

date the new drug application (NDA) for BETAXON (NDA 21-114) was initially submitted. However, FDA records indicate that NDA 21-114 was submitted on August 26, 1999.

3. *The date the application was approved:* February 23, 2000. FDA has verified the applicant's claim that NDA 21-114 was approved on February 23, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 579 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by August 26, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 23, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02-16052 Filed 6-25-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Traumatic Brain Injury Program; State Grants for Traumatic Brain Injury

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that about \$1.2 million in fiscal year (FY) 2002 funds is available for up to 11 State Grants for Traumatic Brain Injury (TBI). The purpose of the TBI program is to assist individuals who have sustained a traumatic brain injury in obtaining health care and other services. Awards will be made in three categories: (1) Planning Grants, to assist States in developing the infrastructure needed to implement a State TBI program; (2) Implementation Grants, to assist States in moving toward statewide systems that assure access to comprehensive and coordinated TBI services, and (3) Post Demonstration Grants, to assist States which have successfully completed a TBI Implementation Grant. HRSA expects to award two Planning Grants, one Implementation Grant, and eight Post-Demonstration Grants this fiscal year. All awards will be made under the program authority of the Public Health Service Act, Title XII, section 1252 (42 U.S.C. 300d-52), and will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Planning Grants may be approved for up to two years; with awards of up to \$75,000. The Implementation Grant may be approved for up to 3 years; the award will be up to \$200,000. Post Demonstration Grants will be approved for only one year; awards will be up to \$100,000. Funding beyond FY 2002 is contingent upon the availability of funds.

DATES: Applicants are requested to notify MCHB of their intent to apply by July 19, 2002. The deadline for receipt of applications is August 2, 2002. Applications will be considered "on time" if they are either received on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 29, 2002.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1-877-477-2123 (1-877-HRSA-123) or register on-line at: http://www.hrsa.gov/g_order3.htm directly. The Traumatic Brain Injury State Grant Program uses the standard Form PHS 5161-1 (rev. 7/00) for applications (approved under OMB No. 0920-0428). Applicants must use the following Catalog of Federal Domestic Assistance (CFDA) numbers to request applications kits: Implementation Grants, #93.234A; Planning Grants, #93.234B; Post Demonstration Grants, #93.234C. The CFDA is a Government-wide

compendium of enumerated Federal programs, project services, and activities that provide assistance. All applications must be mailed or delivered to Grants Management Officer, MCHB: HRSA Grants Application Center, 901 Russell Avenue Gaithersburg, MD 20897; telephone 1-877-477-2123; E-mail: hrsagac@hrsa.gov.

Necessary application forms and an expanded version of this **Federal Register** notice may be downloaded in either Microsoft Office 2000 or Adobe Acrobat format (.pdf) from the MCHB Home Page at <http://www.mchb.hrsa.gov>. Please contact Joni Johns, at jjohns@hrsa.gov, or 301-443-2088, if you need technical assistance in accessing the MCHB Home Page via the Internet.

This notice will appear on the HRSA Home Page at <http://www.hrsa.gov/>. **Federal Register** notices are found on the World Wide Web by following instructions at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

Letter of Intent: Notification of intent to apply should be directed to Betty Hastings, M.S.W., by email, bhastings@hrsa.gov; or mail, MCHB, HRSA; TBI Program, Parklawn Building, Room 18A-38; 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Betty Hastings, M.S.W., 301-443-5599, or email: bhastings@hrsa.gov (for questions specific to project objectives and activities of the program; or the required Letter of Intent); Marilyn Stewart, 301-443-9022, email mstewart@hrsa.gov (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Traumatic Brain Injury Program Background and Objectives

Traumatic brain injury (TBI) is sudden physical damage to the brain, often caused by motor vehicle accidents, falls, sports injuries, violent crimes, or child abuse. TBI can result in physical, behavioral, and/or mental changes, depending on the areas of the brain that are injured. TBI is the leading cause of death and disability among young people in the United States. Approximately 200,000 Americans die each year from traumatic injuries. An additional half million are hospitalized. About 10 percent of the surviving individuals have mild to moderate problems that threaten their ability to live independently. Another 200,000 have serious problems that may require institutionalization or some other form of close supervision.

The number of people surviving TBI has increased significantly in recent

years because of more effective emergency care; transportation to specialized treatment facilities, and acute medical management. Currently, an estimated 5.3 million Americans are living with the effects of TBI. The direct medical costs for treatment of TBI have been estimated to be over \$4.5 billion, annually.

Although TBI can cause chronic physical impairments, often the individual has more disability due to problems with cognition, emotional functioning, and behavior in connection with interpersonal relationships, school, or work. The result is frequently a dramatic change in the individual's life-course, profound disruption of the family, and huge medical and related expenses over a lifetime. Rehabilitation efforts can require years of treatment, starting in the hospital, and extending through formal inpatient and outpatient rehabilitation to a variety of day treatment or residential programs.

The cognitive and communication problems of TBI are best treated early; often beginning while the individual is still in the hospital. Longer-term rehabilitation may be performed individually, in groups, or both, depending on the needs of the individual. This therapy often occurs in a rehabilitation facility designed specifically for the treatment of individuals with TBI. The goal of rehabilitation is to help affected individuals progress to the most independent level of functioning possible. Therapy focuses on regaining lost skills, as well as learning ways to compensate for abilities that have been permanently changed because of TBI.

According to a recent GAO study of services, adults with TBI often have permanent disability that requires long-term supportive services to remain in the community. In an analysis of eleven States, the gap between the number of individuals with TBI receiving long-term services and the estimated number of disabled adults with TBI remains wide.

Until FY 2002, two categories of TBI demonstration grants were available: (1) State TBI Planning Grants and (2) State TBI Implementation Grants. Thirty-three States and the District of Columbia received planning grants to develop an Action Plan to improve the State's TBI service system. Grantees developed four "core capacity" components: (1) A statewide TBI Advisory Board; (2) designated State agency and staff position(s) responsible for State TBI activities; (3) a statewide needs/resource assessment to address the full spectrum of services from initial acute treatment through rehabilitation and long-term

community services for individuals with TBI; and (4) a statewide Action Plan outlining steps needed to develop a comprehensive, community-based system of care encompassing physical, psychological, educational, vocational, and social aspects of TBI services, and addressing the needs of individuals with TBI and their families.

Twenty-six States received Implementation Grants. States used these grants to focus on key priorities identified in their statewide action plans, including: (1) Leadership in integrating individuals with TBI and their families into the broader service delivery system; (2) human resources, personnel, training, and education on TBI issues; (3) data collection, evaluation, and information management to improve delivery of TBI services; (4) public information and education regarding TBI issues; (5) and coordination with other public health and disability community services.

The Children's Health Act of 2000, Public Law 106-310, established two additional grant categories: (1) Post Demonstration Grants for States that have successfully completed a TBI Implementation Grant, and (2) TBI Protection and Advocacy (P&A) grants. This Notice announces availability of funds only for TBI Planning Grants, TBI Implementation Grants and TBI Post Demonstration Grants.

Authorization

Public Health Service Act, Title XII, section 1252, 42 U.S.C. 300d-52, as amended by Public Law 106-310, section 1304.

Purpose

The purpose of the TBI grant program is to improve access, availability, appropriateness and the acceptability of health and other services for people who have sustained a traumatic brain injury (TBI) and their families, through funding systems change initiatives. Planning Grants provide funds to assist States in developing infrastructure in the four identified "core capacity" components identified above. Implementation grants provide funds to implement priority elements of the TBI State Plan. Post Demonstration Grants provide funds for capacity-building initiatives to contribute to sustainable change in their systems of community services and supports that reflect best practices.

Eligibility

For all TBI grants, State governments are the only eligible applicants for funding. It is understood that applications for a TBI Post-

Demonstration Grant will come from the State agency designated as the lead for TBI services; the State must have completed a three-year State TBI Implementation Grant.

Funding Level/Project Period

Approximately \$150,000 is available in FY 2002 to support two State TBI State Planning awards, at up to \$75,000 per award, for project periods of up to two years. Approximately \$200,000 is available in FY 2002 to support one Implementation award for up to 3 years. Approximately \$800,000 is available in FY 2002 to support eight TBI State Post Demonstration awards, at \$100,000 per award, for a one-year project period. For each award, the State must contribute, in cash or in kind (including plant, equipment and services), not less than \$1 for each \$2 of Federal funds provided under the TBI State Grants. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in the amount of such contributions.

The initial budget period for TBI Planning Grants and Implementation Grants is expected to be 12 months, with any subsequent budget period being 12 months each. Continuation of any TBI project from one budget period to the next is subject to satisfactory performance, program priorities and the availability of funds.

Review Criteria

An objective review panel will evaluate applications for TBI grants, using criteria and weights specific to each category of grant, which are outlined below.

- (1) State Planning Grants:
 - a. The strength of the plan to develop a statewide Advisory Board (15 points).
 - b. The adequacy of the State's methodology to develop the four "core capacity" components (35 points).
 - c. The comprehensiveness of the approach to collaboration and partnership (25 points).
 - d. The adequacy of the organizational and management plan (25 points).
- (2) Implementation Grants:
 - a. The capabilities of the designated Lead Agency (20 points).
 - b. The adequacy of the involvement of the Statewide Advisory Board (25 points).
 - c. The strength of the statewide TBI Action Plan in addressing community services and supports that reflect the best practice in the field of traumatic brain injury (25 points).
 - d. The State capacity building efforts (30 points).
- (3) Post Demonstration Grants:

a. The capabilities of the designated State lead agency (20 points).

b. The adequacy of the involvement of the statewide Advisory Board (25 points).

c. The strength of the statewide TBI Action Plan in addressing community services and supports that reflect the best practice in the field of traumatic brain injury (25 points).

d. The State's capacity building efforts (30 points).

Additional criteria used to review and rank applications for this competition are included in the application kit. Applicants should pay strict attention to addressing these criteria, as they are the basis upon which their applications will be judged.

Paperwork Reduction Act

OMB approval for any data collection in connection with this cooperative agreement will be sought, as required under the Paperwork Reduction Act of 1995.

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).

Dated: June 10, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02-16103 Filed 6-25-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 27, 2002, 9 a.m. to June 27, 2002, 10 a.m., Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037 which was published in the **Federal Register** on June 12, 2002, 67 FR 40326-40329.

The meeting will be held on June 28, 2002. The time and location remain the same. The meeting is closed to the public.

Dated: June 18, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-16078 Filed 6-25-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, June 17, 2002, 8 a.m. to June 19, 2002, 6 p.m., Washington Terrace Hotel, 1515 Rhode Island Avenue, NW., Washington, DC, 20005 which was published in the **Federal Register** on April 24, 2002, 67 FR 20143.

The meeting location has been changed to the Wyndham Washington Hotel. The meeting is closed to the public.

Dated: June 18, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-16069 Filed 6-25-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee H—Clinical Groups.

Date: July 22-23, 2002.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton—Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Deborah R. Jaffe, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8038, MSC 8328, Bethesda, MD 20892, (301) 496-7721, dj86k@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 18, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-16080 Filed 6-25-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institution of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice