

information by law enforcement entities.

Please address comments by email to [info@bioethics.gov](mailto:info@bioethics.gov), or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: March 21, 2012.

**Wanda K. Jones,**

*Principal Deputy Secretary for Health,  
Department of Health and Human Services.*

[FR Doc. 2012-7329 Filed 3-26-12; 8:45 am]

**BILLING CODE 4154-06-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Advisory Committee on Minority Health

**AGENCY:** Office of Minority Health, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. The meeting is open to the public. Preregistration is required for both public attendance and comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should email [acmh@osophs.dhhs.gov](mailto:acmh@osophs.dhhs.gov).

**DATES:** The meeting will be held on Thursday, April 26, 2012 from 9 a.m. to 5 p.m. and Friday, April 27, 2012 from 9 a.m. to 1 p.m.

**ADDRESSES:** The meeting will be held at the Doubletree Hotel, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

**FOR FURTHER INFORMATION CONTACT:** Ms. Monica A. Baltimore, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-2882 Fax: 240-453-2883.

**SUPPLEMENTARY INFORMATION:** In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health in improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the Office of Minority Health.

Topics to be discussed during this meeting will include strategies to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities, as well as other related issues.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person at least fourteen (14) business days prior to the meeting. Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to three minutes per speaker. Individuals who would like to submit written statements should mail or fax their comments to the Office of Minority Health at least seven (7) business days prior to the meeting. Any members of the public who wish to have printed material distributed to ACMH committee members should submit their materials to the Executive Director, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business April 19, 2012.

Dated: March 13, 2012.

**Monica A. Baltimore,**

*Executive Director, Advisory Committee on Minority Health, Office of Minority Health, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services.*

[FR Doc. 2012-7330 Filed 3-26-12; 8:45 am]

**BILLING CODE 4150-29-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Decision To Evaluate a Petition To Designate a Class of Employees From the Winchester Engineering and Analytical Center in Winchester, MA, To Be Included in the Special Exposure Cohort

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Winchester Engineering and Analytical Center in Winchester, Massachusetts, to be included in the Special Exposure Cohort under the Energy Employees

Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

*Facility:* Winchester Engineering and Analytical Center.

*Location:* Winchester, Massachusetts.

*Job Titles and/or Job Duties:* All employees of the Department of Energy, its predecessor agencies, and its contractors and subcontractors.

*Period of Employment:* October 1, 1952 to December 31, 1961.

**FOR FURTHER INFORMATION CONTACT:** Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 877-222-7570. Information requests can also be submitted by email to [DCAS@CDC.GOV](mailto:DCAS@CDC.GOV).

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 2012-7292 Filed 3-26-12; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[30-Day-12-12BK]**

### Agency for Toxic Substances and Disease Registry; 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 (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

#### Proposed Project

Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation—New—Agency for Toxic Substances and Disease Registry (ATSDR) and Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The Navajo Nation includes 16 million acres of New Mexico, Utah and Arizona. It is the largest Alaska Native/

American Indian Reservation in the United States. From 1948 to 1986, many uranium mining and milling operations took place in the Navajo Nation, leaving a large amount of uranium contamination on the reservation. Several studies have reported that uranium mostly damages the kidneys and urinary system. However, there is not much research data on uranium exposure and poor birth and reproductive health outcomes. Research involving prenatal exposure to uranium may help to understand and prevent some unfavorable child and maternal health outcomes.

There are important health differences concerning birth outcomes and prenatal care in the Navajo Nation. According to the Indian Health Service *Regional Differences in Indian Health 2002–2003 Edition*, the infant death rate among the Navajo people is 8.5 deaths per 1000 live births, compared to 6.9 deaths per 1000 live births among all races. Only 61% of Navajo mothers with live births received prenatal care in the first trimester as compared to 83% of all US mothers. Early and regular prenatal care is a major predictor of positive birth outcomes. Due to the health differences in birth outcomes and the chance for environmental uranium exposure in the Navajo Nation, ATSDR decided that the upcoming study must include education of women and their families about the importance of prenatal care and the potential poor health risks associated with exposure to uranium.

The House Committee on Oversight and Government Reform requested that federal agencies develop a plan to address health and environmental impacts of uranium contamination in the Navajo Nation. As a result of this request, ATSDR awarded a research cooperative agreement to University of New Mexico Community Environmental Health Program (UNM–CEHP) entitled “A Prospective Birth Cohort Study

Involving Environmental Uranium Exposure in the Navajo Nation (U01),” in August 2010. ATSDR and UNM–CEHP are working with the Navajo Area Indian Health Service (NAIHS), Navajo Nation Division of Health (NNDH), Navajo Nation Environmental Protection Agency (NNEPA), and Navajo culture and language specialists to carry out the study. The study will examine reproductive outcomes in pregnant women, follow and assess their children from birth to 1 year of age, and create a system to follow up the infants through childhood up to 6 years of age to evaluate the impact of uranium exposure on biological and psychosocial endpoints. Biological sample analysis, surveys, and developmental screenings will be performed during this research period for each participant.

In addition to investigating the role of uranium and other chemicals in the environment on birth outcomes and development, the prospective study may aid in understanding causes and prevention measures of chronic conditions. Several research studies have shown that exposure to chemicals in the environment during prenatal and postnatal periods can affect the development of adult chronic diseases. The study will also provide broad public health benefits for Navajo communities through outreach and education on environmental prenatal risks and early assessment. Referrals will also be provided for known developmental delays.

Participants will include Native American mothers from age 14 to 45 with verification of pregnancy who have lived in the study area for at least 5 years. Also, participants must consent to receive prenatal care and deliver at one of the healthcare facilities that are taking part in the study (Northern Navajo Medical Center, Chinle Comprehensive Health Care Facility, Gallup Indian Medical Center, Tuba

City Regional Health-Care Corporation, or Tséhootsooí Medical Center). Fathers will be included in the study with consent regardless of age or residence. We estimate that 550 pregnant women and fathers per year must be enrolled in the study to obtain adequate statistical power. A 10% pregnancy loss will be assumed, which would result in 500 live births per year. Therefore, the total anticipated sample size is 1,500 mother-infant pairs over the three years of the study.

The data collection instruments for pregnant mothers include the following: Enrollment Survey, Ages and Stages Questionnaire (ASQ–I), Mullen Stages of Early Development (MSEL), Postpartum Surveys (12 month Postpartum survey includes Nutritional Assessment/Food Intake Questionnaire) and Eligibility Form. An enrollment survey for fathers who agree to participate will also be administered. Community Health and Environmental Research Specialists (CHERS) will administer surveys using a CDC-approved electronic data entry system. Survey instruments were designed to collect demographic information, assess potential environmental health risks, and mother-child interactions. The survey instruments were developed based on previous surveys conducted by Dine’ Network for Environmental Health (DiNEH) Project, the National Children’s Study, and by other birth cohort studies that have been conducted among other indigenous populations. The final format of the survey instruments was modified based on review and input from the Navajo Nation community liaison group and associated Navajo staff to address issues such as cultural sensitivity, comprehension and language translation.

There is no cost to the respondents other than their time to participate in the study. The total estimated annual burden hours are 3596.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden response (hours)
Mother .....	Enrollment Survey .....	550	1	120/60
	Ages and Stages Questionnaire (2,6,9,12 months) .....	500	4	15/60
	Mullen Stages of Early Development .....	500	1	15/60
	Postpartum Survey (0 months) .....	500	1	60/60
	Post-partum Survey (2,6,9 months) .....	500	3	15/60
	Postpartum Survey (12 months) .....	500	1	15/60
	Eligibility Form .....	550	1	5/60
	Enrollment Survey .....	550	1	90/60
Father .....				

Dated: March 20, 2012.

**Ron A. Otten,**

*Director, Office of Scientific Integrity, Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2012-7351 Filed 3-26-12; 8:45 am]

**BILLING CODE 4163-18-P**

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

### **Food and Drug Administration**

[Docket No. FDA-2012-N-0273]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Graphic Cigarette Warning Labels**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Experimental Study of Graphic Cigarette Warning Labels that is being conducted in support of the graphic label provision of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

**DATES:** Submit either electronic or written comments on the collection of information by May 29, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleman, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleman@fda.hhs.gov](mailto:Daniel.Gittleman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal

Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### **Experimental Study of Graphic Cigarette Warning Labels—(OMB Control Number 0910-0668)—Extension**

Tobacco products are responsible for more than 400,000 deaths each year. The Centers for Disease Control and Prevention report that approximately 46 million adults smoke cigarettes in the United States, even though this behavior will result in death or disability for half of all regular users. Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total \$193 billion annually in medical expenditures and lost productivity. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time. One way to do this is through health warnings that describe and graphically depict the harm caused by cigarette use causing individuals to think harder about the choice to use tobacco.

On June 22, 2009, the President signed the Tobacco Control Act (Public

Law 111-31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act, which amends section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), requires FDA to issue "regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)." FDA conducts research relating to tobacco products under its statutory authority in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)), as amended by the Tobacco Control Act, to conduct research "relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out the act." The study proposed here is an effort by FDA to collect data concerning graphic warnings on cigarette packages and their impact on consumer perceptions, attitudes, and behavior with respect to smoking.

On June 22, 2011, FDA issued a final rule in the **Federal Register** of June 22, 2011 (76 FR 36628) entitled "Required Warnings for Cigarette Packages and Advertisements," which specified nine graphic images to accompany the new textual warnings for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a federal district court has permanently enjoined FDA from implementing the rule in its current form. FDA has appealed this decision to the U.S. Court of Appeals of the District of Columbia. FDA expects that the information that FDA proposes to collect will be relevant to FDA's regulation of cigarette warnings no matter the outcome of the current litigation.

The study, the Experimental Study of Graphic Cigarette Warning Labels, is a voluntary annual experimental survey of consumers. The purpose of the study is to assess the effectiveness of various graphic warnings on cigarette packs for achieving three communication goals: (1) Conveying information about various health risks of smoking, (2) encouraging cessation of smoking among current smokers, and (3) discouraging initiation of smoking among youth and former smokers. The study will collect data from various groups of consumers, including current smokers aged 13 years and older, former smokers aged 13 years and older, and non-smokers aged between 13 and 25 years who may be susceptible to initiation of smoking. The