

**Background and Brief Description**

In 2008, the Congressional Committee on Education and Labor released the report, "Hidden Tragedy: Underreporting of Workplace Injuries and Illnesses," indicating "that work-related injuries and illnesses in the United States are chronically and even grossly underreported." Based in part on the report's results, Congress allocated funds for NIOSH to conduct a follow-up study using NIOSH's occupational supplement to the National Electronic Injury Surveillance System (NEISS-Work) to estimate underreporting among individuals who seek care at an emergency department (ED) for an occupational illness, injury, or exposure.

Objectives for this project are to (1) assess the reporting behavior of workers that are injured, ill, or exposed to a

harmful substance at work; (2) characterize the chronic aspects of work-related injuries or illnesses; and (3) estimate the prevalence of work-related chronic injuries and illnesses among United States workers treated in EDs. Particular attention will be paid to self-employed workers, workers with work-related illnesses, and workers with chronic health problems.

Data collection for the telephone interview survey will be done via a questionnaire containing questions about the respondent's injury, illness, or exposure that sent them to the ED; the characteristics of the job they were working when they were injured, became ill, or were exposed; their experiences reporting their injury, illness, or exposure to the ED and their employer (if applicable); the presence of an underlying chronic condition that

was associated with their ED visit; and the nature of any other work-related chronic conditions they have experienced. The questionnaire was designed to take 30 minutes to complete and includes a brief series of questions to screen out individuals who were not seen in the ED for a work-related injury, illness, or exposure; who are younger than age 20 or older than age 64; who do not speak English or Spanish; or who were working as volunteers or day laborers when the injury, illness, or exposure occurred or was made worse.

Approximately 1,500 to 3,000 interviews will be completed over the two year period. The only cost to the respondent will be the cost of their time spent on the phone completing the telephone interview survey. The total estimated burden hours are 750.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
U.S. workers presenting to an emergency department .....	1,500	1	30/60

**Kimberly S. Lane,**

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

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2012-N-0001]

#### **Advisory Committee for Reproductive Health Drugs; 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:** Advisory Committee for Reproductive Health Drugs.

**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 5, 2012, from 8 a.m. to 4:30 p.m.

**Location:** FDA White Oak Campus, Building 31, the Great Room, White Oak

Conference Center (rm. 1503), 10903 New Hampshire Ave., 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 Building 1.

**Contact Person:** Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [ACRHD@fda.hhs.gov](mailto:ACRHD@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 committee will discuss the benefits and risks of mirabegron (YM178), under new drug application (NDA) 202611, submitted by Astellas Pharma Global Development Inc., for the proposed indication of treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. Mirabegron is a beta-3-adrenoceptor (AR) agonist and is a new molecular entity. The benefit/risk discussion will focus on the adequacy of the demonstration of efficacy and safety in the treatment of OAB.

FDA intends to make background material available to the public no later than two 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 March 22, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 March 14, 2012. 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 March 15, 2012.

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 Kalyani Bhatt 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: February 3, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-2927 Filed 2-8-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Eligibility Criteria for the Centers of Excellence Program in Health Professions Education for Under-Represented Minority Individuals

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Final Notice.

**SUMMARY:** The Centers of Excellence (COE) program in health professions education for under-represented minority (URM) individuals is authorized by section 736 of the Public Health Service Act (PHS Act), 42 U.S.C. 293 (2011). The purpose of this final notice is to inform interested individuals of the criteria that will be used to determine the eligibility of designated health professions schools to apply for COE funding in fiscal year (FY) 2012 and subsequent fiscal years. The Supplementary Information in this Notice provides a brief synopsis of the public comments that the Health Resources and Services Administration (HRSA) received on the updates to the proposed eligibility criteria in response to the November 7, 2011 **Federal Register** Notice, specifically addressing: 1) the proposed graduation threshold eligibility criteria, 2) the COE eligibility criteria in general, and 3) the purpose of the COE program as authorized by the PHS Act.

**DATES:** *Effective Date:* February 9, 2012.

**FOR FURTHER INFORMATION CONTACT:** Dr. Joan Weiss, Director, Division of Public Health and Interdisciplinary Education, Bureau of Health Professions, Health Resources and Services Administration. Dr. Weiss may be reached in one of three following methods: 1) via written request to: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9-36, 5600 Fishers Lane Rockville, Maryland 20852; 2) via telephone at (301) 443-6950; or 3) via email at [jweiss@hrsa.gov](mailto:jweiss@hrsa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

For more than 20 years, the COE program has supported programs of excellence in health professions education for under-represented minority (URM) individuals in designated health professions schools. The authorized categories of designated health professions schools are: (1) Designated Historically Black Colleges and Universities (HBCUs), (2) Hispanic, (3) Native American, and (4) "other" health professions schools that meet the program requirements. COEs provide academic enhancement programs to URM individuals; develop a large and competitive applicant pool to pursue health professions careers; and improve the capacity of schools to recruit, train, and retain URM faculty. The COE program facilitates faculty and student research on health issues particularly

affecting URM groups. In addition, the program carries out activities to improve information resources, clinical education, curricula and cultural competence of schools' graduates relating to minority health issues. COEs also train students to provide health services to URM individuals at community-based health facilities and provide financial assistance, as available and appropriate. To be eligible for funding, the PHS Act requires designated schools to meet each of four general conditions. The schools must: (1) Have a significant number of URM individuals enrolled in the school, including individuals accepted for enrollment in the school; (2) have been effective in assisting URM students of the school to complete the program of education and receive the degree involved; (3) have been effective in recruiting URM individuals to enroll in and graduate from the school, including providing scholarships and other financial assistance to such individuals and encouraging URM students from all levels of the educational pipeline to pursue health professions careers; and (4) have made significant recruitment efforts to increase the number of URM individuals serving in faculty or administrative positions at the school (See PHS Act, Section 736(c)(1)(B)(i)–(iv)).

##### 1. Proposed Graduation Threshold Eligibility Criteria

The **Federal Register** Notice (FRN), published November 7, 2011, updated the eligibility criteria and requires eligible health professions schools to demonstrate effectiveness in assisting URM students to successfully complete the program of education and receive the appropriate degree. The eligibility criteria requires applicants to meet or exceed a specified minimum number of URM students graduating with appropriate degrees. Graduation rates are calculated and provided by health professions schools applying for COE funding. To account for varying class sizes across the landscape of health professions schools, the threshold percentage for Hispanic, Native American, and "Other" COEs within the designated health professions will be determined by the total number of URM students graduating from the health professions school with degrees divided by the total number of students graduating with degrees in a given health professions school. The percentage representing the cut-off point for the top quartile (75th percentile) will serve as the minimum percentage that Hispanic, Native American, and "Other" COEs must meet.