

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for Licensing: Vasostatin, an Inhibitor of Endothelial Cell Growth and Angiogenesis

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Health (NIH), Public Health Service (PHS), Department of Health and Human Services (DHHS), seeks licensee(s) to develop a therapeutic anti-angiogenic agent(s) that would be effective in the treatment of a variety of disease states, in particular, cancer. Scientists at the Food and Drug Administration (FDA) have isolated at NH₂-terminal fragment (1–180 a.a.), vasostatin, from calreticulins which can inhibit endothelial cell proliferation in vitro, suppress neovascularization in vivo and prevent or reduce growth of experimental tumors while having minimal effect on other cell types. Vasostatin is the most conserved domain among calreticulins so far cloned and has no homology to other protein sequences. Data suggests that the antitumor effects of vasostatin are related to inhibition of new blood vessel formation rather than a detrimental effect on established tumor vasculature.

The NIH seeks licensee(s), who in accordance with requirements and regulations governing the licensing of government-owned inventions (37 CFR § 404), has the most meritorious plan for the development of a therapeutic agent(s) to meet the needs of the public and with the best terms for the government. NIH intends to grant the selected firm(s) a world-wide royalty-bearing license(s) to practice the inventions embodied in USSN 60/103,438 from Dr. Giovanna Tosato and Dr. Sandra Pike entitled "Use of Calreticulin and Calreticulin Fragments to Inhibit Endothelial Cell Growth and Angiogenesis, and Suppress Tumor Growth" (DHHS Ref. No. E-082-98/0). The patent rights in these inventions have been assigned to the United States of America.

EFFECTIVE DATE: In view of the priority for developing new antitumor agents, all proposals for either exclusive or non-exclusive licensing must be received on or before September 17, 1999.

ADDRESSES: Licensing information, copy of the U.S. patent application referenced above or a copy of the NIH License Application may be obtained by contacting Richard U. Rodriguez,

M.B.A., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 287, fax 301/402-0220; and E-mail rr154z@nih.gov). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION: Vasostatin has key differences from other inhibitors of angiogenesis, for example, angiostatin, thrombospondin and endostatin. It is small, soluble, stable for greater than 9 months in aqueous solution and is easily produced and delivered. By comparison, angiostatin, endostatin and thrombospondin can be difficult to isolate, purify and deliver. Additionally, studies have shown that the effective dose of vasostatin is 4–10 fold lower than the effective doses of endostatin and angiostatin. Therefore, this new and potent and anti-angiogenic molecule should prove highly useful for the prevention and treatment of human disease states that involve mis-regulated endothelial cell proliferation and/or angiogenesis.

In addition to the criteria set forth in 37 CFR § 404.7(a)(1) (ii)–(iv), the NIH is particularly interested in the following capabilities:

1. Prior manufacturing experience for GMP (Good Manufacturing Practice) production of a therapeutic agent(s) and a production plan for said agent(s);
2. Experience in preclinical and clinical drug development;
3. Experience in the evaluation, monitoring and interpretation of data for investigational biologics under an IND;
4. Experience in the evaluation, monitoring and interpretation of data from Phase I and Phase II clinical studies;
5. Ability to produce, package, market and distribute pharmaceutical products in the United States;
6. Willingness to sustain the cost of vasostatin development as outlined above (i.e., bulk drug synthesis, data management, animal studies, clinical studies, etc.);
7. Agreement to be bound by DHHS rules involving human and animal studies; and
8. An aggressive development plan that includes appropriate milestones and deadlines for preclinical and clinical development and for marketing approval.

Dated: July 12, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99-18377 Filed 7-16-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10c of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT-013804.

Applicant: Michael Barrett, Finley, California

The applicant requests a permit to import 4.3 Hawaiian goose (*Branta sandvicensis*), 1.1 Blyth's tragopan (*Tragopan blythii*), and 2.0 Cabot's tragopan (*Tragopan caboti*) from Qualicum Beach, British Columbia, Canada, for scientific research and enhancement of the survival of the species through captive propagation.

PRT-013176.

Applicant: University of New Mexico, Albuquerque, NM

The applicant request a permit to import wild and captive bred samples from chimpanzees (*Pan troglodytes*), bonobo chimpanzee (*Pan paniscus*), gorilla (Gorilla gorilla), and orangutan (*Pongo pygmaeus*) from various countries for the purpose of scientific research.

PRT-011201.

Applicant: Denver Museum of Natural History

The applicant requests a permit to import and re-export museum artifacts made by the indigenous peoples of Brazil that contain jaguar (*Panthera onca*) and harpy eagle (*Harpia harpyja*), for enhancement of survival of the species.

PRT-012019 and 012020.

Applicant: Hawthorn Corporation, Grayslake, IL

The applicant requests a permit to re-export and re-import wild Asian elephants (*Elephas maximus*) and progeny of the animals currently held by the applicant and any animals acquired in the United States by the applicant to/from worldwide locations to enhance the survival of the species through conservation education. This

notification covers activities conducted by the applicant over a three year period.

PRT-014554.

Applicant: San Diego Wild Animal Park, Escondido, CA

The applicant requests a permit to import one captive-held Somali wild ass (*Equus africanus somalicus*) from Hai Bar Reserve, Israel for the purpose of enhancement of the species through captive breeding.

The public is invited to comment on the following application for a permit to conduct certain activities with marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

PRT 014704

Applicant: The Toledo Zoo, Toledo, OH

Permit Type: Import for Public Display.

Name and Number of Animals: Polar Bear (*Ursus maritimus*), 1.

Summary of Activity to be

Authorized: The applicant requests a permit to import 1 captive born female polar bear for public display purposes and scientific study.

Source of Marine Mammals: Born 12 November 1997, Cologne Zoo, Cologne, Germany.

Period of Activity: Up to 5 years, if issued.

Concurrent with the publication of this notice in the **Federal Register**, the Office of Management Authority is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

PRT-013353

Applicant: Randy Pope, Reno, NV

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Lancaster Sound polar bear population, Northwest Territories, Canada for personal use.

Written data or comments, requests for copies of the complete application, or requests for a public hearing on this application should be sent to the U.S. Fish and Wildlife Service, Office of Management Authority, 4401 N. Fairfax Drive, Room 700, Arlington, Virginia 22203, telephone 703/358-2104 or fax 703/358-2281 and must be received within 30 days of the date of publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358-2104); FAX: (703/358-2281).

Dated: July 13, 1999.

Pamela Hall,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 99-18233 Filed 7-16-99; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Applicant: Hayworth, Meyer, and Boleyn, Inc. (HAB.), Frankfort, Kentucky (Peggy A. Measel, P.I.)

The applicant requests a permit to take (capture and release) endangered Gray bats (*Myotis grisescens*) and Indiana bats (*Myotis sodalis*) in the State of Indiana. Activities are proposed for the enhancement of survival of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056. Telephone: (612/713-5343); FAX: (612/713-5292).

Dated: July 13, 1999.

T.J. Miller,

Acting Program Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 99-18363 Filed 7-16-99; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-910-0777-26-241A]

State of Arizona Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Arizona Resource Advisory Council Meeting notice of meeting.

SUMMARY: This notice announces a meeting of the Arizona Resource Advisory Council. The one-day business meeting will be held on August 20, 1999 Wilcox, Arizona. The RAC meeting will be begin at 9:30 a.m. and will conclude at approximately 3:00 p.m. The meeting will be held at the Best Western-Plaza Inn located at 1100 W. Rex Allen Drive. The agenda items to be covered at the meeting include review of April 9, and June 11, 1999, meeting minutes; BLM State Director's Update on legislation, regulations and statewide planning efforts; Briefings on the Empire-Cienega Plan Amendment, FWS Proposal to designate Pygmy-owl and Huachuca Water Umbel Critical Habitat, and San Pedro River Water Issues and Visitor Use Information; Updates on Secretarial Initiatives, regarding Proposed Arizona National Monument and Empire Cienega National Conservation Area, and proposed legislation; Update on Wild Horse and Burro Herd Management Areas, Update Proposed Field Office Rangeland Resource Teams; Reports from BLM Field Office Managers; Reports by the Standards and Guidelines; Recreation and Public Relations, Wild Horse and Burro Working Groups; Reports from RAC members; and Discussion on future meetings. A public comment period will be provided at 11:30 a.m. on August 20, 1999, for any interest publics who wish to address the Council. For Further Information Contact: Deborah Stevens, Bureau of Land Management, Arizona State Office, 222 North Central Avenue, Phoenix, Arizona 85004-2203, (602) 417-9215.

Gary D. Bauer,

Acting Arizona State Director.

[FR Doc. 99-18295 Filed 7-16-99; 8:45 am]

BILLING CODE 4310-32-M