

causes and risk factors. State surveillance data can be used to: Identify trends in TBI incidence; enable the development of cause-specific prevention strategies focused on populations at greatest risk and monitor the effectiveness of such programs.

This project will develop and sustain injury surveillance programs including those with a focus on TBI and emergency department surveillance for mild TBI. The goal of this program is to produce data of demonstrated quality that will (a) be useful to State injury prevention and control programs, (b)

enable states to produce injury indicators, (c) enable estimates of TBI incidence and public health consequences and (d) facilitate the use of TBI surveillance data to link individuals with information about TBI services.

Program recipients will collect information from pre-existing state data sets to calculate injury indicators in their state. In addition a small group of states will review and abstract medical records to obtain data for variables that address severity of injury, circumstances and etiology of injury,

and early outcome of injury, in a large representative sample of reported cases of TBI-related hospitalization and mild TBI-related emergency department visits. The abstracted data will be stripped of all identifying information before submitting to CDC. States will use standardized data elements. The number of state health departments to be funded for data abstraction may be as high as 12. The only cost to the respondents is the time involved to complete the data abstraction. The estimated total burden hours are 12000.

*Estimated annualized burden table*

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
State Health Departments .....	12	1000	60/60

Dated: February 9, 2006.

**Betsey Dunaway,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-06-06AU]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-4766 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74,

Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Issues Related to the Use of Mass Media in African-American Women: Phase II—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Coordinating Center for Health Promotion (CoCHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Women's health programs, including the National Breast and Cervical Cancer Early Detection Program (NBCCEDP),

offer low-cost or free breast cancer screening to uninsured, low-income women. In 1991, CDC established the NBCCEDP to increase breast and cervical cancer screening among uninsured, underserved, low-income women. To date, over 1.5 million women have received services from NBCCEDP-sponsored programs. Yet NBCCEDP-sponsored programs are estimated to reach only 18% of women 50 years old and older who are eligible for screening services. A research priority for the NBCCEDP is to identify effective strategies to increase enrollment among eligible women who have never received breast or cervical cancer screening. Why women do not participate in this screening is not well understood.

As part of an ongoing study, the purpose of this task is to (1) test consumer response to concepts that arose in the Phase I formative research related to breast cancer screening and (2) test a series of radio health messages aimed at increasing mammography screening among low-income African American women for cultural appropriateness.

There are no costs to respondents except their time to participate in the survey.

*Estimated annualized burden table:*

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hours)
Black women, aged 40-64, GA residents .....	80	1	90/60	120
Total .....	80	.....	.....	120

Dated: February 10, 2006.

**Joan F. Karr,**

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

[FR Doc. E6-2210 Filed 2-15-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 18 and 19, 2006, from 8:30 a.m. to 5 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Mimi T. Phan, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6778, e-mail: PHANM@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On April 18, 2006, the subcommittee will: (1) Receive topic updates for ongoing activities pertaining to the International Conference on Harmonisation (ICH) Q8, Q9, Q10, and future ICH quality topics; and (2) discuss and provide comments on modernized Current Good Manufacturing Practice (CGMP) approaches to process validation that encourage continuous improvement over the product life-cycle. On April 19, 2006, the subcommittee will: (1) Discuss and provide comments on the agency's

new approaches to Chemistry, Manufacturing, and Control (CMC) guidance development, as illustrated by the comparability protocol guidance; (2) discuss and provide comments on the CMC Pilot Program; and (3) receive an update on the Cooperative Research and Development Agreement (CRADA) with Conformia Software, Inc., to obtain information on factors influencing pharmaceutical development. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to the Advisory Committee for Pharmaceutical Science meetings.)

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 11, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on April 18, 2006, and between approximately 11:30 a.m. and 12 noon on April 19, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 11, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Mimi Phan at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9, 2006.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. E6-2237 Filed 2-15-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999N-1852] (formerly 99N-1852)

#### Guidance for Industry on Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." This guidance provides recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing study commitments; and information about postmarketing study commitments that will be available to the public. The guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800.

Submit written comments on the 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>. See