

phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* January 24, 2000. The applicant claims October 2, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 24, 2000, which was the date the IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* April 7, 2006. The applicant claims December 6, 2005, as the date the new drug application (NDA) for ZOLINZA (NDA 21-991) was initially submitted. However, FDA records indicate that NDA 21-991 was submitted in several modules under the fast track drug development program. It is FDA's position that the approval phase begins when the marketing application is complete for review. The final module of the NDA making it complete for review was submitted on April 7, 2006.

3. *The date the application was approved:* October 6, 2006. FDA has verified the applicant's claim that NDA 21-991 was approved on October 6, 2006.

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 1,433 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 14, 2008. 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 November 10, 2008. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

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

[FR Doc. E8-10689 Filed 5-13-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Preference for Healthy Start Grantees

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

ACTION: General notice.

BACKGROUND: This notice supplements the 2007 HRSA announcement (HRSA 08-023/08-031) of the availability of fiscal year (FY) 2008 funding for new and competing continuation applications for Healthy Start. Healthy Start strengthens communities to effectively address the causes of infant mortality, low birth weight and other poor perinatal outcomes for women and infants. Recently, new guidance became available with regards to funding FY 2008 Healthy Start programs.

SUMMARY: The Conference Report (H.R. Rep. No. 110-107) accompanying the Consolidated Appropriations Act 2008 (Pub. L. 110-161), Division G—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, indicates concurrence with the Senate report language regarding the recompetition of Healthy Start programs. Following the Senate Committee's recommendation, the Health Resources and Services Administration (HRSA) will give funding preference during the FY 2008 competition to current Healthy Start grantees.

Senate Report 110-107 urges "HRSA to give preference to current and former

grantees with expiring or recently expired project periods."

FOR FURTHER INFORMATION CONTACT:

Maribeth Badura, Director, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, Room 18-12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-0543; e-mail MBadura@hrsa.gov.

Dated: May 2, 2008.

Dennis Williams,

Acting Administrator.

[FR Doc. E8-10684 Filed 5-13-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of 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 a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. The grant applications and/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: May 19-20, 2008.

Closed: May 19, 2008, 1 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Closed: May 20, 2008, 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Open: May 20, 2008, 10:30 a.m. to 12:30 p.m.

Agenda: A report of the FIC Director on updates and overviews of new FIC initiatives. Topics to be discussed include the Global Programs and Strategies of the NCI and NHLBI.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Closed: May 20, 2008, 1:30 p.m. to 3:15 p.m.

Agenda: To review and evaluate a report and discussion on the Global Health Leaders Consultation.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Contact Person: Robert Eiss, Public Health Advisor, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, (301) 496-1415, eissr@mail.nih.gov.

This meeting is being published less than 15 days prior to the meeting due to timing limitations imposed by administrative matters.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Centers home page: <http://www.nih.gov/fic/about>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: May 6, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-10550 Filed 5-13-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of 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 a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: June 12, 2008.

Open: 8 a.m. to 1:30 p.m.

Agenda: (1) A report by the Director, NICHD; (2) A report of the Subcommittee on Planning and Policy; (3) A Contraception and Reproductive Health Branch Presentation; and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Closed: 1:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Yvonne T. Maddox, PhD, Deputy Director, National Institute of Child Health and Human Development, NIH, 9000 Rockville Pike, MSC 7510, Building 31, Room 2A03, Bethesda, MD 20892, (301) 496-1848.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance

onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nichd.nih.gov/about/nachhd.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 5, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-10469 Filed 5-13-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

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 meetings.

The meetings 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 Center for Research Resources, Special Emphasis Panel R24 Applications Review.

Date: June 17, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NCRR/OR, Democracy 1, 6701 Democracy Blvd., Room 1064, Bethesda, MD. (Telephone Conference Call).

Contact Person: Guo Zhang, PhD., Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1064, Bethesda, MD 20814-9692, (301) 435-0812, zhangumail.nih.gov.