establishments. We estimate that a maximum average of 4 manager interviews will be conducted per outbreak. Each interview will take about 20 minutes.

The second activity is entering all requested environmental assessment data into NVEAIS. This will be done once for each outbreak. This will take approximately 2 hours per outbreak.

Additionally, all food safety program personnel participating in NVEAIS will also have to take training on how to conduct environmental assessments, how to enter data into NVEAIS, and how to conduct the manager interview. We estimate the burden of this training to be a maximum of 12 hours. Respondents will only have to take this training one time. Assuming a maximum number of outbreaks of 1,400, the estimated burden for this training is 16,800.

The total estimated annual burden is 21,467 hours (see Table). There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)
Food safety program personnel	Manager interview	1,400	4	20/60
Food safety program personnel	NVEAIS Data Reporting Instrument	1,400	1	2
Food safety program personnel (No form used).	Food safety program personnel training	1,400	1	12

Dated: October 2, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–24758 Filed 10–5–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA NUMBER: 93.297]

Announcement of the Award of Single-Source Expansion Supplement Grants to Nine Personal Responsibility Education Program Innovative Strategies (PREIS) Grantees

AGENCY: Family and Youth Services Bureau, ACYF, ACF, HHS.

ACTION: Notice of the award of single-source expansion supplement grants to nine Personal Responsibility Education Program Innovative Strategies (PREIS) grantees to support the expansion of program services necessary to meet the requirements for reporting performance measures, conducting evaluation-related activities, and strengthening program outcomes for youth participants.

SUMMARY: The Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB), Division of Adolescent Development and Support (DADS) announces the award of single-source expansion supplement grants to nine PREIS grantees for the purpose of expanding program participation and/or sites to support the increase of data necessary to determine the level of program effectiveness. In FY 2010, FYSB awarded thirteen cooperative agreement grants under Funding Opportunity Announcement (FOA) number: OPHS/OAH/TPP PREP Tier 2–2010. Under this FOA a total of $9.7 million was made available on a competitive basis to implement and test innovative strategies.

Single-source program expansion supplement awards are made to the following PREIS grantees:

Grantee organization	City	State	Supplement award amount
Child & Family Resources, Inc	Tucson	AZ	$171,981.00
Children's Hospital Los Angeles	Los Angeles	CA	92,000.00
Cicatelli Associates Inc	New York	NY	65,000.00
Education Development Center, Inc	Newton	MA	50,954.00
Lighthouse Outreach	Hampton	VA	78,769.00
Oklahoma Institute for Child Advocacy	Oklahoma City	OK	110,815.00
Philadelphia Health Management Corporation	Philadelphia	PA	61,068.00
Teen Outreach Pregnancy Services	Tucson	AZ	49,880.00
The Village for Families & Children, Inc	Hartford	CT	78,409.00

DATES: September 30, 2012–September 29, 2013.

FOR FURTHER INFORMATION CONTACT: Marc Clark, Program Director, Adolescent Pregnancy Prevention Program, Division of Adolescent Development and Support, Family and Youth Services Bureau, 1250 Maryland Avenue SW. Suite 800, Washington, DC 20024. Telephone: 202–205–8496; Email: *marc.clark@acf.hh.gov*.

SUPPLEMENTARY INFORMATION: The award of nine single source expansion supplement grants to PREIS grantees is required because of the necessary expansion of the original scope of approved activities. In reviewing grantees' aggressive program and evaluation plans, combined with recruitment efforts to date, FYSB has determined that that these nine grantees

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).