

the District of Columbia. As funding allows, CDC's strategic plan calls for expanding the program to health departments in all U.S. States and territories. CDC works with HDSP program awardees to implement and evaluate evidence-based public health prevention and control strategies that address risk factors and reduce disparities, disease, disability, and death from heart disease and stroke.

The DHDSP MIS provides a standardized, electronic interface for the collection of progress and activity information from HDSP awardees. The information collection includes work

plans, objectives, partners, data sources, and policy and environmental assessments. The MIS produces both State-specific and aggregate reports that are used for performance monitoring, program evaluation, and technical assistance. The monitoring and evaluation plan for HDSP awardees is part of an overall initiative within CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) to promote more efficient ways of using resources and achieving greater health impact.

CDC will continue to use the information collected through the

DHDSP MIS to identify State-specific heart disease and stroke prevention priorities and objectives, and to describe the impact and reach of program interventions. Respondents will be 42 health departments in 41 States and the District of Columbia (DC). Respondents will continue to submit their progress and activity information to CDC semi-annually. There are no costs to respondents other than their time. The total estimated annualized burden hours are 504.

Estimated annualized burden hours

| Respondents  | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--|-----------------------|------------------------------------|--|
| State-Based Heart Disease and Stroke Prevention Programs ..... | 42                    | 2                                  | 6                                      |

Dated: February 22, 2011.

**Carol Walker,**

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

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Maternal Vitamin D Status and Preterm Birth, DP11-002, Initial Review**

*Correction:* The notice was published in the **Federal Register** on December 17, 2010, Volume 75, Number 242, Page 78999. The time and date should read as follows:

*Time and Date:* 11 a.m.-5 p.m., April 12, 2011 (Closed).

*Contact Person for More Information:* Donald Blackman, Ph.D., Scientific Review Officer, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, Georgia 30341, Telephone: (770) 488-3023, E-mail: [DBY7@cdc.gov](mailto:DBY7@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 17, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-D-0074]

**Draft Guidance for Industry on Medication Guides—Distribution Requirements and Inclusion of Medication Guides in Risk Evaluation and Mitigation Strategies; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS).” This draft guidance addresses two topics pertaining to Medication Guides for drug and biological products. First, the draft guidance addresses when FDA intends to exercise enforcement discretion regarding dispensing requirements for Medication Guides that must be distributed with a drug or biological product dispensed to a healthcare professional for

administration to a patient instead of being dispensed directly to the patient for self-administration or to the patient's caregiver for administration to the patient. Second, the draft guidance addresses when a Medication Guide will be required as part of a REMS. The draft guidance is intended to answer questions that have arisen concerning these topics.

**DATES:** Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 31, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug