DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–0920–11CE]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES) 1999–2010 Birth Certificate Linkage Study—Pregnant Women—New—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States.

Division of Health and Nutrition Examination Surveys (DHANES) proposes to re-contact women who were pregnant at the time of their participation in NHANES in 1999–2010 and ask permission to link their data to the child's birth certificate data, for the birth that resulted after the survey. This study is funded in collaboration with CDC's National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health (DRH). Participation is completely voluntary and confidential.

NHANES was conducted periodically between 1970 and 1994, and continuously since 1999 by the NCHS. A supplemental sample of pregnant women was selected in NHANES from 1999–2006. This resulted in a total of 1,350 pregnant women. Although this supplemental sample was discontinued after 2006, there are an estimated 150 pregnant women in the NHANES sample for the years 2007–10. This results in a total estimate of 1,500 women for this project.

The NHANES only collected information about the pregnant women at the time of interview. Having information on their children's birth certificates and birth outcomes could provide insight into issues related to maternal and child health. No other survey has the physical examination and nutritional data that NHANES collects on pregnant women.

Consents for these projects will be sent to the appropriate U.S. states, local areas, or territories, where the birth certificate retrievals will then be conducted. Electronic retrieval per records is estimated at five minutes.

NHANES data users include the U.S. Congress; the World Health Organization; numerous Federal agencies such as the National Institutes of Health, the Environmental Protection Agency, and the United States Department of Agriculture; private groups such as the American Heart Association; schools of public health; private businesses; individual practitioners; and administrators. This submission requests approval for two years. There is no cost to respondents other than their time. The total estimated annual burden is 312 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
1. Women who were pregnant during NHANES 1999–2010.	Health Questionnaire/Consent Form	750	1	20/60
3. State/local vital statistics staff (one per U.S. State or Territory).	Locate and transmit birth certificates	57	13	5/60

Kimberly S. Lane,

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

[30Day–12–11JZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Underreporting of Occupational Injuries and Illnesses by Workers—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

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,* 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