DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Quality Workgroup

ACTION: Announcement of meeting.

SUMMARY: This notice announces the fifth meeting of the American Health Information Community Quality Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.).

DATES: January 9, 2007, from 1 p.m. to 5 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090. (You will need a photo ID to enter a Federal building.)

FOR FURTHER INFORMATION CONTACT: *http://www.hhs.gov/healthit/ahic/quality_main.html.*

SUPPLEMENTARY INFORMATION: During the meeting, the Workgroup will continue their discussion on a core set of quality measures and on the specific charge to the Workgroup. The Workgroup members will continue discussion on their work to envision and describe a world in which quality measurement and reporting are automated and clinical decision support is used to improve performance on those quality measures. This shared vision will be used to inform potential recommendations to the AHIC addressing the broad and specific charges to the Workgroup.

The meeting will be available via internet access. For additional information, go to *http://www.hhs.gov/healthit/ahic/quality_instruct.html.*

Dated: December 14, 2006.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 06–9809 Filed 12–20–06; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–07–0612]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System—EXTENSION—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The WISEWOMEN program, which focuses on reducing cardiovascular disease risk factors among at-risk women, was in response to the Secretary of Health and Human Services' Continuous Improvement Initiative, asking for the development of programs that examine ways in which service delivery can be improved for select populations. Title XV of the Public Health Service Act, Section 1509 originally authorized the secretary of the Department of Health and Human Services to establish up to three demonstration projects. Through appropriations language, the CDC WISEWOMAN program is now allowed to fund up to 15 projects. Currently, WISEWOMAN funds 12 demonstration projects, which at full implementation are expected to screen approximately 30,000 women annually for cardiovascular disease risk factors. The program targets women already participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and provides screening for select cardiovascular disease risk factors (including elevated cholesterol, hypertension and abnormal blood glucose levels), lifestyle interventions, and medical referrals as required in an effort to improve cardiovascular health among participants.

The CDC proposes to collect and analyze baseline and follow-up date (12 months post enrollment) for all participants. These data called the minimum data elements (MDE's), includes demographic and risk factor information about women served in each program and information concerning the number and type of intervention sessions attended. The MDE's will be reported to CDC in April and October each year. The MDE allows or an assessment of how effective WISEWOMAN is at reducing the burden of cardiovascular disease risk factors among participants. The CDC also proposes to collect programmatic data for all WISEWOMAN programs. Programmatic data includes information related to grantee management, public education and outreach professional education service delivery, cost, and an assessment of how well each program is meeting their stated objectives.

All required data will be submitted electronically to the contractor hired by CDC to conduct the WISEWOMAN evaluation. MDE and cost data will be submitted to RTI twice a year. All information collected as part of the WISEWOMAN evaluation will be used to assess the costs, effectiveness and cost-effectiveness of WISEWOMAN in reducing cardiovascular disease risk factors, for obtaining more complete health data among vulnerable populations, promoting public education of disease incidence and risk-factors, improving the availability of screening and diagnostic services for under-served women, ensuring the quality of services provided to women and developing strategies for improved interventions. Because certain demographic data are already collected as part of NBCCEDP, the additional burden on grantees will be modest.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 2,160.

ESTIMATED ANNUALIZED BURDEN TABLE

Report	Number of respondents	Responses per respondent	Average burden per response (in hours)
Screening MDE Report	15	2	16
Intervention MDE Report	15	2	8
Cost Report	15	2	16
Quarterly Report	15	4	16

Dated: December 15, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–21809 Filed 12–20–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0348]

Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' The guidance provides a standard format and content for submitting post-approval studies. The guidance is issued to help ensure that sponsors provide adequate information about the conduct of post-approval studies and that the Center for Devices and Radiological Health (CDRH) can properly track and evaluate post-approval studies.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Steven H. Chasin, Center for Devices and Radiological Health (HFZ– 520), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3421.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations to sponsors and CDRH staff on expectations concerning format, content, and review of reports related to post-approval studies imposed by premarket approval application order to help ensure that the studies are conducted effectively and efficiently, and in a least burdensome manner. The guidance has been drafted in response to concerns by Congress, the Institute of Medicine, and FDA about the agency's ability to monitor and track these studies and industry's requests for more clarity about the agency's expectations. FDA received a few comments on the draft document (announced at 70 FR 54561, September 15, 2005) and has made minor changes to the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on post-approval studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Procedures for Handling Post-Approval Studies Imposed by PMA Order,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1561) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA's regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB Control No. 0910–0231; the collections of information in 21 CFR part 822 have been approved under OMB Control No. 0910–0449.

V. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), written or electronic