

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 7 and 8, 2011. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before November 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 23, 2011.

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 James Clark at James.Clark@fda.hhs.gov or 301-796-5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: October 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee; 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 Committees: Drug Safety and Risk Management Advisory Committee and Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 1, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus". Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: DSaRM@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about

possible modifications before coming to the meeting.

Agenda: The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) requires FDA to bring, at least annually, one or more drugs with Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) before its Drug Safety and Risk Management Advisory Committee (DSaRM). On December 1, 2011, the DSaRM and the Dermatologic and Ophthalmic Drugs Advisory Committees will meet in joint session to discuss REMS-related topics. During the morning session, the committees will discuss the REMS program for isotretinoin, also known as iPLEDGE, as an example of a REMS that has ETASU. During the afternoon session, the committees will discuss general issues related to the impact of REMS with ETASU on the health care system and patient access, such as how programs with ETASU can be better integrated into existing health systems.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 16, 2011. Oral presentations from the public will be scheduled between approximately 9:40 a.m. and 10:10 a.m. (for comments related to iPLEDGE), and between 2:20 p.m. and 2:50 p.m. (for other REMS-related comments). Those individuals interested in making formal oral presentations should notify the contact person 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 on or before November 7, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may

conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 8, 2011.

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

Dated: October 11, 2011.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-26588 Filed 10-13-11; 8:45 am]

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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, e-mail paperwork@hrsa.gov or 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: Bureau of Health Professions (BHP) Performance Data Collection (OMB No. 0915-0061) — [Revision]

This request is for approval from the Office of Management and Budget (OMB) of revised data collection activities required for collection of data at application, progress and performance reporting for the Health Resources and Services Administration (HRSA), Bureau of Health Professions (BHP).

Over 40 BHP programs award grants to health professions schools and training programs across the United States to develop, expand, and enhance training, and to strengthen the distribution of the health workforce. These programs are governed by the Public Health Service Act (42 U.S.C. 292 *et seq.*), specifically Titles III, VII, and VIII. Performance information is collected in the HRSA Performance Report for Grants and Cooperative Agreements (PRGCA). This report was formerly called the Uniform Progress Report.

The proposed data collection satisfies statutory and programmatic requirements for performance measurement and evaluation (including specific Title III, VII and VIII requirements), as well as Government Performance and Results Act (GPRA)

requirements. The Affordable Care Act (Pub. L. 111-148) impacted a broad range of health workforce programs administered by BHP. It reauthorized most of these programs and, in some cases, expanded eligibility, modified program activities, and/or established new requirements. The Affordable Care Act also created new health professions programs. Therefore, it was necessary to reexamine BHP's existing performance measures to ensure that they address these changes, meet evolving program management needs, and respond to emerging workforce concerns.

The proposed data collection will enhance analysis and reporting of grantee training activities and education, outcomes, and intended practice locations. Data collected from these grant programs will also provide a description of the program activities of more than 2,000 reporting grantees to better inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The proposed measures focus on five key outcomes:

- (1) Increasing the workforce supply of diverse well-educated practitioners;
- (2) influencing the distribution of practitioners to practice in underserved and rural areas;
- (3) enhancing the quality of education;
- (4) diversifying the pipeline for new health professionals; and,
- (5) supporting educational infrastructure to increase the capacity to train more health professionals.

Revisions include improving performance management at three levels of measurement: individual-level, program-specific and program cluster-level. Data collection revisions will also require the collection of some baseline data at the grant application and award stages.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Application	2500	1	2500	9	22,500
Program Aggregate Data Collection	1500	1	1500	10	15,000
Individual-level Data Collection	800	1	800	5	4,000
Total					41,500

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct

all correspondence to the "attention of the desk officer for HRSA."

Dated: October 7, 2011.

Reva Harris,
Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-26591 Filed 10-13-11; 8:45 am]

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