

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.*

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#### **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.*

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## **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.