

Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Annette Ragosta, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:** FDA acknowledges that changes in product manufacture may occur during product development and subsequent to product approval. Manufacturers frequently upgrade and refine a product's production process as technology advances and as they gain experience with the product. Historically, because of the limited ability to characterize the identity and structure of the clinically active component(s) and measure its activity, a biological product was often defined by its manufacturing process, and manufacturers of biological products sought to minimize changes to the manufacturing process to avoid performing additional clinical studies to verify the safety, purity, and potency of the finished product. Due to advances in biologics research and manufacturing, including the ability to make well-characterized biotechnology-derived products, a manufacturer may change a manufacturing process without FDA requiring additional clinical studies if test data demonstrate that the product is comparable to the product manufactured before the change. Therefore, FDA is publishing this guidance document to further clarify situations in which sponsors may make manufacturing changes and perform comparability testing to assure that the approved product is pure, potent, and safe.

Manufacturers should perform comparability testing to demonstrate that identity, purity, potency, and safety of the product have not been affected by changes in the manufacturing process, equipment, or facilities. This guidance document discusses principles and categories of tests which may be performed to demonstrate product comparability, but does not discuss specific manufacturing changes. Comparability testing programs may include a combination of analytical testing, bioassays, preclinical animal studies, and clinical studies. Since each product may present unique concerns, the type of change, the relevance of validated analytical and biological assays used, the stage of product development, and the clinical program should be considered by manufacturers when designing a comparability program. FDA will take all of these into

consideration when reviewing the comparability data that are submitted. Sponsors are encouraged to discuss proposed testing programs with FDA before implementing them, especially in those cases where they expect differences to result from the manufacturing changes. This document does not describe how changes are to be reported or which changes require prior approval. Manufacturers should consult current regulations and guidance documents regarding reporting and approval submissions.

As with other guidance documents, FDA does not intend this document to be all inclusive. The document is intended to provide information and does not set forth requirements. Manufacturers may follow the document or may choose to use alternative procedures that are not provided in this document. If a manufacturer chooses to use alternative procedures, that manufacturer may wish to discuss the matter further with FDA to prevent expenditure of resources to generate data on activities that FDA may later determine to be unacceptable.

Although this guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the demonstration of comparability of human biological products, including therapeutic biotechnology-derived products.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance document. FDA will review the comments received and if appropriate consider preparing a revised guidance document based upon that review. However, CBER notes that it has made comparability assessments when approving /products in the past and will continue to do so during the comment period. FDA will announce the availability of this revised guidance document in the Federal Register if FDA revises its comparability policy as a result of public comment.

Dated: April 22, 1996

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-10426 Filed 4-25-96; 8:45 am]

BILLING CODE 4160-01-F

## Health Resources and Services Administration

### Maternal and Child Health Services; Federal Set-Aside Program; Continuing Education and Development Cooperative Agreements

**AGENCY:** Health Resources and Services Administration (HRSA), PHS.

**ACTION:** Notice of availability of funds.

**SUMMARY:** The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS) Continuing Education and Development (CED) cooperative agreements to support national education, information, and public policy projects in maternal and child health. Awards will be made under the program authority of section 502(a)(2)(A) of the Social Security Act, the training provision of the MCH Federal Set-Aside Program. SPRANS training projects may be awarded only to public or nonprofit private institutions of higher learning. Within the HRSA, MCH CED cooperative agreements are administered by the Maternal and Child Health Bureau (MCHB). Awards under this announcement are made for grant periods of up to 5 years in duration.

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the SPRANS program, the amount of available funding for this specific grant program cannot be estimated.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The MCH Block Grant Federal Set-Aside Program addresses issues related to the Healthy People 2000 objectives of improving maternal, infant, child and adolescent health and developing service systems for children with special health care needs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report: Stock No. 017-001-00473-1) through the

Superintendent of Documents,  
Government Printing Office  
Washington, DC 20402-9325  
(telephone: 202 783-3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

**ADDRESSES:** Grant application materials for MCH CED cooperative agreements must be obtained from and submitted to: Chief, Grants Management Branch, Office of Operations and Management, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18-12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-1440. Applicants will use Form PHS 6025-1, approved by OMB under control number 0915-0060. You must obtain application materials in the mail.

Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: <http://www.os.dhhs.gov/hrsa/mchb>. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or) Wordperfect 5.1 file. To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a Wordperfect 5.1 file. If you have difficulty accessing the MCHB Home Page via the Internet and need technical assistance, please contact Linda L. Schneider at 301-443-0767 or "lschneider@hrsa.ssw.dhhs.gov".

**DATES:** The deadline for receipt of applications for CED cooperative agreements is June 7, 1996.

Applications will be considered to have met the deadline if they are either: (1) Received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants should request a legibly dated receipt from a commercial carrier or the U.S. Postal Service, or obtain a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications or those sent to an address other than specified in the **ADDRESSES** section will be returned to the applicant.

**FOR FURTHER INFORMATION CONTACT:**

Requests for technical or programmatic information should be directed to the

contact persons identified below. Requests for information concerning business management issues should be directed to: Acting Grants Management Officer (GMO), MCHB, at the address specified in the **ADDRESSES** section.

**SUPPLEMENTARY INFORMATION:**

**Program Background and Objectives**

Under Section 502 of the Social Security Act, 15 percent of the funds are to be set-aside by the Secretary to support (through grants, contracts, or otherwise) special projects of regional and national significance, including research, and training with respect to maternal and child health and children with special health care needs (including early intervention training and services development). The MCH SPRANS set-aside was established in 1981. Support for projects covered by this announcement will come from the SPRANS set-aside.

Continuing Education and Development (CED) training includes efforts conducted by an institution of higher learning such as short-term, non-degree programs, courses, workshops, conferences, symposia, institutes, and long distance learning strategies; and/or development or enhancement of curricula, guidelines, standards of practice, and educational tools/strategies. Continuing Education and Development focuses on increasing leadership skills of MCH professionals; facilitating timely transfer and application of new information, research findings, and technology related to MCH; and updating and improving the knowledge and skills of health and related professionals in programs serving mothers and children, including children with special health care needs (CSHCN). As a result of the CED, professionals and the public are more adequately prepared to provide comprehensive services and to provide leadership in advancing the field to better serve mothers and children.

The undertaking for which applications are being solicited in this notice is intended to expand on at least one similar project in resource and policy development—the National Education and Information Project—conducted since 1989 by the National Center for Education in Maternal and Child Health, Georgetown University. The general purpose of that project was to gather, classify, store, and disseminate information on maternal and child health. Major services included dissemination of information and education through workshops and conferences, and production of

publications drawn from customized databases.

**Special Concerns**

In its administration of the MCH Services Block Grant, the MCHB places special emphasis on improving service delivery to women and children from racial and ethnic minority populations who have had limited access to care. This means that SPRANS projects are expected to serve and appropriately involve in project activities individuals from the populations to be served, unless there are compelling programmatic or other justifications for not doing so. The MCHB's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB. This same special emphasis applies to improving service delivery to children with special health care needs.

In keeping with the goals of advancing the development of human potential, strengthening the Nation's capacity to provide high quality education by broadening participation in MCHB programs of institutions that may have perspectives uniquely reflecting the Nation's cultural and linguistic diversity, and increasing opportunities for all Americans to participate in and benefit from Federal public health programs, a funding priority will be placed on projects from Historically Black Colleges and Universities (HBCU) or Hispanic Serving Institutions (HSI) in both categories in this notice. An approved proposal from a HBCU or HSI will receive a 0.5 point favorable adjustment of the priority score in a 5 point range before funding decisions are made.

**Evaluation Protocol**

An MCH discretionary project, including a SPRANS, is expected to incorporate a carefully designed and well planned evaluation protocol capable of demonstrating and documenting measurable progress toward achieving the project's stated goals. The protocol should be based on a clear rationale relating the project activities, the project goals, and the evaluation measures. Wherever possible, the measurements of progress toward goals should focus on health outcome indicators, rather than on intermediate measures such as process or outputs. A project lacking a complete and well-conceived evaluation protocol

as part of the planned activities will not be funded.

#### Project Review and Funding

Within the limit of funds determined by the Secretary to be available for the activities described in this announcement, the Secretary will review applications for funds as competing applications and may award Federal funding for projects which will, in her judgment, best promote the purpose of Title V of the Social Security Act, with special emphasis on improving service delivery to women and children from culturally distinct populations; best address achievement of Healthy Children 2000 objectives related to maternal, infant, child and adolescent health and service systems for children at risk of chronic and disabling conditions; and otherwise best promote improvements in maternal and child health.

#### Criteria for Review

The criteria which follow are used, as pertinent, to review and evaluate applications for awards under all SPRANS cooperative agreement categories announced in this notice. Further guidance in this regard is supplied in application guidance materials.

- The quality of the project plan or methodology.
- The need for the training.
- The extent to which the project will contribute to the advancement of maternal and child health and/or improvement of the health of children with special health care needs;
- The extent to which the project is responsive to policy concerns applicable to MCH grants and to program objectives, requirements, priorities and/or review criteria for specific project categories, as published in program announcements or guidance materials.
- The extent to which the estimated cost to the Government of the project is reasonable, considering the anticipated results.
- The extent to which the project personnel are well qualified by training and experience for their roles in the project and the applicant organization has adequate facilities and personnel.
- The extent to which, insofar as practicable, the proposed activities, if well executed, are capable of attaining project objectives.
- The strength of the project's plans for evaluation.
- The extent to which the project will be integrated with the administration of the MCH Block Grant, State

primary care plans, public health, and prevention programs, and other related programs in the respective State(s).

- The extent to which the application is responsive to the special concerns and program priorities specified in this notice.

#### Award Categories

For FY 1996, CED cooperative agreements will be awarded in two categories: one concerned with resource, educational and analytic activities; and the other concerned with population-focused analytic and related activities.

There will be substantial Federal programmatic involvement in these cooperative agreements. This means that after award, awarding office staff provide technical assistance and guidance to, or coordinate and participate in, certain programmatic activities of award recipients beyond their normal stewardship responsibilities in the administration of grants. Federal involvement may include, but is not limited to, planning, guidance, coordination and participation in programmatic activities. Periodic meetings, conferences, and/or communications with the award recipient are held to review mutually agreed upon goals and objectives and to assess progress. Additional details on the scope of Federal programmatic involvement in cooperative agreements, consistent with HRSA grants administration policy, will be included in the application guidance for these cooperative agreements.

#### Purpose

The purpose of these cooperative agreements is to support a program of continuing education and development (CED) through interrelated national education, information and public policy projects in maternal and child health. This effort would build on the National Education and Information Project, which has been conducted by the National Center for Education in Maternal and Child Health, at Georgetown University. The cooperative agreements seek to improve the health status of mothers and children through:

- Development and dissemination of new information,
- Initiation or demonstration of new or improved ways of delivering care or otherwise enhancing the capacity of Title V and related programs to provide or assure the provision of appropriate services, or
- Advancing the knowledge, skills and leadership of personnel in specialties relevant to MCH.

Based on state-of-the-art analysis, the continuing education offered is intended to develop or improve standards, practices or delivery of health care for the MCH population, and may be provided through such activities as workshops, seminars, institutes, and other relevant activities.

Awardees for these cooperative agreements will be expected to work closely with a national maternal and child health clearinghouse and with each other in handling referrals of inquiries and requests for publications and other information.

#### Categories/Priorities

The following two categories of cooperative agreements will be funded through this announcement:

- Category I: Resource, educational, and analytic activities to assist in policy formulation and program development across target populations. These would focus on such functional areas as child health supervision, nutrition, oral health, injury prevention, immunizations, mental health, community systems, financing, and economics.
- Category II: Population-focused education and analytic, and related activities to assist in policy formulation and program development to advance a national agenda concentrating on the following maternal and child health subpopulations: perinatal and women, infancy and early childhood, and middle childhood and adolescence. These would focus on such issues as those relating to program content, systems development, accountability/quality improvement, and special concerns noted earlier.

#### Project Period

Project durations are up to 5 years.

#### Contact

For programmatic or technical information, contact Woodie Kessel, M.D., telephone 301-443-2340, or David Heppel, M.D., telephone 301-443-2250.

#### Public Comment

The categories, priorities, special considerations and preferences described above are not being proposed for public comment this year. In July 1993, following publication of the Department's Notice of Proposed Rulemaking to revise the MCH special project grant regulations at 42 CFR 51a, the public was invited for a 60-day period to submit comments regarding all aspects of the SPRANS application and

review process. In responding to those comments, the Department noted the practical limits on Secretarial discretion in establishing SPRANS categories and priorities owing to the extensive prescription in both the statute and annual Congressional directives.

Comments on this SPRANS notice which members of the public wish to make are welcome at any time and may be submitted to: Director, MCHB, at the address listed in the **ADDRESSES** section. Suggestions will be considered when priorities are developed for the next solicitation.

#### Eligible Applicants

MCH training awards may be made only to public or nonprofit private institutions of higher learning.

#### Executive Order 12372

The MCH Federal set-aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

The OMB Catalog of Federal Domestic Assistance number is 93.110.

Dated: April 22, 1996.

Ciro V. Sumaya,  
Administrator.

[FR Doc. 96-10425 Filed 4-25-96; 8:45 am]

BILLING CODE 4160-15

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-3778-N-82]

### Office of the Assistant Secretary for Community Planning and Development; Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

**EFFECTIVE DATE:** April 26, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-1226; TDD number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

**SUPPLEMENTARY INFORMATION:** In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: April 19, 1996.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 96-10241 Filed 4-25-96; 8:45 am]

BILLING CODE 4210-29-M

## DEPARTMENT OF THE INTERIOR

### Western Water Policy Review Advisory Commission Meeting

**AGENCY:** Department of the Interior.

**ACTION:** Notice of open meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Western Water Policy Review Advisory Commission (Commission), established by the Secretary of the Interior under the Reclamation Projects Authorization and Adjustment Act of 1992, will hold its second meeting. The meeting will be open to the public.

**DATES:** The meeting will be Thursday, May 16, 1996, from 1:00 to 5 p.m. and Friday, May 17, 1996, from 8:30 a.m. to 12:00 noon.

**ADDRESSES:** The Commission meeting will be at the Executive Tower Hotel, 1405 Curtis Street, Denver, Colorado.

**FOR FURTHER INFORMATION CONTACT:** Western Water Policy Review Office, PO Box 25007, Denver, Colorado, 80225, (303) 236-6211.

**SUPPLEMENTARY INFORMATION:** The Reclamation Projects Authorization and Adjustment Act of 1992, Public Law 102-575, Section 30 directs the President to undertake a comprehensive review of Federal activities in the 19 Western States which affect the allocation and use of water resources, and to submit a report on the President's finding and recommendations to Congress. The Secretary of the Interior established the Commission to provide assistance regarding the President's report to Congress. The President's report is due to Congress by October 2, 1997.

At this meeting, the Commission will discuss the information obtained at a series of scoping of meetings held recently throughout the Western United States to obtain suggestions for the Commission's work plan. A final work plan will be proposed and discussed by the Commission. Members of the public may submit written statements to the Commission at the address listed above, or at the meeting. There will be an opportunity for public comment to the Commission on Friday morning, May 17, 1996. If you are interested in addressing the Commission, please notify the Commission office by May 10, 1996, to facilitate scheduling. Seating at the meeting will be limited and therefore on a first come basis.

Dated: April 22, 1996.

Lawrence J. MacDonnell,

Executive Director, Western Water Policy Review Advisory Commission.

[FR Doc. 96-10357 Filed 4-25-96; 8:45 am]

BILLING CODE 4310-94-M

## Fish and Wildlife Service

### Endangered and Threatened Species Permit Application

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of document availability; request for comments.

Availability of an Environmental Assessment and Receipt of an Application for a Permit to Authorize Incidental Take of Threatened and Endangered Species by Port Blakely Tree Farms, L. P., on the Robert B. Eddy Tree Farm, Pacific and Grays Harbor Counties, Washington.

**SUMMARY:** This notice advises the public that Port Blakely Tree Farms, L. P., of Seattle, Washington (Applicant) has applied to the U.S. Fish and Wildlife Service (FWS) for an incidental take permit pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The application has been assigned permit number PRT-813744. The Applicant has also requested to enter into a consensual agreement with the U.S. National Marine Fisheries Service (NMFS) to address the needs of anadromous salmonids being considered for listing under the Act, and with the FWS to conserve other fish and wildlife species which may be associated with habitats on their Robert B. Eddy Tree Farm in Pacific and Grays Harbor Counties, Washington (Tree Farm). The requested permit would authorize the incidental take of northern spotted owls (*Strix occidentalis caurina*), marbled