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 Otitis Media: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the overall clinical development of drugs to support an indication for the treatment of ABOM, defined in the guidance as ''the recent or acute onset of inflammation of the middle ear caused by a bacterial pathogen.'' This guidance finalizes the revised draft guidance issued on January 18, 2008, which in turn revised the draft guidance for industry entitled ''Acute Otitis Media—Developing Antimicrobial Drugs for Treatment'' issued in 1998. Changes from the revised draft guidance are incorporated in the appropriate sections of the guidance and are based on comments received to the docket for the draft guidance. In addition, developments in scientific and medical information and technology in the treatment of ABOM are included in this guidance. This guidance fulfills the statutory requirement described in the Food and Drug Administration Amendments Act of 2007 that directed FDA to update the guidance within 5 years.[1] This guidance also responds to the requirement set forth in the Food and Drug Administration Safety and Innovation Act of 2012 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 ABOM. 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. The collections of information referred to in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

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

Dated: September 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24211 Filed 10–1–12; 8:45 am]

BILLING CODE 4160–01–P

[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 of 2012 (Pub. L. 112–144).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Health Resources and Services Administration (HRSA) periodically publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Healthy Weight Collaborative Evaluation (OMB No. 0915–xxxx)—[NEW]

Background: Supported by the Prevention and Public Health Fund created by Section 4002 of the Affordable Care Act, HRSA awarded $5 million to the National Initiative for Children's Healthcare Quality (NICHQ) to create the Collaborative for Healthy Weight, a national initiative to bring together primary care providers, public health professionals, and leaders of community-based organizations to use quality improvement methods to address the obesity epidemic in communities across the country. A key part of that initiative was creation of the Healthy Weight Collaborative (HWC), a quality improvement project working with 50 community teams to identify, test, and evaluate a national ''change package'' of evidence-based program and policy interventions to address childhood obesity. The HWC is being implemented in two consecutive phases, each with a series of learning sessions and action periods. The first phase (July 2011 to July 2012) includes 10 community teams; the second phase (March 2012 to March 2013) includes 40 additional teams.

Purpose: The purpose of this evaluation is to assess the quality and effectiveness of the HWC. This one-year information collection will supplement the analysis of existing quantitative HWC administrative and team data by collecting primary data using individual and group interviews with two groups of stakeholders: (a) NICHQ project leadership, staff, and faculty; and (b) community team members at 11 selected sites (four Phase 1 teams and seven Phase 2 teams). Data from these interviews will be used to evaluate the quality and effectiveness of the HWC. NICHQ leadership, staff, and faculty interview topics include: the design and implementation of the HWC project; the content and quality of the HWC learning sessions, coaching assistance, and other action period activities; the community teams' experiences implementing the

HWC change package and quality improvement indicators; and stakeholders' perceptions of the quality and effectiveness of the HWC in accelerating community efforts to address childhood obesity. Community team interviews will be conducted with the team coordinator, the quality improvement data manager, and other team members, including primary care providers, public health officials, school administrators, and other community volunteers. Separate interview protocols will be developed for the Phase 1 and Phase 2 community teams. Phase 1 protocols will examine community team strategies, activities, and approaches that have been sustained and spread after the end of Phase 1. Phase 2 protocols will examine: (1) Team goals, objectives, and program elements; (2) team implementation of the HWC change package; (3) team engagement in HWC activities; and (4) team linkages and organizational and policy changes resulting from the team's participation in the HWC.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
NICHQ Leaders Interview	4	1	4	1.0	4.0
NICHQ Staff Interview	5	1	5	1.0	5.0
NICHQ Faculty Group Interview	*6	1	6	1.0	6.0
Phase 1 Team Group Interview	**24	1	24	1.5	36.0
Phase 1 Team Coordinator Interview	4	1	4	1.5	6.0
Phase 1 Team Data Manager Interview	4	1	4	.5	2.0
Phase 2 Team Group Interview	***42	1	42	1.5	63.0
Phase 2 Team Coordinator Interview	7	1	7	1.5	10.5
Phase 2 Team Data Manager Interview	7	1	7	.5	3.5
Total	103	.....	103	.....	136.0

* One group interview: 6 people per group.
** Four group interviews: 6 people per group.
*** Seven group interviews: 6 people per group.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: September 26, 2012.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2012–24249 Filed 10–1–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Noncompetitive Supplements to Nursing Assistant and Home Health Aide Program Grantees

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

ACTION: Notice of Noncompetitive Program Expansion Supplements to Develop, Implement, and Evaluate Educational Curricula in Medication Administration and Management; Care Coordination and Follow Up; and Behavioral Health and Social Support for Home Health Aides.

SUMMARY: The Health Resources and Services Administration (HRSA) will offer noncompetitive program expansion supplements of $100,000 to 10 Nursing Assistant and Home Health Aide (NAHHA) Program grantees to develop, implement, and evaluate enhanced training programs to build competency in medication administration and management, care coordination and follow up, and behavioral health and social support for home health aides. Approximately $1,000,000 is available in fiscal year (FY) 2012. The NAHHA grantees have the capability, expertise, experience and infrastructure to expeditiously and effectively implement this enhanced training program. Their existing curricular efforts have built-in opportunities to offer continuing/expanded training, and these skills represent ones that have been identified by program participants and employers as highly desirable areas for training.

SUPPLEMENTARY INFORMATION:

Grantees of record are:

American Red Cross, Greater Cleveland Chapter, 3747 Euclid Avenue, Cleveland, OH 44115–2501, T51HP20694

American Red Cross of Sonoma, Mendocino & Lake Counties, 5297 Aero Drive, Santa Rosa, CA 95403, T51HP20693

College of Menominee Nation, PO Box 1179, Keshena, WI 54135, T51HP20696

Erie 1 BOCES (Board of Cooperative Educational Services), 355 Harlem Road, West Seneca, NY 14224, T51HP20701

Hazard Community and Technical College, One Community Drive, Hazard, KY 41701, T51HP20697

Jewish Vocational Service and Employment Center, 216 W. Jackson Boulevard, Suite 700, Chicago, IL 60606–6921, T51HP20695

Penn Asian Senior Services, 420 York Road, Jenkintown, PA 19046, T51HP20699

Sears Methodist Retirement System, Inc., Texas Tech University Health Sciences Center (TTUHSC) School of Nursing, 302 Pine Street, Abilene, TX 79601, T51HP20702

Southwestern Oregon Community College, 1988 Newmark Avenue, Coos Bay, OR 97420, T51HP20698

St. Joseph Medical Center, P.O. Box 316, Reading, PA 19603–0316, T51HP20700

Intended Recipients of the Award: 10 Existing NAHHA awardees.

Intended Amount of Each Award: $100,000.

CFDA Number: 93.503

Project Period: September 30, 2012, through September 29, 2013.

Authority: Public Health Service Act, Title VIII, Section 831, 42 U.S.C. 296p, as amended by the Affordable Care Act (Pub. L. 111–148).

Justification: These program expansion supplements allow the Bureau of Health Professions to consolidate resources and provide enhanced curricular offerings and technical assistance, grant monitoring and oversight to the NAHHA initiative within currently existing grants. Moreover, providing additional funding to existing grantees offers the opportunity to expand upon the program evaluation imbedded in the existing NAHHA program, increasing the knowledge yield for HRSA and the