TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Hours	Hours Per Recordkeeper	Total Hours
820.140	8,963	1	8,963	6.34	56,825
820.150(a) and (b)	8,963	1	8,963	5.67	50,820
820.160(a) and (b)	8,963	1	8,963	0.67	6,005
820.170(a) and (b)	8,963	1	8,963	1.50	13,445
820.180(b) and (c)	8,963	1	8,963	1.50	13,445
820.181(a) through (e)	8,963	1	8,963	1.21	10,845
820.184(a) through (f)	8,963	1	8,963	1.41	12,638
820.186	8,963	1	8,963	0.40	3,585
820.198(a) through (c)	8,963	1	8,963	4.94	44,277
820.200(a) and (d)	8,963	1	8,963	2.61	23,393
820.25	8,963	1	8,963	0.67	6,005
Totals					3,072,337

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

Burden (labor) hour and cost estimates were originally developed under FDA contract by Eastern Research Group, Inc. (ERG), in 1996 when the CGMP/QS regulation became final. These figures are still accurate. Additional factors considered in deriving estimates included:

- Establishment Type: Query has been made of CDRH's registration/listing databank and has counted 8,963 domestic firms subject to CGMPs. In addition, hospitals which reuse or remanufacture devices are now considered manufacturers under new FDA guidance. After investigations of many hospitals and the changes in enforcements of FDA's requirements for hospitals, the number of reuse or remanufactures of SUDs have decreased from the estimated 66 to an estimated 18 hospitals. Because the total number of registered firms is not static, the number of respondents will fluctuate from year to year resulting in slight changes to the overall burden. Currently, there are 8,963 firms subject to the CGMPs; an increase from the last renewal of 8,254.
- Potentially Affected Establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to FDA's quality policy regulations (§ 820.20(a)), document control regulations (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to FDA's design controls regulations (§ 820.30). The type of firm subject to each requirement was identified by ERG.

FDA estimates the burden hours (and costs) based on the last approved renewal for this information collection.

FDA estimates that some 650 ''new'' establishments (marketing devices for the first time) will expend some 143,052 ''development'' hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: 40 percent goes to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent goes to requirements dealing with components and acceptance activities; 25 percent goes to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent goes to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: September 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Educational Workshops on Current Good Manufacturing Practices; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of educational workshops on quality pharmaceutical production under current good manufacturing practice (CGMP). The workshops, which will be held in collaboration with the Parenteral Drug Association (PDA), are intended to educate participants on current methods for compliance with good manufacturing practices (GMP). The workshops are being offered to help ensure effective CGMP programs and to further the common goals of FDA and providers of quality pharmaceutical products.

DATES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Erik N. Henrikson, Center for Drug Evaluation and Research (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9190, *erik.henrikson@fda.hhs.gov*, or

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.

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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