

while 613 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 FD&C Act) (21 U.S.C. 355(i)) became effective:*

November 5, 2000. The applicant claims October 5, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 5, 2000, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* May 23, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for Victoza (NDA 22-341) was initially submitted on May 23, 2008.

3. *The date the application was approved:* January 25, 2010. FDA has verified the applicant's claim that NDA 22-341 was approved on January 25, 2010.

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 1,826 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) either electronic or written comments and ask for a redetermination by July 2, 2012. 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 October 24, 2012. 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.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,
Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012-10517 Filed 5-1-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Healthy Tomorrows Partnership for Children Program

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

ACTION: Notice of a non-competitive one-year extension with funds for the National Healthy Tomorrows Technical Assistance Resource Center (U50).

SUMMARY: The Health Resources and Services Administration (HRSA) will be

issuing a non-competitive one-year extension with funds for the National Healthy Tomorrows Technical Assistance Resource Center at the American Academy of Pediatrics (AAP). Up to \$176,855 will be awarded over a one-year extended project period. The National Healthy Tomorrows Technical Assistance Resource Center provides support for the activities of the Healthy Tomorrows Partnership for Children Program (HTPCP), community-based grants that address priority issues determined by the community. Through a cooperative agreement, the Resource Center also offers consultation to HTPCP program participants to ensure successful implementation and sustainability of community-based initiatives; facilitates involvement of local partners such as pediatricians, State/local AAP chapters, State/local maternal and child health agencies, and other private sector partners in HTPCP projects to promote successful implementation of community-based maternal and child health initiatives; and conducts a national evaluation of HTPCP projects that assesses critical factors contributing to program sustainability, effectiveness and impact of community-based projects post HTPCP funding, and the ability of projects to develop meaningful evaluation and sustainability plans. A 2005 national evaluation found that 80 percent of HTPCP projects are fully or partially sustained 5 years post-Federal funding. The proposed extension with funds will allow the Maternal and Child Health Bureau (MCHB) to align the National Healthy Tomorrows Technical Assistance Resource Center with the National Center for Medical Home Implementation.

SUPPLEMENTARY INFORMATION: Recipient of record and intended award amount is:

Organization name	Cooperative agreement number	State	FY2011 Authorized funding level	FY2012 Estimated funding level
The American Academy of Pediatrics (AAP)	U50MC07618	IL	\$176,855	\$176,855

Amount of the Award: Up to \$176,855 for one recipient over a one-year project period.

CFDA Number: 93.110.

Current Project Period: 9/1/2011 through 8/31/2012.

Period of Supplemental Funding: 9/1/2012 through 8/31/2013.

Authority: Title V of the Social Security Act, Section 501(a)(2), (42 U.S.C. 701 (a)(2)).

Justification

Over 75 percent of Healthy Tomorrows projects are involved in case management/care coordination or establishing a medical home in underserved and vulnerable communities. HTPCP has long encouraged Healthy Tomorrows projects involved in case management/care coordination or medical home to adopt the medical home model, so the

combination of these investments achieves efficiencies. The National Healthy Tomorrows Technical Assistance Resource Center provides resources to grantees interested in medical home implementation, but has limited capacity to offer detailed technical assistance to grantees assessing the benefits and challenges of implementing a meaningful medical home in communities with finite resources. A strategic partnership with

the National Center for Medical Home Implementation would provide the National Healthy Tomorrows Technical Assistance Resource Center with the capacity, capability, and efficiency to foster effective examples of medical home in underserved and vulnerable communities.

During the one-year extension period, MCHB will hold discussions with the project officers of the two resource centers to develop a plan to incorporate the goals and objectives of the National Healthy Tomorrows Technical Assistance Resource Center into the FY 2013 competitive guidance for the National Center for Medical Home Implementation. This partnership will strengthen and advance the medical home model in small, community-driven projects that strive to increase access to direct services for pregnant women, infants, children and youth and promote prevention initiatives. A one-year extension will also ensure that there is no disruption in the provision of technical assistance (via site visits), training and evaluation of Healthy Tomorrows grantees as MCHB plans for this consolidation.

FOR FURTHER INFORMATION CONTACT: Madhavi Reddy, MSPH, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18A-55, Rockville, Maryland 20857; email mreddy@hrsa.gov.

Dated: April 25, 2012.

Mary K. Wakefield,
Administrator.

[FR Doc. 2012-10507 Filed 5-1-12; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program Solicitation of Comments

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

ACTION: Notice of opportunity to provide written comments.

SUMMARY: This **Federal Register** Notice solicits comments on Parts A through F of the Ryan White HIV/AIDS Program. Comments are solicited to inform the 2013 reauthorization of the Program, which was most recently reauthorized under Title XXVI of the Public Health Service Act (PHS), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program). Stakeholders will be

invited to share written comments regarding reauthorization of the Ryan White HIV/AIDS Program through the Web portal at www.regulations.gov.

HRSA's HIV/AIDS Bureau will also host listening sessions in the form of teleconferences or webinars to engage stakeholders across the U.S. At least four listening sessions will be conducted, each targeting different geographic areas. The listening sessions will offer stakeholders the opportunity to discuss reauthorization of the Ryan White HIV/AIDS Program.

Listening sessions will be announced as dates are determined. Dates will be announced at <http://hab.hrsa.gov/reauthorization/>.

DATES: Submit written comments no later than July 31, 2012.

ADDRESSES: Written comments should be submitted on-line through www.regulations.gov. Individuals wishing to submit comments on the Ryan White HIV/AIDS Program should search for the following term: "HRSA-2012-0003." Navigate directly to the appropriate section at <http://hab.hrsa.gov/reauthorization/>.

SUPPLEMENTARY INFORMATION: Written comments addressing Parts A through F of the Ryan White HIV/AIDS Program are welcome from all Ryan White stakeholders, including grantees, advocacy organizations, State and local administrators, and other members of the Ryan White HIV/AIDS Program and the HIV/AIDS community. Stakeholders are strongly encouraged to clearly organize comments and include headings to indicate which part of the Ryan White HIV/AIDS Program the comment(s) address(es), such as Parts A, B, C, D or F. For stakeholders who plan to submit comments addressing multiple parts of the Program, it is suggested that comments pertaining to the same part are grouped and that each group of comments is preceded with a heading stating the relevant part of the Program.

To ensure an opportunity for all stakeholders to contribute to regional aspects of disease/epidemic, HRSA recommends that individuals participate in the listening session assigned to their geographic area.

Dated: April 25, 2012.

Mary K. Wakefield,
Administrator.

[FR Doc. 2012-10508 Filed 5-1-12; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute of Child Health and Human Development Special Emphasis Panel; Nature and Acquisition of Speech Code.

Date: May 8, 2012.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marita r. Hopmann, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6911, hopmannm@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: April 26, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-10584 Filed 5-1-12; 8:45 am]

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