would be required to increase the number of program participants and/or sites for program implementation. Increased funding will help the grantee programs increase recruitment and retention strategies for program participants that will allow grantees to obtain the minimal statistical power required to report significant outcome data. Outcome data will determine the effectiveness of the implemented pregnancy prevention models used in the program. Thus, the increased number of program participants supports the evaluation requirements outlined in the FOA and the ACA.

Additionally, grantees are required to report on performance measures that were specifically defined by FYSB. The data collection will require additional grantee staff time and other resources to compile and report on performance indicators. Performance indicators are based upon the performance measures established by HHS to include: (a) The number of youth served and hours of service delivery; (b) fidelity to the program model, or adaptation of the program model for the target population; (c) community partnerships and competence in working with the target population; (d) reported gains in knowledge and intentions, and changes in self-reported behaviors of participants; and (e) community data, such as birth rates and the incidence of sexually transmitted infections.

Award amounts for the nine single source expansion supplement grants total $758,876 and will support activities from September 30, 2012 through September 29, 2013.

Statutory Authority: Section 2953 of the Patient Protection and Affordable Care Act of 2010, Pub. L. 111–148, which adds a new Section 513 to Title V of the Social Security Act, to be codified at 42 U.S.C. § 713, authorizing the Personal Responsibility Education Program.

Bryan Samuels,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 2012–24764 Filed 10–5–12; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0375 (Formerly 2007D–0395)]

Guidance for Industry on Acute Bacterial Sinusitis: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Acute Bacterial Sinusitis: Developing Drugs for Treatment.'' This guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for the treatment of acute bacterial sinusitis (ABS). This guidance finalizes the revised draft guidance of the same name issued on October 30, 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Acute Bacterial Sinusitis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the overall clinical development program of drugs to support an indication for the treatment of ABS. This guidance finalizes the revised draft guidance published on October 30, 2007, which in turn revised the draft guidance for industry, entitled ''Acute Bacterial Sinusitis—Developing Antimicrobial Drugs for Treatment,'' published in 1998. Changes from the revised draft guidance are incorporated in the appropriate sections of the guidance and are based on comments submitted to the docket for the draft guidance. In addition, developments in scientific and medical information and technology in the treatment of ABS are reflected in this guidance. This guidance fulfills the requirement set forth in the Food and Drug Administration Amendments Act of 2007 that directed FDA to update the ABS guidance within 5 years.[1] This guidance also responds to the requirement set forth in the Food and Drug Administration Safety and Innovation Act that FDA review guidances for the conduct of clinical trials with respect to antibacterial and antifungal drugs, and revise such guidances as appropriate.[2]

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for the treatment of ABS. 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

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

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

[1] See Title IX, section 911, of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85).

[2] See Title VIII, section 804(a)(1), of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144).

Guidances/default.htm or *http://www.regulations.gov*.

Dated: October 3, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24748 Filed 10–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Nursing Research Special Emphasis Panel; Addressing Needs of Informal Caregivers of Individuals with Alzheimer's Disease in the Context of Sociodemographic Factors.

Date: November 7, 2012.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Tamizchelvi Thyagarajan, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: October 2, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–24684 Filed 10–5–12; 8:45 am]

BILLING CODE 4140–01–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 Initial Review Group Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: November 2, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Anne Krey, 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, 301–435–6908, *ak41o@nih.gov*.

(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: October 2, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–24685 Filed 10–5–12; 8:45 am]

BILLING CODE 4140–01–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; Population Educational Training.

Date: November 2, 2012.

Time: 1:00 p.m. to 2:30 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: Carla T. Walls, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–7510, 301–435–6898, *wallsc@mail.nih.gov*.

(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: October 2, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–24686 Filed 10–5–12; 8:45 am]

BILLING CODE 4140–01–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,