Dated: August 30, 2007.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E7–17617 Filed 9–5–07; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Rocky Flats Plant, Golden, Colorado, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On August 6, 2007, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Employees of the Department of Energy (DOE), its predecessor agencies, or DOE contractors or subcontractors who were monitored or should have been monitored for neutron exposures while working at the Rocky Flats Plant in Golden, Colorado, for a number of work days aggregating at least 250 work days from January 1, 1959, through December 31, 1966, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on September 5, 2007, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

Dated: August 30, 2007.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E7–17618 Filed 9–5–07; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health

Determination Concerning a Petition to Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a determination concerning a petition to add a class of employees at the Rocky Flats Plant, Golden, Colorado, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384q. On August 6, 2007, the Secretary of HHS determined that the following employees do not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

Department of Energy employees or its contractor or subcontractor employees at the Rocky Flats plant in Golden, Colorado, who were exposed to radiation dose from 1967 through 2005 and who were exposed to any radiation dose other than neutron dose from 1952 through 1966.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

Dated: August 30, 2007.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E7–17620 Filed 9–5–07; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Medicaid Program: Notice of Single Source Grant Award to the State of Louisiana for the Grant Entitled ''Deficit Reduction Act—Hurricane Katrina Healthcare Related Primary Care Access Stabilization Grant''

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

Funding Amount: $100,000,000.

Period of Performance: July 23, 2007 through September 30, 2010.

CFDA: 93.776.

Authority: Section 6201(a)(4) of the Deficit Reduction Act of 2005 (DRA).

Purpose: This grant program has been made available to the State of Louisiana to restore and expand access to primary care, including primary mental health care, in the Greater New Orleans area. This area is facing inadequate primary care access as a result of Hurricane Katrina and its subsequent floods causing a unique negative impact on the low income and uninsured populations of Greater New Orleans. Funding under this grant program must be used by the State of Louisiana to assist it to make payments for purposes of addressing primary health care access issues in Greater New Orleans' ''impacted communities'', defined for purposes of this grant, to be those four parishes located in the State of Louisiana's Region 1, as defined by the Louisiana Department of Health and Hospitals, namely, Orleans, Jefferson, St. Bernard, and Plaquemines. This grant includes $4,000,000 for the City of New Orleans Health Department to help restore its ability to meet its primary care mission in new and emerging neighborhoods being repopulated.

The grant funds must be used only for funding eligible primary care clinics that: Provide at least one or more of the core primary care services with its own practitioners in an outpatient setting; formally commit to provide care to all individuals, regardless of ability to pay; are either a public or not-for-profit (NFP) entity that is sustainable; and demonstrate commitment to practice in the Greater New Orleans area for the long term. Because of the urgent need to get funds out as timely as possible under less than ideal local circumstances, the State of Louisiana has selected a locally based partner (that was able to meet certain criteria) to oversee and monitor local conditions,

and run the grant day-to-day. Administrative expenses will be capped at .5 percent for the State and 5 percent for the local partner.

The State of Louisiana, in consultation with its local partner, has flexibility subject to approval by the Centers for Medicare & Medicaid Services (CMS) in determining the funding allocation methodology to grantee clinics/subawardees, as long as it includes a standardization of ''units of care'' across all grantee clinics, and includes a base award and supplementary payments that meet the intent of the grant.

This award was made based on the authority granted by section 6201 of the Deficit Reduction Act (DRA). In particular, section 6201(a)(4) of the DRA provides authority to the Secretary, Department of Health and Human Services (DHHS), to make payments to States to restore access to health care in communities impacted by Hurricane Katrina.

Under the authority of section 6201(a)(4) of the DRA of 2005, the Secretary has invoked his authority to restore health care in impacted communities affected by Hurricane Katrina by offering this unique funding opportunity to stabilize primary health care access to the Greater New Orleans area, which is facing inadequate primary care access as a result of Hurricane Katrina and its subsequent floods.

Louisiana is the only State with the knowledge and ability to administer a grant designed to affect impacted Louisiana communities. For this reason, the Secretary has directed CMS to offer a single-source award to the State of Louisiana to help strengthen and increase primary care access to the Greater New Orleans area and by helping to increase the supply of health care providers negatively impacted as a result of this hurricane.

FOR FURTHER INFORMATION CONTACT: Wendy J. Taparanskas, Ph.D., Health Insurance Specialist, Finance, Systems, and Budget Group, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Mail Stop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244, (410) 786–5245.

Authority: Section 6201(a)(4) of the Deficit Reduction Act of 2005 (DRA).

Dated: August 30, 2007.

Herb B. Kuhn,

Acting Deputy Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–17560 Filed 9–5–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0218]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Pilot Program for Medical Products (Formally Medical Device Adverse Event Reporting Program)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 9, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0471. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1427.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Adverse Event Pilot Program for Medical Products—21 U.S.C. 360(i) (OMB Control Number 0910–0471)—Extension

Under section 519 of the Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(i)), FDA is authorized to require: Manufacturers to report medical device related deaths, serious injuries, and malfunctions; and user facilities to report device-related deaths directly to manufacturers and FDA, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA), amended section 519(b) of the act (21 U.S.C. 360 i(b)) relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a ''. . . subset of user facilities that constitutes a representative profile of user reports'' for device related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act. The current universal reporting system remains in place during the pilot stages of the new program, and until FDA implements the new national system by regulation. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is continuing to conduct a pilot of the MedSun system before the agency issues a regulation to change from universal mandatory reporting for medical device user facilities to reporting by a representative sample of facilities. This data collection has been ongoing since February 20, 2002, and this notice is for continuation of this data collection.

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on the 3500A Form related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and to pilot a few additional questions which will permit FDA to better understand the cause of the reported adverse event. During the pilot program, participants will be asked to complete an annual outcome measures form to aid FDA in evaluating the effectiveness of the program. Participation in this pilot is voluntary and currently includes 400 facilities and over 100 beds. The use of an interactive electronic data collection system is easier and more efficient for the participating user facilities to use than the alternative paper system. The paper form takes approximately 1 hour to complete and the electronic version takes approximately 45 minutes or less to complete. Much of the data which must be filled in by hand on the paper system is automatically filled in by the electronic version.

In addition to collecting data on the electronic adverse event report form, MedSun also collects data electronically in the Device-Safety Exchange (DS-X).