as mandated by FDAAA, the provisions of the proposed rule went into effect on that date.

FDAAA mandated one change to the proposed rule. Section 502(f)(2) of FDAAA stated that the toll-free number proposed rule shall not apply to over-the-counter (OTC) drugs marketed with an application approved under section 505 of the act (application OTC drug products) if these application OTC drug products meet certain labeling requirements. Because the agency's rulemaking process was ongoing on January 1, 2008, an interim final rule was issued on January 3, 2008 (73 FR 402) that codified the provisions of the proposed rule as modified by FDAAA. The interim final rule stated that FDA anticipated that affected entities would need time to update labeling and systems to comply with the new requirements and that FDA intended to exercise its enforcement discretion and not take action to enforce the toll-free number requirements in the interim final rule until January 1, 2009. The interim final rule also stated that the agency planned to complete research begun on the proposed labeling statements and would issue a final rule taking into account the results of that research. In the **Federal Register** of October 28, 2008 (73 FR 63886), FDA issued a final rule with an effective date of November 28, 2008, and a compliance date of July 1, 2009. The agency is publishing this guidance to assist manufacturers in complying with the final rule.

This level 1 guidance is being issued for immediate implementation consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA has determined that prior public participation is not feasible or appropriate because the side effects statement is required by Congress and the compliance deadline for its inclusion in Medication Guides is July 1, 2009 (21 CFR 10.115(g)(2)). If comments are received on this level 1 guidance, FDA will review the comments and revise the guidance if appropriate. The guidance represents the agency's current thinking on adding a toll-free number to Medication Guides and reporting this to the agency. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

The required side effects statement is not subject to the Office of Management and Budget (OMB) review under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520) because it is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' and is not considered a collection of information under the PRA (5 CFR 1320.3(c)(2)). The guidance on notifying FDA in the drug's annual report that the side effects statement has been added to the drug's Medication Guide is covered by previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 314.70(d) (changes to an approved application to be described in an annual report) and 314.81(b)(2)(iii)(c) (a summary of labeling changes that have been made since the last annual report) have been approved under OMB control number 0910–0001 for human drugs.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: June 1, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–13273 Filed 6–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal Child Health Bureau, Healthy Start Eliminating Disparities in Perinatal Health

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

ACTION: Notice of Non-competitive Supplemental Funding to Northern Manhattan Perinatal Partnership.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing non-competitive supplemental funding under the Maternal Child Health Bureau, Healthy Start Eliminating Disparities in Perinatal Health program to ensure that the Northern Manhattan Perinatal Partnership (NMPP), the primary provider of prenatal services in Central Harlem, can continue to provide much needed services to help stem the rise in and ultimately reduce the Infant Mortality Rate (IMR) in the affected service area.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Northern Manhattan Perinatal Partnership.

Amount of the Non-Competitive Supplemental Funding: $510, 417.

Project Period: The original project period for this grant is through May 31, 2009.

Period of Supplemental Support: June 1, 2009 through January 31, 2010.

Authority: This activity is under the authority of the Public Health Service Act, Section 33OH.

Catalogue of Federal Domestic Assistance Number: 93.926.

Justication for Non-Competitive Supplemental Funding

Northern Manhattan Perinatal Partnership (NMPP), known as Central Harlem Healthy Start, has historically been the primary provider of prenatal services in Central Harlem and has been highly effective in reducing the high rate of infant morality (IMR) in that project/service area. As a consequence of NMPP's leadership and collaborated efforts with other providers in the community, the IMR has declined significantly in Central Harlem since the initiation of the project in 1990 when it was 27.7 infant deaths per 1,000 live births. By 2001, the IMR had dropped to 13.1 infant deaths per 1,000 live births, 54% less than the 1990 rate. The IMR in Central Harlem from 2002 to 2004 showed a decline from the previous years; however, there were fluctuations in the rate of decline in the community. The IMR was at a low of 6.2% in 2002 and increased to 7.3% in 2003, and then in 2004, decreased to 5.1%. The apparent trend in the following two years saw a steady increase to 7.4% for 2005 and 11.2% for 2006. An additional indicator of this trend is the escalating IMR for teen births which saw an increase in the 3 year average from

2002–2004 of 5.93% increase to 12.54% for 2005–2007.

The reduction in the earlier years IMR (2002–2004) for Central Harlem made them ineligible for the FY 2009 Healthy Start Eliminating Disparities Open competition. To be eligible, the IMR for the service area had to be 1.5 times the national average for the period of 2002–2004 or 10.35. In FY 2010 there will be another Healthy Start Eliminating Disparities Open competition and grantees will be required to the use the most recently available IMR data (2004–2006 or 2005–2007) to compete. To be eligible for the competition, grantees will have to have an IMR that is 1.5 times the national average for the project area for either 2004–2006 or 2005–2007. Data supplied the New York City Bureau Statistics indicates that Central Harlem would be eligible for this competition because they have 12.54% IMR for teen births for 2005–2007.

The award of non-competitive supplemental funding will enable NMPP to provide much need services in Central Harlem. Given the current economic situation and the rising IMR rate in the project area, the loss of this experienced provider of health services would be devastating and would contribute to the rise in infant deaths in Central Harlem, NMPP is the primary provider of comprehensive community-based perinatal services and the only Healthy Start site serving the project area. The project's dedication and commitment to the residents of Harlem since 1999 could not be replaced another community based provider.

FOR FURTHER INFORMATION CONTACT: John McGovern, Public Health Analyst, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; phone 301–443–5805; E-mail *jmcgovern@hrsa.gov*.

Dated: May 29, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–13279 Filed 6–5–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel Competitive Revision—ARRA Funds.

Date: June 11, 2009.

Time: 1:45 p.m. to 3:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN18, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Rebecca H Johnson, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892. 301–594–2771. *johnsonrh@nigms.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. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: June 1, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–13199 Filed 6–5–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel—Program Project.

Date: July 10, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Democracy II, 6701 Democracy Plaza II, 200, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John K. Hayes, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3398, *hayesj@mail.nih.gov.*

Dated: June 1, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–13282 Filed 6–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. Animal Models of Infectious Diseases 1.

Date: June 29–July 1, 2009.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate contract proposals.

Place: Crowne Plaza—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Tracy A. Shahan, PhD, MBA, Scientific Review Officer, Scientific Review Program, NIH/NIAID/DHHS, Room 3121, 6700B Rockledge Drive, MSC 7616,