The role of Merck & Co. under the CRADA will include the following:

1. Participate in the selection of the CRADA collaborator and in the development of the CRADA Research Plan.

2. Provide for the licensing of Merck intellectual property rights to the selected Collaborator as necessary for the clinical development and commercialization of CAI as an anti-cancer agent.

The role of the successful pharmaceutical company under the CRADA will include the following:

1. Provide plans to independently secure future continuing supplies of GMP produced and formulated material to assure continued collaborative clinical development of CAI.

2. Provide funds to supplement the clinical trials support contracts and offer any other necessary support to the NCI for continued collaborative clinical development of this compound. This includes both financial support as well as personnel for data management and clinical care.

3. Provide planning and support for clinical development leading to FDA approval for marketing.

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

1. Experience in preclinical and clinical drug development.

2. Experience and ability to produce, package, market and distribute pharmaceutical products.

3. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

4. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from clinical trials of investigational agents.

5. The provision of adequate quantities of GMP produced and formulated CAI as needed for clinical development of this agent for the specified field of use to be determined upon mutual agreement of the parties.

6. Provide defined financial and personnel support for the clinical trials to be mutually agreed upon.

7. An agreement to be bound by the DHHS rules involving human and animal subjects.

8. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

9. Provisions for equitable distribution of patent rights to any 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 (when a company employee(s) is (are) the sole inventor(s)) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee(s) is (are) the sole inventor(s) or where a joint invention arises).

Dated: April 13, 1995.

Thomas D. Mays,

Director, Office of Technology Development, OD, NCI.

[FR Doc. 95–10109 Filed 4–24–95; 8:45 am]

BILLING CODE 4140–01–P

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (''CRADA'') for the Scientific and Commercial Development of Certain Signal Transduction Inhibitors as Anticancer Agents

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a pharmaceutical company which can effectively pursue the preclinical development and possible eventual clinical development of a family of agents which inhibit the signal transduction pathways required for the growth and metastasis of cancer cells. The National Cancer Institute has preclinical data suggesting that these agents may have potential for the treatment and/or prevention of cancer. The selected sponsor will be awarded a CRADA for the co-development of these agents in a specified field of use to be determined upon mutual agreement of the parties.

ADDRESSES: Questions about this opportunity may be addressed to Mark W. Noel, Office of Technology Development, NCI, Building 31/Room 4A51, 9000 Rockville Pike, Bethesda, Maryland 20892, (301) 496–0477, facsimile (301) 402–2117, from whom further information including a summary copy of the preclinical data may be obtained.

DATES: In view of the important priority of developing new drugs for the treatment or prevention of cancer, interested parties should notify this office in writing no later than June 26, 1995. Respondents will then be provided an additional 60 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 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 Government-developed agents (37 CFR 404.8), can develop the subject agents to a marketable status to meet the needs of the public and with the best terms for the Government. These agents are a novel, chemically-defined family of agents being investigated in the Laboratory of Pathology of the Division of Cancer Biology, Diagnosis and Centers, National Cancer Institute. These agents have been demonstrated to inhibit the signal transduction pathways required for the growth and metastasis of cancer cells and have shown promising antitumor activity in preclinical investigations. The majority of the agents which are the subject of the CRADA opportunity are the subject of patent U.S. Patent 5,359,078 which is assigned to the Dept. of Health and Human Services. A method for the detection and quantitation of the levels of these agents in blood is claimed in U.S. Patent 5,405,782 which is also assigned to the Dept. of Health and Human Services. The Cooperative Research and Development Agreement (''CRADA'') will allow a pharmaceutical company to provide resources, in collaboration with the NCI, for the continuing preclinical development and possibly the clinical development for this group of agents.

The government will provide all relevant available expertise and information to date and will, jointly pursue further preclinical development of these agents with the chosen Collaborator. Relevant background patent rights are available for licensing to the Collaborator.

The successful pharmaceutical company will provide the necessary quantities of the agents plus the necessary technical expertise, financial and organizational support to complete further development of these agents to establish their efficacy and possible commercial status.

The expected duration of the CRADA will be three (3) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. The government will continue preclinical development of the agents as

signal transduction inhibitors *in vitro* and *in vivo*. Data from these studies will be provided to the Collaborator and evaluated jointly.

2. The government will provide data for the production of the subject agents. The successful pharmaceutical company will be allowed exclusive access to this resource.

3. As appropriate, agents showing promise in preclinical studies may proceed to collaborative clinical development under NCI's clinical trials network, as mutually agreed upon by both parties and subject to appropriate amendment of this CRADA or alternatively by negotiation and execution of a Clinical Trials CRADA. The Clinical Trial CRADA is a modification of the standard NIH Model Agreement wherein additional language has been drafted to enable the Collaborator to access and utilize clinical trial data.

4. Relevant Government patent rights are available for licensing through the Office of Technology Transfer, National Institutes of Health. For further information contact Jack Spiegel, Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892; (301) 496–7735; Facsimile (301) 402–0220.

The role of the successful pharmaceutical company under the CRADA will include the following:

1. Provide plans to independently secure future continuing supplies of the selected agents for their continued preclinical development. The collaborator will also supply sufficient quantities of GMP produced and formulated material for the selected agents which, upon mutual consent of the parties, proceed to collaborative clinical development.

2. Provide scientific development strategy and financial and other support for the collaborative preclinical development of the selected agents.

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

1. Experience in preclinical and clinical drug development.

2. Experience and ability to produce, package, market and distribute pharmaceutical products.

3. Experience in the monitoring, evaluation and interpretation of the data from preclinical studies and investigational agent clinical studies under an Investigational New Drug Application (IND).

4. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from preclinical investigations and clinical trials, as appropriate, of investigational agent(s).

5. The ability to provide adequate quantities of the subject agents for their continued preclinical investigation and ability, as appropriate to provide adequate quantities of GMP produced and formulated material as needed for clinical development of one or more of these agents, as mutually agreed by the parties.

6. Provide defined financial and personnel support for the preclinical studies and clinical trials (as appropriate) to be mutually agreed upon.

7. An agreement to be bound by the DHHS rules involving human and animal subjects.

8. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

9. Provisions for equitable distribution of patent rights to any 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 (when a company employee(s) is (are) the sole inventor(s)) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee(s) is (are) the sole inventor(s) or where a joint invention arises).

Dated: April 13, 1995.

Thomas D. Mays,

Director, Office of Technology Development, OD, NCI.

[FR Doc. 95–10108 Filed 4–24–95; 8:45 am]

BILLING CODE 4140–01–P

Division of Research Grants; Amended Notice of Meeting

Notice is hereby given of a change in the meeting May 8–9, 1995, starting at 8:30 a.m., Building 31C, Conference Room 6, of the Division of Research Grants Advisory Committee, which was published in the **Federal Register** on April 3 (60 FR 16880).

This committee was to have convened at 8:30 a.m. on May 8 to adjournment on May 9, but has been changed to May 10–11, 1995, Building 31C, Conference Room 6, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

The meeting will be open to the public from 8:30 a.m. on May 10 to adjournment on May 11.

Dated: April 18, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–10107 Filed 4–24–95; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permit for Incidental Take of Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

On February 9, 1995, a notice was published in the **Federal Register** (60 FR 7785) that an application had been filed with the U.S. Fish and Wildlife Service (Service) by Heritage Arts Foundation, Inc., St. George, Utah, for a permit to incidentally take, pursuant to section 10(a)(1)(B) of the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 *et seq.*), threatened desert tortoises (*Gopherus agassizii*) in conjunction with operation of an access road to the Tuacahn School and Performing Arts Center in Padre Canyon, town of Ivins, Washington County, Utah, pursuant to an implementation agreement which implements the Heritage Arts Foundation's Habitat Conservation Plan. Thirty-seven comments were received. Thirty-six commenters expressed support for issuance of the incidental take permit, and one commenter opposed issuance of any incidental take permits in this area and questioned the evaluation of alternatives to, and impacts of, the proposal. These comments have been addressed and are incorporated into the final environmental assessment.

Notice is hereby given that on March 31, 1995, as authorized by the provisions of the Act, the Service issued an incidental take permit (PRT–798634) to the above-named party subject to certain conditions set forth therein. The permit was granted only after it was determined that it was applied for in good faith, that by granting the permit it will not be to the disadvantage of the threatened species, and that it will be consistent with the purposes and policy set forth in the Act, as amended.

Additional information on this permit action may be obtained by contacting the Assistant Field Supervisor, U.S. Fish and Wildlife Service, 145 East 1300 South, Suite 404, Salt Lake City, Utah 84114, telephone (801) 524–5001, between the hours of 7:30 a.m. to 4:30 p.m. weekdays.