anticipated to be three (3) to five (5) years.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to either Michelle Rhyu or Bill Cotreau (Tel # 301–496–0477, Fax# 301–402–2117), Office of Technology Development, National Cancer Institute, Building 31, Room 4A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

DATES: Interested parties should notify this office in writing by September 11, 1995. Respondents will then be given an additional sixty (60) days for filing a formal proposal.

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987. Under the present proposal, the CRADA will focus on developing the following technology:

An instrument has been devised that utilizes conventional scintillation cameras to support single photon planar imaging, single photon emission computed tomography (SPECT), and positron emission tomography (PET). These multiple capabilities rely on the device's ability to efficiently detect gamma rays at single photon energies (<200 keV) and higher positron annihilation energies (511keV) required for PET. This dual ability is conferred by pivoting the detectors in conventional scintillation devices, which are capable of only SPECT and planar imaging, thereby increasing the path length of the high energy positron in the detector and enabling its detection. The cameras may rotate about a fixed target, or stationary cameras may surround a rotating target. The invention makes PET scanning on small animals feasible, allowing the economical collection of test data. Moreover, the invention presents a promising approach to economically increasing the detection capability of conventional SPECT scanners for humans.

Two broad advantages are provided by the present invention: (1) Resolution of PET is improved from 6mm to 2–3mm, making possible the resolution of organs in small animals. This expands the usefulness of small animals in research, for example in determining how test tracer molecules are incorporated into tumors, or how specific therapies affect tumor growth. The invention affords the advantage of using small animals, which are easier and less costly to maintain than larger animals. The ability to carry out PET analysis on smaller animals also circumvents the need to dissect the animal in order to assay an effect, greatly reducing the number of animals required for a study. (2) Applying this technology to human imagers, the invention provides a cost-effective way of improving diagnostic capabilities for

a relatively modest expense. For hospitals that may be financially prohibited from operating a full scale PET imaging system (including onsite cyclotron and radiochemistry lab) the present invention could impart PET scanning capabilities to the lower cost SPECT instruments, reducing overall cost and promoting widespread PET use. The collaboration would likely focus on demonstration of concept with a prototype system, development of methods to further increase coincidence detection efficiency, e.g., use of 3D reconstruction, and development of efficient methods for performing transmission imaging and other required corrections.

Background patent rights to this technology are available for licensing through the Office of Technology Transfer, NIH. Pertinent patent application claims may be obtained under a NIH Confidentiality Agreement for the Purpose of Reviewing Patent Application Claims. For this and further licensing information contact Mr. John Fahner-Vihtelic, Office of Technology Transfer, National Institutes of Health, Suite 325, 6011 Executive Boulevard, Rockville, Maryland 20852, Tel (301) 496–7057, Fax (301)402–0220.

Party Contributions

The role of the Warren Grant Magnuson Clinical Center includes the following:

(1) Cooperate with Collaborator to create a prototype SPECT/PET scanning device following the above described specifications; advise Collaborator on how best to scale up the invention into a prototype device.

(2) Evaluate prototypes produced by collaborator using small animal subjects.

(3) Provide personnel and laboratory space for these studies.

The role of the successful corporate sponsor(s) will include:

(1) Build a prototype SPECT/PET scanning device.

(2) Provide expertise in commercial scale up of imagers.

(3) Provide funding for assistance in supporting the research.

(4) Provide resources to bring product to market.

Selection Criteria

Proposals submitted for consideration should fully address each of the following qualifications:

(1) Expertise and experience in devising, producing and manufacturing imaging devices; specifically, sufficient expertise to collaborate on development of a SPECT/PET device.

(2) Willingness to produce a scanner optimized for small animal studies and/or a scanner for use on human subjects.

(3) Demonstrated ability to market invention to a broad client base.

(4) Willingness to cost share in laboratory studies including the funding of personnel dedicated to completion of the CRADA research project.

(5) Willingness to provide the Clinical Center with a prototype SPECT/PET device for future research.

(6) Submission of an initial response to the NIH Model CRADA boilerplate provisions.

(7) Provisions for equitable distribution of patent rights to any inventions generated in the performance of research under the CRADA. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the government when a company employee is the sole inventor or (2) the grant of an option to negotiate for an exclusive or a nonexclusive license to the Collaborator when a government employee is the sole inventor.

Dated: May 7, 1995.

Steven M. Galen,

Technology Development Coordinator, Warren Grant Magnuson Clinical Center, National Institutes of Health.

[FR Doc. 95–17156 Filed 7–12–95; 8:45 am]

BILLING CODE 4140–01–P

Public Health Service

Office of Minority Health; Announcement of Cooperative Agreement With the Public Health Foundation, ASTHO

The Public Health Service (PHS), through the Office of Minority Health (OMH), announces that it will enter into a cooperative agreement with the Public Health Foundation (PHF) of the Association for State and Territorial Health Officials.

The purpose of the agreement is to provide core organizational support for the PHF so that it may serve as a link and forum for dialogue between PHS and State and local health officials on a variety of public health issues and topics. In support of the agreement, PHF will (1) participate in the planning and design of new strategies for collecting public health infrastructure data; (2) enhance the infrastructure for public health data at the State level; (3) serve as a forum for continuing dialogue in the area of integrated health information systems and public health applications of the National Information Infrastructure; and (4) expand its sphere to include the local public health community as well as State health agencies and develop and maintain linkages with organizations representing public sector alcohol, drug abuse and mental health agencies.

The PHS, through OMH and in coordination with other PHS agency officials, will maintain liaison with PHF staff to identify emerging topics and issues in the field of public health and meet to discuss the development and shaping of activities which address key problems and issues in public health.

Authorizing Legislation

This cooperative agreement is authorized under Section 1707(d)(1) of the Public Health Service Act, as amended by Public Law 101–527.

Background

Assistance will be provided only to the Public Health Foundation of the Association of State and Territorial Health Officials (ASTHO). No other applications will be solicited. ASTHO is the only organization capable of administering this cooperative agreement because it is the official organization that represents the chief public health officials of each State and territory. Through its own membership, PHF has developed a unique knowledge and understanding of the needs and perspectives of State health agencies.

This cooperative agreement will be awarded in FY 1995 for a 12-month budget period in the approximate amount of $200,000, within a 5-year project period. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Where To Obtain Additional Information

If you are interested in obtaining additional information relating to this project, please contact:

James Scanlon, Director, Data Policy Staff, Office of Health Planning and Evaluation, Office of the Assistant Secretary for Health, Hubert H. Humphrey Building, Room 737F, 200 Independence Avenue SW., Washington DC 20201, Telephone: (202) 690–7100

or

Dr. Clay E. Simpson, Jr., Acting Deputy Assistant Secretary for Minority Health, Rockwall II, Suite 1000, 5515 Security Lane, Rockville, MD 20852, Telephone: (301) 443–5084.

There is no Catalogue of Federal Domestic Assistance number for this program since it is viewed as a one-time project.