

Dated: August 20, 1998.

Madeline Mocko,

Director, Office of Legislative Affairs and Budget.

[FR Doc. 98-22902 Filed 8-25-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Bioresearch Monitoring: Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Office of Regulatory Affairs, Nashville District Office is announcing the following public workshop: Bioresearch Monitoring: Public Workshop. The workshop is being co-sponsored by Vanderbilt University Medical Center and Meharry Medical College, both of Nashville, TN. Topics to be discussed are FDA regulatory requirements for the conduct of investigational product research and practical issues, such as, how to prepare for a data audit, what to expect during an inspection, and how to get current information from FDA.

Date and Time: The workshop will be held on Thursday and Friday, September 17 and 18, 1998, from 8:30 a.m. to 5 p.m. each day.

Location: The workshop will be held at Vanderbilt University Medical Center, Light Hall, Nashville, TN 37232. Maps and further information may be obtained from the contact person or the registrar (listed below).

Contact: Sandra S. Baxter, Public Affairs Specialist, Nashville District Office, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217, at 615-781-5385 ext. 122., FAX 615-781-5383.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), to the Institutional Review Board at 615-322-2918 or FAX 615-343-2648 or e-mail to "IRB@mcm.vanderbilt.edu" by September 10, 1998. Attendance will be limited to the first 300 applicants, therefore, interested parties are encouraged to register early.

A \$25.00 registration fee is being charged by Vanderbilt University Medical Center to cover cost of materials, box lunches, and beverages for breaks.

If you need special accommodations due to a disability, please contact

Sandra S. Baxter (fax number above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA's survey of the bioresearch industry shows that many of these firms are either unaware of applicable regulations and guidelines or not in compliance with applicable requirements. The workshop is designed to assist the industry in complying with regulations for clinical investigators, institutional review boards and sponsor-monitors; and to promote and encourage open dialogue between FDA and professionals involved in investigational product research: Physicians, researchers, research coordinators, nurses, allied health professionals, and other interested parties. In addition, break out sessions will be available on new and emerging issues.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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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 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT-001719

Applicant: Wildlife Conservation Society, Bronx, NY.

The applicant requests a permit to import samples taken from wild and captive radiated tortoise (*Geochelone radiata*) in Madagascar for the purpose of scientific research.

PRT-839108

Applicant: Dr. Russell Jacobs, California Institute of Technology, Pasadena, CA.

The applicant requests a modification to his permit to import live Lesser Mouse Lemurs (*Microcebus murinus*) for the purpose of scientific research. The modification would replace two of the animals on his permit and add two more animals.

PRT-001542

Applicant: International Center for Gibbon Studies, Santa Clarita, CA.

The applicant requests a permit to import one, female captive-born pileated gibbon (*Hylobates pileatus*) for

the purpose of captive propagation and scientific (behavioral) research.

PRT-001454

Applicant: Kenneth L. Barr, Kelseyville, CA.

The applicant requests a permit to import the personal sport-hunted trophy of one male Karaganda argali (*Ovis ammon colium*) from Kazakhstan for the purpose of enhancement of the survival of the species.

PRT-001435

Applicant: Edwin W. Obrecht, Owings Mill, MD.

The applicant requests a permit to import the personal sport-hunted trophy of one male Karaganda argali (*Ovis ammon colium*) from Kazakhstan for the purpose of enhancement of the survival of the species.

PRT-001904

Applicant: U.S. Fish and Wildlife Service, Mexican Wolf Reintroduction Project, Region 2, Albuquerque, NM.

The applicant requests a permit to import, export and reexport live Mexican or lobo wolves (*Canis lupus baileyi*) for breeding and reintroduction and to import biological samples for genetic studies for the enhancement of the propagation or survival of the species. This notification covers activities by this applicant over a period of five years.

PRT-001761

Applicant: David Terk, Sycamore Creek Ranch, Del Rio, TX.

The applicant requests a permit to authorize interstate and foreign commerce, export and cull of excess male barasingha (*Cervus duvauceli*) from his captive herd for the purpose of enhancement of survival of the species. This notice shall cover a period of three years. Permittee must apply for renewal annually.

PRT-001778

Applicant: U.S. Fish and Wildlife Service, International Sea Turtle Coordinator, Atlanta, GA.

The applicant requests a permit to authorize the import of up to 200 biological samples per year from all endangered and/or threatened species of sea turtle for the purpose of scientific research for the enhancement of survival of the species. This notification covers activities by this applicant over a period of five years.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.