approximate time required to make their comments.

Open committee discussion. On April 17, 1997, the committee will hear presentations and discuss the teratogenicity and labeling issues regarding approved NDA 19–821 for Soriatane (acitretin capsules, Hoffman-LaRoche, Inc.) for use in treating severe psoriasis.

Closed presentation of data. On April 18, 1997, the committee will hear trade secret and/or confidential commercial information relevant to pending IND's or NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. On April 18, 1997, the committee will review trade secret and/or confidential commercial information relevant to pending IND's and/or NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 21, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–7790 Filed 3–26–97; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Special Project Grants; Traumatic Brain Injury Demonstration Grants

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that approximately $2.8 million in fiscal year (FY) 1997 funds will be available for demonstration projects to improve access to health and other services for people who have sustained a traumatic brain injury (TBI). Discretionary grants

to States are authorized under section 1252 of the Public Health Service (PHS) Act, as amended by Public Law 104–166 (42 USC 300d-52), which provides for the conduct of expanded studies and the establishment of innovative programs with respect to TBI. Funds for TBI State demonstration projects are appropriated by Public Law 104–208. At present, funding for this program is available for one year. Within the HRSA, TBI grants are administered by the Maternal and Child Health Bureau (MCHB).

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS lead national activity for setting priority areas. The TBI grant program will directly address the Healthy People 2000 objectives related to chronic disabling conditions, particularly in relation to service system expansion and objectives related to secondary injury prevention. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Healthy People 2000 Midcourse Review and 1995 Revisions (Stock No. 017–001–00526–6) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (telephone: 202–512–1800).

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: **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.

For applicants for TBI Demonstration Grants who are unable to access application materials electronically, a hard copy (Revised PHS form 5161–1, approved under OMB clearance number 0937–0189) may be obtained from the HRSA Grants Application Center. The Center may be contacted by: Telephone Number: 1–888–300-HRSA, FAX Number: 301–309–0579, E-mail Address: HRSA.GAC@ix.netcom.com. Completed applications should be returned to: Grants Management Officer (CFDA #93.TBA–1), HRSA Grants Application Center, 40 West Gude Drive, Suite 100, Rockville, Maryland 20850.

DATES: The application deadline date is May 30, 1997. Competing applications will be considered to be on time 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.

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information from MCHB should be directed to the Division of Maternal, Infant, Child and Adolescent Health (DMICAH), Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The DMICAH telephone number for TBI inquiries is 301–443–5559. Requests for information concerning fiscal, business or administrative management issues should be directed to: Maria E. Carter, Grants Management Specialist, Grants Management Branch, Maternal and Child Health Bureau, 5600 Fishers Lane, Room 18–12, Rockville, Maryland 20857, telephone: 301–443–3268.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

In July, 1996, Congress enacted Public Law 104–166, ''to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury'' (TBI). Under Public Law 104–166, a program of grants to States for demonstration projects to improve access to health and other TBI-related services for people of all ages is established within HRSA. The National Institutes of Health has responsibility for conducting basic and applied research regarding TBI. Responsibility for activities related to prevention of TBI is assigned to the Centers for Disease Control and Prevention. Information on CDC grant activities which relate to TBI surveillance may be obtained from David J. Thurman, M.D., M.P.H., Division of Acute Care, Rehabilitation Research, and Disability Prevention, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, Mailstop F–41, Atlanta, GA 30341, telephone: 770–488–4031. Public Law 104–166 also mandates a national consensus conference of appropriate PHS agencies to study a range of TBI-related issues, including development of a uniform reporting system, evaluation of the effectiveness of common therapeutic interventions, assessment of the adequacy of existing outcome measures, and development of practice guidelines for rehabilitation.

The law requires any State seeking TBI demonstration grant funds to agree to establish an advisory board within the appropriate health department of the State or within another department as designated by the chief executive officer of the State. The Board's composition is specified; it must include: representatives of the involved State agencies; public and nonprofit private health related organizations; disability advisory or planning groups; members of an organization or foundation representing TBI survivors; State and local injury control programs if they exist, and a substantial number of TBI survivors or their family members. The State must also make available matching funds, in cash non-Federal contributions, in an amount that is not less than $1 for each $2 of Federal funds provided under the grant.

Definitions

1. *State:* For purposes of this grant program, the term ''State'' includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Northern Mariana Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, and the Federated States of Micronesia.

2. *Traumatic Brain Injury:* For purposes of this grant program ''Traumatic Brain Injury'' (TBI) means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to near drowning.

3. *Survivor:* For purposes of this grant program the term ''survivor'' refers to a person who has sustained and has survived a traumatic brain injury.

4. *Person-and family-centered care:* For purposes of this grant program ''person-and family-centered care'' requires: involvement of survivors and their families in all phases of the TBI continuum of care; clear and continuous communication between family members and the care team; attention to the psychosocial needs of survivors and family members; and cultural competence of providers.

5. *Core Capacity:* Core capacity includes 4 components: (1) a statewide TBI Advisory Board which meets the requirements set forth earlier in this Notice; (2) designation of a State agency and a designated staff position responsible for State TBI activities; (3) a Statewide needs assessment of the full spectrum of care/services from initial acute treatment through community reintegration for individuals with TBI; and (4) a Statewide action plan to develop a comprehensive, community-based system of care that encompasses physical, psychological, educational, vocational, and social aspects of TBI services and addresses the needs of the family as well as the TBI survivor.

Eligible Applicants

Only State governments are eligible to apply for funding under the TBI demonstration grant program. The application for implementation funds may only come from the State agency designated as the lead for TBI services, while planning grant applications may emanate from an agency or office within the State responsible for planning and/or program coordination. The involvement of the State MCH program in both grant categories is expected.

Only one application from each State may enter the review process and be considered for an award under this program.

Funding Categories

Approximately $2.8 million will be available in FY 1997 to fund two categories of grants—Category 1: State planning grants; and Category 2: State implementation grants.

The major funding emphasis is on implementation activities which will move States toward Statewide systems that assure access to comprehensive and coordinated TBI services. It is recognized, however, that States are in different stages of development and that some will need assistance in establishing infrastructure as a prerequisite to implementation. Therefore, planning grants, as well as implementation grants, are being offered.

Applicants may apply for either Category 1 or Category 2 funding as appropriate, but not both.

Category (1): State Planning Grants

Planning grants are intended to support the development of 4 State level core capacity components to provide TBI services (see DEFINITIONS section, above). States may apply for a planning grant for one year. Up to 15 planning grants will be awarded. Planning grants will range from $20,000 to $75,000 per year. States should apply for an amount within that range which is appropriate to their needs in establishing full core capacity.

Category (2): State Implementation Grants

Implementation grants are intended for States that have the 4 core capacity components in place. These grants will support activities that represent the next logical step(s) in building a Statewide system to assure access to comprehensive and coordinated TBI services.

Implementation grants can address a wide range of activities and should reflect gaps or needed system enhancements identified through the Statewide TBI needs assessment. The grant may be used for Statewide implementation or targeted implementation in a specific locality within the State prior to Statewide implementation. Proposals under this category may address one or more of the following:

—Develop and implement protocols for point of entry personnel to improve early identification and appropriate triage, care and management of patients.

—Develop a replicable, pre-discharge model to be used in acute care sites in the development of long term resource plans for TBI survivors. Such a model should include person- and family-centered care coordination and resource management services.

—Develop and implement a plan to increase the number of public and private payers, including major managed care plans in the State, which will coordinate financial resources to provide services that most effectively meet the needs of TBI survivors.

—Improve data collection through: linking existing data systems; improving information on currently underserved populations; or improving ongoing tracking of service needs, patient outcomes, or program evaluation.

—Develop and implement education and training programs to address various stages of recovery along the continuum of care (acute care, rehabilitation, education, vocational, psychosocial, long term care and community reintegration) for survivors, families, and/or professionals. Such programs are expected to recognize culturally diverse populations, address currently underserved populations, and promote person- and family-centered care.

—Develop (or translate), implement and evaluate materials specifically directed at TBI survivors and their families to meet the specific needs of low literacy and culturally or ethnically distinct populations.

—Increase interagency collaboration and linkages to improve access to comprehensive individual and family-centered services along the continuum of care.

Up to 8 State implementation grants, not to exceed $200,000 per grant for a one-year period, will be awarded in FY 1997. The planned project period for State implementation grants is one year.

Applicants should be aware that, at present, funding for this program is available only for one year. Therefore, applicants must clearly identify the accomplishments they can achieve in one year's time and identify approaches that could be used to continue activities in the absence of future Federal funding. If additional Federal funds become available in the next fiscal year, planning grants will be considered for renewal for up to an additional year and implementation grants will be considered for renewal for an additional two years. If applicants will require greater than one year to complete their projects,they should include proposed plans for their second and third years of funding in their applications.

Special Concerns

HRSA's Maternal and Child Health Bureau places special emphasis on improving service delivery to people from communities with limited access to comprehensive care. In order to assure access and cultural competence, projects must involve individuals from the populations to be served in the planning and implementation of the project. The Bureau'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.

Evaluation Protocol

A project awarded as part of the TBI Demonstration Grants program 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 grant 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 may not be funded.

Project Review and Funding

The Department will review applications in the preceding categories as competing applications and will fund those which, in the Department's view, are consistent with the statutory purpose of the program, which best promote a comprehensive and coordinated system that assures access to appropriate care for TBI survivors and their families, and which address achievement of applicable Healthy People 2000 objectives related to chronic disabling conditions and secondary injury prevention.

Review Criteria

Specific review criteria have been established for each of the two TBI demonstration grant categories as follows:

Category 1: State Planning Grants

—The strength of the required Statewide Advisory Board as evidenced by:
  —The composition of the Board.
  —Commitments from all identified organizations or individuals.
  —Organizational and meeting arrangements.
—The adequacy of the State's proposed method for developing a Statewide needs assessment that includes—and a plan of action that emphasizes—the physical, psychosocial, educational, vocational and social needs of TBI survivors and their families.
—The adequacy of the State's proposed method for linking its plan of action to the findings of the Statewide needs assessment.
—The extent to which the proposal reflects the involvement of necessary public/private organizations and agencies to assure a comprehensive approach.
—The qualifications and experience established for the designated lead person for TBI within the State.
—The reasonableness of the proposed budget, soundness of the arrangements for fiscal management, effectiveness of use of personnel and likelihood of project completion within the proposed grant period.
—The adequacy of proposed methodology to assure full core capacity is developed during the grant period.

Category 2: State Implementation Grants

—The adequacy of the State's evidence that the four components for core capacity are in place.
—The relevance of the goals and objectives to the identified needs described in the Statewide needs assessment.
—The soundness of the plan for evaluating progress in achieving project objectives and outcomes.
—The adequacy of the plan for organizing and carrying out the project, including: (a) Reasonableness of proposed budget and soundness of the plan for fiscal management; (b) adequacy of proposed methodology for achieving project goals and outcome objectives; and (c) qualifications and experience of the Project Director and staff.
—The extent to which the involvement and participation of TBI survivors, families and organizations are considered in project implementation.
—Extent of collaboration and coordination among the entities in the TBI continuum identified by the State as necessary to carry out the proposed plan.
—The extent to which the project involves a multi-disciplinary and multi-system approach to TBI development.
—Adequacy of the plan for sustaining the proposed project.

Allowable Costs

The HRSA may support reasonable and necessary costs of TBI Demonstration Grant projects within the scope of approved projects. Allowable costs may include salaries, equipment and supplies, travel, contracts, consultants, and others, as well as indirect costs as negotiated. The HRSA adheres to administrative standards reflected in the Code of Federal Regulations, 45 CFR Part 92 and 45 CFR Part 74.

Executive Order 12372

This program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice will contain a listing of States which have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date. (See Part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements).

The OMB Catalog of Federal Domestic Assistance number is 93.TBA–1.

Dated: March 21, 1997.

Claude Earl Fox, M.D., M.P.H.,

Acting Administrator.

[FR Doc. 97–7727 Filed 3–26–97; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

1997/98 World Health Organization Study of Health Behavior in School Children (WHO–HBSC)

In compliance with Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH) is publishing this notice to solicit public comment on the data collection proposed for U.S. participation in the ''1997/98 World Health Organization Study of Health Behavior in School Children (WHO–HBSC)'' for the Epidemiology Branch. To request copies of the data collection plans and instruments, call Dr. Mary Overpeck, (301) 496–1711 (not a toll-free number).

Comments are invited on: (a) Whether the proposed collection is necessary, including whether the information has a practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Written comments are requested within 60 days of the publication of this notice. Send comments to Dr. Mary Overpeck, Epidemiology Branch, Division of Epidemiology, Statistics, and Prevention Research (DESPR), NICHD, NIH, Building 6100, Room 7B03, 6100