

delayed several days after the test is offered and information given to the patient. This would give people considering testing the opportunity to absorb information about the test, contemplate the implications of testing, and discuss testing with others.

Rare Genetic Diseases

Physicians who encounter patients with symptoms and signs of rare genetic diseases should have access to the best available information about rare genetic diseases. This will enable them to include such diseases in their differential diagnosis, to know where to turn for assistance in clinical and laboratory diagnosis, and to find laboratories that test for rare diseases. The quality of laboratories providing tests for rare diseases must be assured, and a comprehensive system to collect data on rare diseases must be established. Although these are issues that relate primarily to the diagnosis of patients with symptoms and signs, they have major implications for predictive testing in asymptomatic relatives who may be at risk of disease or who are carriers of alleles for the disease and whose future children may be at risk.

The Task Force is aware of a number of efforts to address one or more of these issues, including the availability of disease-based databases on research projects by the NIH Office of Rare Diseases (ORD), on information for consumers and providers by the National Organization of Rare Disorders, the Alliance of Genetic Support Groups and its member organizations, and by the American Academy of Pediatrics, and on clinical laboratories providing tests through the Helix National Directory (available to providers only). In addition, the Society for Inherited Metabolic Disorders is compiling information for providers on diagnostic evaluations of rare disorders, and the ACMG is developing databases on tests that should be used for diagnosis of specific disorders.

The Task Force recommends that NIH give ORD a mandate to coordinate these public and private efforts to improve awareness of rare genetic diseases. Such coordination is important to avoid unnecessary duplication, to use expertise most efficiently and to address the concerns of the various groups. ORD could serve as a gateway for provider and public inquiries about these disorders.

In cooperation with other organizations, and on a regular basis, ORD should identify laboratories worldwide that perform tests for rare genetic diseases, the methodology employed, and whether the tests they provide are

in the investigational stage, or are being used for clinical diagnosis and decision making. Laboratories should notify ORD about impending cessation of their testing so that provisions for a transition to other laboratories can be made.

ORD should also be responsible for assuring that tests for rare genetic diseases, which have been demonstrated to be safe and effective, continue to be available if and when their developers leave the field, and no other laboratory is prepared to offer the test, and/or the methodology is too complex to be readily adopted by other laboratories. The Task Force urges that additional funds be appropriated for ORD to undertake this expanded role.

In accordance with current law, the Task Force is of the opinion that any laboratory performing any genetic test on which clinical diagnostic and/or management decisions are made should be certified under CLIA. If specimens must be sent to a non-CLIA licensed research facility, the referring physician must be made aware of the investigative nature of the test.

The Task Force recognizes that the current CLIA certification process may place a heavy burden on some laboratories doing small numbers of diagnostic tests for rare diseases. Several laboratories currently performing these tests are primarily engaged in research, with the tests stemming from their research efforts. Without accommodation, some tests may cease to be available. Therefore, the Task Force recommends that the proposed Genetics Advisory Committee to CLIA explore means to simplify compliance with CLIA without sacrificing quality, just as accommodations have been made for rare genetic disease testing within the New York State Department of Health laboratory permit process. Recognizing current deficiencies under CLIA in the assessment of genetic tests (discussed above), the Task Force also encourages CAP/ACMG to make its clinical accreditation programs available to low-volume laboratories that are unaffiliated with a hospital, and modify its procedures to accommodate such laboratories.

Directories of laboratories providing tests for rare diseases should indicate whether or not the laboratory is CLIA-certified and whether it has satisfied other quality assessments, such as the CAP/ACMG program.

The recommendation made earlier, calling on the CDC to expand its data monitoring capabilities, is intended to include rare diseases. Collecting data on rare diseases will require coordinating data from multiple sources. It is particularly needed to validate tests,

describe the natural history of rare diseases and determine the safety and effectiveness of interventions to prevent disease or ameliorate its severity.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research.)

Elke Jordan,

Executive Secretary, National Advisory Council for Human Genome Research.

[FR Doc. 97-2286 Filed 1-29-97; 8:45 am]

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Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, contact the SAMHSA Reports Clearance Officer at (301) 443-8005.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Mandatory Guidelines for Federal Workplace Drug Testing Program and Associated Forms—Extension of OMB approval will be requested for the Federal Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines, for the application and inspection forms for the National Laboratory Certification Program (NLCP), and for the reporting and recordkeeping language in the Guidelines. The Federal Custody and Control Form is used by all Federal agencies and employers regulated by the

Department of Transportation to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination. No changes are

proposed to this form. Prior to an inspection, a laboratory is required to submit specific information regarding its laboratory procedures to allow inspectors to become familiar with a laboratory's procedures before arriving

at the laboratory. The annual total burden estimates for the custody and control form, the NLCP application, the NLCP inspection checklist, and NLCP recordkeeping requirements is 1,517,935 hours, as shown below:

	Time per response	Number of responses	Total annual burden (hours)
Custody and Control Form:			
Donor	5 minutes	6,000,000	500,000
Collector	4 minutes	6,000,000	400,000
Laboratory	3 minutes	6,000,000	300,000
Medical Review Officer	3 minutes	6,000,000	300,000
Application	3 hours	5	15
Inspection Checklist	3 hours	140	420
Recordkeeping	250 hours	70	17,500
Total			1,517,935

Send comments to Beatrice Rouse, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 24, 1997.

Richard Kopanda,
Executive Officer, SAMHSA.
[FR Doc. 97-2318 Filed 1-29-97; 8:45 am]
BILLING CODE 4162-20-P

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-802636

Applicant: Parker Creek Ranch, San Antonio TX.

The applicant requests renewal of a permit to authorize interstate and foreign commerce, export, and cull of excess male barasingha (*Cervus duvauceli*), red lechwe (*Kobus leche*), and Eld's brow-antlered deer (*Cervus eldi*) 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-803337

Applicant: Thomas J. Moore, III, Ingram, TX.

The applicant requests renewal of 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-824266

Applicant: David C. Eldridge, Mt. Zion, IL.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

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 430, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

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 430, Arlington, Virginia 22203. Phone: (703/358-2104); FAX: (703/358-2281).

Dated: January 24, 1997.

Caroline Anderson,
Acting Chief, Branch of Permits, Office of Management Authority.
[FR Doc. 97-2291 Filed 1-29-97; 8:45 am]
BILLING CODE 4310-55-P

Emergency Exemption: Issuance

On January 22, 1997 the Fish and Wildlife Service (Service) issued a permit (PRT-824324) to SOS Care, Inc., CA, to export one neonate margay (*Leopardus weidii*) born 1/9/97 to Canada and reimport to the United States. The 30-day public comment period required by section 10(c) of the Endangered Species Act was waived. The Service determined that an emergency affecting the survival of the margay existed and that no reasonable alternative was available to the applicant. This animal was at risk because of the need to remove the animal from its mother due to weather extremes and lack of care and the need for constant care by experienced personnel during the initial 6 weeks of life.

Dated: January 24, 1997.

Caroline Anderson,
Acting Chief, Branch of Permits, Office of Management Authority.
[FR Doc. 97-2290 Filed 1-29-97; 8:45 am]
BILLING CODE 4310-55-P

North American Wetlands Conservation Act: Request for Small Grants Proposals for 1997

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of request for proposals.

SUMMARY: The purpose of this notice is to advise the public that the Fish and Wildlife Service (Service) is currently entertaining proposals that request match funding for wetland conservation projects under the Small Grants program. Projects must meet the purposes of the North American Wetlands Conservation Act of 1989, as