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.

[FR Doc. 2011–4330 Filed 2–25–11; 8:45 am]

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.*

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.

[FR Doc. 2011–4305 Filed 2–25–11; 8:45 am]

BILLING CODE 4163–18–P

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

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristen E. Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6226, Silver Spring, MD 20993–0002, 301–796–5400; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Medication Guides—Distribution Requirements and Inclusion of Medication Guides in Risk Evaluation and Mitigation Strategies (REMS)." This draft guidance is intended to address two topics pertaining to Medication Guides for drug and biological products.

Medication Guides are primarily for prescription drug and biological products used on an outpatient basis without direct supervision by a healthcare professional. Questions have arisen concerning when a Medication Guide must be distributed with a drug or biological product dispensed to a healthcare professional for administration to a patient in certain situations, for example, in an inpatient setting or an outpatient setting such as a clinic or infusion center. This draft guidance is intended to articulate the circumstances under which FDA intends to exercise enforcement discretion regarding Medication Guide distribution.

The second topic addressed by the draft guidance is when a Medication Guide will be required as part of a REMS. Under section 505–1(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355–1(e)), FDA may require that a REMS for a drug include one or more of the elements described in section 505–1(e), including (when the criteria in part 208 (21 CFR part 208) are met), the requirement for an applicant to develop a Medication Guide for distribution to each patient when the drug is dispensed. Since the enactment of the Food and Drug Administration Amendments Act of 2007, FDA has, as a matter of policy, considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the Agency has the authority to determine, based on the risks of a drug and public health concern, how a Medication Guide should be required when the standard in part 208 is met. Based on the risks and public health concern, the Agency may require:

(1) A Medication Guide in accordance with part 208 that is not a part of a REMS or

(2) A Medication Guide in accordance with part 208 and section 505–1 of the FD&C Act that is part of a REMS, which will include other parts of a REMS (such as the timetable for submission of assessments) and possibly other REMS elements (including elements to assure safe use).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on when FDA intends to exercise enforcement discretion regarding Medication Guide distribution and inclusion of Medication Guides in REMS. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA 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 §§ 314.70 and 600.12 have been approved under OMB control numbers 0910–0001 and 0910–0338; the collections of information in part 208 have been approved under OMB control number 0910–0393.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: February 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4341 Filed 2–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: March 15, 2011.

Time: 11 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Ken D. Nakamura, PhD, Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852. 301–402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: February 18, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–4304 Filed 2–25–11; 8:45 am]

BILLING CODE 4140–01–P