

2. Thrift Savings Plan activity report by the Executive Director.
- a. Monthly Participant Activity Report.
- b. Legislative Report.
- c. Investment Performance Review.
3. Securities Lending Activity.
4. 2008 Participant Survey.
5. Internal Controls Update.
6. Vendor Financials Follow-up.
7. 2009 FRTIB Meeting Calendar.

Parts Closed to the Public

8. Security.

CONTACT PERSON FOR MORE INFORMATION:
Thomas J. Trabucco, Director, Office of External Affairs, (202) 942-1640.

Dated: November 7, 2008.

Thomas K. Emswiler,

Secretary, Federal Retirement Thrift Investment Board.

[FR Doc. E8-27020 Filed 11-12-08; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-08-07AA]

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 Maryam I. Daneshvar, the CDC Reports Clearance Officer, at (404) 639-5960 or send an e-mail 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

Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 U.S.C. 241, section 301, which authorizes “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.” (2) 42 U.S.C. 247b-4, section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106-310, also known as “the Children’s Health Act of 2000.” This portion of the code has also been amended by Public Law 108-154, which is also known as the “Birth Defects and Developmental Disabilities Prevention Act of 2003”.

The use of a number of medications during pregnancy is known to be associated with serious adverse effects in children. However, because pregnant and lactating women are traditionally excluded from clinical trials, and because premarketing animal studies do not necessarily predict the experience of humans, little information is available about the safety of most prescription medications during pregnancy and lactation at the time they are marketed. Nevertheless, many women inadvertently use medications early in gestation before realizing they are pregnant, and many maternal conditions require treatment during pregnancy and breastfeeding to safeguard the health of both mother and infant. Currently, the United States does not have a comprehensive early warning system for major adverse pregnancy or infant outcomes related to medication exposures.

Teratology Information Services (TIS) utilize trained specialists to provide free phone consultation, risk assessment, and counseling about exposures during pregnancy and breastfeeding—including medications—to women and healthcare providers. Altogether, they respond to approximately 70,000–100,000 inquiries each year in the United States and Canada. Because they have direct contact with pregnant and breastfeeding women, TIS are in a unique position to monitor the adverse effects of medication exposures during pregnancy and lactation. The objective of this

project is to conduct a pilot study to assess whether TIS in the United States can serve as an effective monitoring and early warning system for major adverse effects on (1) pregnancy outcomes (e.g., live birth, stillbirth, premature birth, low birth weight, etc.) and (2) maternal and infant health. The project will assess the willingness of pregnant and breastfeeding women who contact a TIS about medication exposure to participate in and complete a follow-up study; whether these women are similar in demographic characteristics to the U.S. population of child-bearing age women; the specificity and completeness of the information obtained from such a study about adverse pregnancy outcomes, and maternal and infant health; and the amount of time required to conduct the follow-up.

Within a continuous six-month period, three individual TIS will recruit all women who contact their service (up to a maximum of 250 enrollees per TIS) who have used any prescription or over-the-counter medication, vitamin, herbal, or other dietary supplement during pregnancy or while breastfeeding to participate in a follow-up study. Informed consent to participate will be obtained from each woman by telephone. For each pregnant woman who agrees to participate, the TIS will then conduct 4 telephone interviews: (1) At enrollment; (2) during the third trimester of pregnancy; (3) approximately one month after delivery; and (4) when the infant is about 3 months old. For each breastfeeding woman who agrees to participate, the TIS will then conduct 3 telephone interviews: (1) At enrollment; (2) approximately one month after enrollment; and (3) 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, and maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time. The total estimated annualized burden is 516 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)
All Respondents	Telephone script for permission to seek consent (C1a or C1b).	294	1	3/60
Screened Eligible Respondents—	Tracking Form (C1c)	250	1	5/60
Pregnancy Exposure (group 1)	Consent (C2a or C2b)	250	1	20/60
Lactation Exposure (group 2)
Pregnancy and Lactation Exposure (group 3).
Groups 1, 2 and 3	Enrollment (D1)	250	1	10/60
Group 1 and 3	Initial pregnancy Questionnaire (D2)	200	1	30/60
	Follow-up pregnancy questionnaire (D3)	200	1	20/60
	Initial infant questionnaire (D4)	200	1	20/60
	Follow-up infant questionnaire (D5)	200	1	15/60
Groups 2 and 3	Initial breastfeeding questionnaire (D6) ...	100	1	20/60
	Follow-up breastfeeding questionnaire (D7).	100	1.5	15/60

Dated: November 6, 2008.

Maryam I. Daneshvar,

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

[FR Doc. E8-27084 Filed 11-13-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Time and Date: 8:30 a.m.–3:30 p.m., December 4, 2008.

Place: Marriott Crystal City at Reagan National, 1999 Jefferson Davis Highway, Arlington, VA 22202.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people. Teleconference available toll-free; please dial (866) 700-6634, Participant Pass Code 3756066.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors shall provide guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and

evaluating hypotheses, systematically documenting findings and disseminating results. The Board shall evaluate the degree to which the activities of the National Institute for Occupational Safety and Health:

(1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters To Be Discussed: Agenda items include a Report by the Acting Director of NIOSH; National Academies (NA) Recommendations for NIOSH Programs; Implementation of NA Recommendations in Agriculture, Forestry and Fishing; Occupational Safety and Health Surveillance Needs; NIOSH Nanotechnology Research Strategic Plan; National Occupational Research Agenda; Future Meetings and Closing Remarks.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Roger Rosa, Executive Secretary, BSC, NIOSH, CDC, 395 E Street, SW., Suite 9200, Patriots Plaza Building, Washington, DC 20201, telephone (202) 245-0655, fax (202) 245-0664.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 6, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-74, CMS-R-107, CMS-2786U, CMS-R-285 and CMS-R-245]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Income and Eligibility Verification System; *Use:* This collection is necessary to verify income and eligibility requirements for Medicaid beneficiaries, as required by Section 1137 of the Social Security Act. *Form Number:* CMS-R-74 (OMB#