

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<sup>1</sup>

	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

<sup>1</sup> 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.*

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## 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.*

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## 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