appointed to serve as public members are authorized also to receive honorarium for attending Committee meetings and to carry out other authorized Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive honorarium for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to fill positions on the NVAC that are scheduled to be vacated in the public member category. The positions are scheduled to be vacated on March 31, 2009.

Nominations

In accordance with the charter, persons nominated for appointment as members of the NVAC should be among authorities knowledgeable in areas related to vaccine safety, vaccine effectiveness, and vaccine supply. Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity); (2) a statement from the nominee, bearing an original signature, that, if appointed, he or she is willing to serve as a member of the Committee; (3) the nominator's name, address and daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (4) a current copy of the nominee's curriculum vitae.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable. Applications cannot be submitted by facsimile. The names of Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made that a broad representation of geographic areas, gender, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special Government employees (SGEs). SGEs are Government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of NVAC are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: December 8, 2008.

Bruce Gellin,

Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. E8–30614 Filed 12–23–08; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0045] (formerly Docket No. 2004N–0408)

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is reannouncing the invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this notice is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit a written or electronic request for participation in this program by January 23, 2009. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, or if your biologics facility responded to a previous RSVP notice announced in the **Federal Register**, you should submit a request to participate in the program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lonnie Warren Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, *email: matt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness and timely delivery of biological products to patients. To support this primary goal, CBER has initiated various training and development programs to promote high performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to improve: (1) Its understanding of current industry practices, and regulatory impacts and needs; and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005, and through these annual notices, is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest, as well as

encouraging new interested parties to apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include packaging facilities, quality control and pathology/toxicology laboratories, and regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

All travel expenses associated with the site visits will be the responsibility of CBER; therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. A key element of site selection is a successful compliance record with CBER or another agency for which we have a memorandum of understanding. Facilities should also be advised that if a site visit involves a separate physical location of another firm under contract to the applicant, then this contract site must be in agreement to participate in the program, as well as have a satisfactory compliance history.

III. Requests for Participation

Requests are to be identified with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30659 Filed 12–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Intervention Trials To Retain HIV-Positive Patients in Medical Care (NEW)

The purpose of this project is to develop, implement, and test the efficacy of an intervention designed to increase client appointment attendance among patients at risk of missing scheduled appointments at HIV clinics. This project is a collaboration between the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and six university-affiliated HIV clinics in the United States. The proposed intervention will be implemented in two phases. Phase 1 is a clinic-wide intervention that includes the following components: a theme slogan for the intervention, brochures, posters with messages to patients, brief verbal retention in care messages from providers to patients, buttons printed with the theme of the intervention worn by providers, and appointment reminder cards with information on how to cancel appointments. All clinic patients will receive the Phase 1 intervention. Phase 2 of the project is a two-arm randomized trial in which 300 patients will be enrolled and randomly assigned to one of two study arms. In Arm 1 (control arm), patients (n=100) will receive the clinic-wide intervention only. Patients (n=200) assigned to Arm 2 (intervention arm) will continue to receive the clinic-wide intervention plus a client-centered intervention from two trained interventionists.

The efficacy of the intervention will be assessed through data collection efforts tailored to each phase of the intervention. Phase 1 uses a pre-post comparison of clinic attendance rates before and during a clinic-wide intervention. Specifically, in Phase 1, the attendance rate for HIV primary care is currently being assessed via electronic medical records during the 12-month period before the clinic-wide intervention begins. This pre-intervention assessment is being collected for all patients who had at least one HIV primary care visit at the clinic during the preceding 12 months. This cohort of patients will be reassessed via electronic medical records during the 12-month intervention period. In addition, provider surveys will be administered quarterly during Phase 1 and semi-annually during Phase 2 to obtain information from primary care providers (MD, DO, nurse practitioner, physician assistant) about whether they talked to their patients about the importance of regular care.

In Phase 2, participants will be enrolled over a period of 4–9-months to allow flexibility for faster or slower enrollment in the clinics. It is anticipated that most clinics will complete their enrollment in approximately 6 months. On a daily basis, clinic staff or the study coordinator will generate a list of patients who meet eligibility criteria based on attendance history. The list will be given to the study coordinator who will approach patients to ask about their interest in being screened for eligibility in the study. When patients agree to be screened for eligibility, the study coordinator will administer an eligibility screener. Patients who are found to be eligible will be enrolled in the project and all enrollees will complete a baseline survey (that will take approximately 30 minutes) before being randomized to the intervention or control arm. No follow-up surveys will be collected. The survey will be