Superbowls (football) and World Series (baseball); the political conventions of both major US political parties; and the Presidential Inauguration (2009).

Today, EARS is a highly successful and sustainable system and has over 200 users at the Federal, State, local, and international levels. These users include international Ministries of Health and domestic state and local public health departments. Additionally, EARS detection methods have been integrated in well-known surveillance platforms such as BioSense at CDC, ESSENSE at Johns Hopkins, NAMRD at US Department of Defense, and Emergint at Northrop Grumman.

EARS is widely-accepted and easily sustainable due to its being free to all end users, the capacity to use multiple forms of data, flexibility and user-driven design and maintenance. EARS is a service provided by CDC as share-ware and is available by download at no cost from the CDC Web site *http://www.bt.cdc.gov/surveillance/EARS.*

In an effort to continue to improve and enhance EARS, the collection of registration information is needed to track users and organizations to assist in future needs assessments. Requiring the users to register will provide CDC with contact information (*i.e.,* e-mail addresses) to use for broadcast e-mails regarding new releases for upgrades and enhancements; track the number of users, the download frequency, and the type of data that users will monitor with EARS; and solicit users for feedback for future upgrades and enhancements. CDC estimates that there will be 150 respondents registered for EARS. Each respondent will need an average of 10 minutes to complete the EARS registration form which leads to a total public burden of 25 hours.

There is no cost to respondents to participate in this program.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Users	150	1	10/60	25

Dated: April 21, 2010.

Maryam I. Daneshvar,

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

[FR Doc. 2010–10586 Filed 5–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–0741]

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) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Study to Explore Early Development (SEED) (OMB No. 0920–0741 exp. 6/30/2010)—Revision—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 Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, correlates, and causes of autism and related disabilities. Under the provisions of this act, CDC funded five Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) including the California Department of Health and Human Services, Colorado Department of Public Health and Environment, Johns Hopkins University, the University of Pennsylvania, and the University of North Carolina at Chapel Hill. CDC National Center on Birth Defects and Developmental Disabilities participates as the sixth CADDRE site. The SEED multi-site, collaborative project is an epidemiological investigation of possible causes for the autism spectrum disorders.

Study participants are to be selected from children born in and residing in the following six areas: Atlanta metropolitan area, San Francisco Bay area, Denver metropolitan area, Baltimore metropolitan area, Philadelphia metropolitan area, and Central North Carolina. Children with autism spectrum disorders are compared to children with other developmental problems, referred to as the neurodevelopmentally impaired group (NIC), as well as children who do not have developmental problems, referred to as the sub-cohort.

Data collection methods consist of the following: (1) Medical record review of the child participant; (2) medical record review of the biological mother of the child participant; (3) packets sent to the participants with self-administered questionnaires and a buccal swab kit; (4) a telephone interview focusing on pregnancy-related events and early life history (biological mother and/or primary caregiver interview); (5) a child development evaluation (more comprehensive for case participants than for the control group participants); (6) parent-child development interview (for case participants only) administered over the telephone or in-person; (7) a physical exam of the child participant; (8) biological sampling of the child participant (blood and hair); and, (9)

biological sampling of the biological parents of the child participant (blood only). Minor changes to some of the self administered questionnaires and the telephone interview include clarification of instructions to the respondent and clarifying specific questions to make the instruments easier to complete and further improve data quality. The only study design change that is being proposed is to expand the eligible study participant birth date range from September 1, 2003–August 31, 2005 to September 1, 2003–August 31, 2006.

There is no cost to respondents other than their time. The total estimated annualized burden is 4,948 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
Parent	Response Card	2,458	1	10/60
Parent	Invitation packet	1,008	1	30/60
Parent	Questionnaire packet	347	1	3.5
Parent	Caregiver Interview packet	402	1	1.5
Parent	Follow-up telephone call packet	347	3	20/60
Parent and Child	Biosample packet	1,041	1	40/60
Parent and Child	Blood Draw	966	1	15/60
Child	Clinic Visit—control children packet	214	1	1
Parent	Clinic Visit—control parent	80	1	45/60
Parent	Control parent consent form	214	1	10/60
Child	Clinic Visit—Case children packet	107	1	1.5
Parent	Clinic Visit—Case parent packet	107	1	3.5
Parent	Medical Record Abstraction	347	5	3/60

Maryam I. Daneshvar,

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

[FR Doc. 2010–10585 Filed 5–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0483]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device User Fee Cover Sheet—Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Device User Fee Cover Sheet—Form FDA 3601" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2010 (75 FR 2866), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0511. The approval expires on February 28, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: April 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10579 Filed 5–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0486]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry, Food and Drug Administration, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2010 (75 FR 2874), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0508. The approval expires on February 28, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: April 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10581 Filed 5–4–10; 8:45 am]

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