Wanda Neal, Parenteral Drug Association, 4350 East West Hwy., suite 200, Bethesda, MD 20814, 301–656–5900, FAX: 301–986–0296, *neal@pda.org*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Should Attend?

This announcement is directed towards professionals involved in the manufacture, control, and regulation of pharmaceutical products who will benefit from these workshops, including process/production engineers, manufacturing personnel, quality assurance/quality control and regulatory affairs professionals, consultants, regulatory investigators, and CGMP compliance officials. Other entities or individuals may also be interested in attending.

B. Where and When Will These Workshops Be Held?

We have scheduled four workshops. The locations and times are listed in table 1 of this document.

TABLE 1.—WORKSHOP LOCATIONS AND SCHEDULES

Workshop Address	Dates and Local Times
Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814	November 1 and 2, 2007, from 9 a.m. to 5 p.m. each day
The Gresham Hotels, 23 Upper O'Connell St., Dublin 1, Ireland	December 10 and 11, 2007, from 9 a.m. to 5 p.m. each day
Peking University, Beijing, China 100871	April 21 and 22, 2008, from 9 a.m. to 5 p.m. each day
Grand Hyatt Shanghai, Jin Mao Tower, 88 Century Blvd., Pudong, Shanghai, China 200121	April 24 and 25, 2008, from 9 a.m. to 5 p.m. each day

C. How Can I Participate?

You can participate in person. Anyone interested in the GMP workshops can register through the contact person (see **FOR FURTHER INFORMATION CONTACT**).

D. Is There a Registration Fee for This Workshop?

Yes, a registration fee is required for this workshop. The registration fee includes workshop reference materials and meals. Registration fees for the Bethesda, MD and Dublin, Ireland workshops are listed in table 2 of this document. The registration fee for both China locations (Beijing and Shanghai) is $550 with no discounts. All fees are given in U.S. dollars.

TABLE 2.—REGISTRATION FEES FOR THE BETHESDA, MD AND DUBLIN, IRELAND WORKSHOPS

Date of Registration	PDA Member	Nonmember	Government Employee or Health Authority	Academic	Student
Through October 1, 2007	$1,295	$1,695	$350	$350[1]	$150
After October 1, 2007	$1,495	$1,895	$405	$405[1]	$180

[1] Must be PDA member to receive this rate.

E. How Can I Get Additional Information?

The notice of participation form, information about the workshops, and other related documents are available from the contact person (see **FOR FURTHER INFORMATION CONTACT**) and on the Internet at *http://www.fda.gov/cder/workshop.htm*.

II. Background Information

A. Why Is FDA Cosponsoring These Workshops?

FDA is cosponsoring these 2-day workshops to provide information and training opportunities for industry as well as CGMP compliance officials.

B. What Will Be Covered?

The workshops will provide information on specific topics designed to educate and guide participants on methodologies and implementation of CGMP as applied to quality drug manufacturing. Presentations by both FDA and industry will provide a regulatory and practical perspective on the current relevant critical topics.

Dated: September 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18556 Filed 9–19–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) 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, call the HRSA Reports Clearance Office on (301) 443–1129.

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

Proposed Project: Children's Hospital Graduate Medical Education (CHGME) Payment

Program Annual Report: NEW

The CHGME Payment Program was enacted by Public Law 106–129 to provide Federal support for graduate medical education (GME) to freestanding children's hospitals, similar to Medicare GME support received by other non-children's hospitals. The legislation mandates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are

designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

The CHGME Payment Program was reauthorized for a period of five years in October 2006 by Public Law 109–307. The reauthorizing legislation requires that children's hospitals participating and receiving funds from the CHGME Payment Program provide information about their residency training programs in an annual report that will be an addendum to the hospitals' annual applications for funds. Specifically, data are required to be collected on: (1) The types of training programs that the hospital provided for residents such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties including both American Board of Pediatrics certified medical subspecialties and non-medical subspecialties approved by other medical certification boards; (2) the number of training positions for residents, the number of such positions recruited to fill, and the number of positions filled; (3) the types of training that the hospital provided for residents related to the health care needs of difference populations such as children who are underserved for reasons of family income or geographic location, including rural and urban areas; (4) changes in residency training the hospital made during an academic year, including changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes and changes for purposed of training residents in the measurement and improvement and the quality and safety of patient care; and (5) the numbers of residents (disaggregated by specialty and subspecialty) who completed training in the academic year and provide care within the borders of the service area of the hospital or within the borders of the State in which the children's hospital is located. For purposes of the annual report data collection, ''residents'' are those who are (1) in full-time equivalent resident training positions in any training program sponsored by the hospital; or (2) in a training program sponsored by an entity other than the hospital who spend more than 75 percent of their time training at the hospital.

The annual report data collection instruments consist of Excel workbooks with several pages (worksheets) each. These data collection instruments for the annual report were pre-tested by nine participating CHGME Payment Program hospitals. Each hospital provided an estimate of the number of hours required to complete each part of the annual report. Following the pre-test, the data collection instruments were significantly reduced by collapsing certain categories, shifting several questions from the individual GME training program level to the hospital level instrument, and by omitting several questions. As a result, the estimated burden to each respondent was significantly reduced.

The estimated annual burden is as follows:

Form name	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Screening Instrument	57	1	57	10.0	570.0
Annual Report, Hospital and Program-Level Information	57	1	57	74.8	4263.6
Total	57		57	84.8	4833.6

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 e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: September 14, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7–18561 Filed 9–19–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Guidance

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Agency Guidance and Response to Public Comments.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing a final Agency Guidance (''Policy Information Notice'' (PIN) 2007–16) to describe and clarify the circumstances under which Federal Tort Claims Act (FTCA)—deemed Health Center Program grantees are covered under the FTCA as they respond to emergencies. The PIN, ''Federal Tort Claims Act Coverage for Health Center Program Grantees Responding to Emergencies,'' and the Agency's ''Response to Public Comments'' are available on the Internet at *http://bphc.hrsa.gov/policy/pin0716.*

DATES: The effective date of this final Agency guidance is August 22, 2007.

BACKGROUND: HRSA administers the Health Center Program, which supports more than 3,800 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve clients that are primarily low-income and minorities, and deliver comprehensive, culturally competent, quality primary health care services to patients regardless of their ability to pay. Charges for health care services are set according to income.

On March 15, 2007, HRSA made the draft PIN, ''Federal Tort Claims Act Coverage for Health Center Program Grantees Responding to Emergencies,'' available for public comment on HRSA's Web site. Comments were due to HRSA by May 31, 2007.

Comments were received from 14 organizations and/or individuals. After review and careful consideration of all comments received, HRSA has amended the PIN to incorporate certain recommendations from the public. The final PIN reflects these changes.

In addition to making the final PIN available on HRSA's Web site, HRSA is also posting the Agency's ''Response to Public Comments.'' The purpose of that document is to summarize the major comments received and describe the Agency's response, including any corresponding changes made to the PIN. Where comments did not result in a