related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained above. The guidance also covers the following topics.

• The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.

• Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.

• Public availability of decisions reached during the dispute resolution process to promote consistent application and interpretation of drug quality-related regulations.

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: Based on the number of requests for tier-one and tier-two DR received by FDA since the guidance published in January 2006, FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier-one DR, and that there will be one appeal of these requests to the DR Panel (request for tier-two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR, and approximately 8 hours to prepare and submit each request for a tier-two DR. Table 1 of this document provides an estimate of the annual reporting burden for requests for tier-one and tier-two DRs.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for Tier-One DR	2	1	2	30	60
Requests for Tier-Two DR	1	1	1	8	8
TOTAL					68

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

Dated: January 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1004 Filed 1–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0241]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Institutional Review Boards'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 11, 2007 (72 FR 57948), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0130. The approval expires on December 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: January 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1005 Filed 1–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 February 21, 2008. 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. Facilities should also be advised that if a site visit involves a separate physical location of another firm under contract to the applicant that this site must be in agreement to participate in the program, as well as have a satisfactory compliance history.

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.fda.gov/dockets/ecomments* or *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, e-mail: *matt@cber.fda.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. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with CBER or another agency for which we have a memorandum of understanding.

Dated: January 11, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1006 Filed 1–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Framingham Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 6, 2007, page 62659, and allowed 60 days for public comment. Two comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, any information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Framingham Study. *Type of Information Request:* Revision (OMB No. 0925–0216). *Need and Use of Information Collection:* The Framingham Study will conduct examinations and morbidity and mortality follow-up in original, offspring, and third generation participants for the purpose of studying the determinants of cardiovascular disease. *Frequency of response:* Both individuals and physicians will be contacted annually. One response per contact per year is anticipated from physicians and informants; participants will average 1.49 responses to various components within each annual contact. *Affected public:* Individuals or households; businesses or other for profit; small businesses or organizations. *Types of Respondents:* Adult men and women; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 5,569 and *Estimated Total Annual Burden Hours Requested:* 5,794.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Number of respondents	Average time per response	Annual hour burden
Individuals (Participants and Informants)	4719	1.107	5224
Physicians	850	0.671	570
Totals	5569	.....	5794

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and