new facilities; (2) develops project management requirements (including determination of methods, means of project completion, and selection of resources); (3) provides critical path method scheduling support for all large capital construction projects and all repair and improvements (R&I) projects; and (4) provides central cost estimating support for all large capital construction projects, all R&I projects, special projects, feasibility studies, as requested, and certain work orders, as requested.

Design Engineering Management Office (CAJCC). (1) Prepares architectural and engineering designs, and specifications for construction of modifications and renovations to CDC-owned facilities; (2) provides architectural and engineering technical expertise and is the technical authority on new facilities, and modifications and renovations on facility project designs; (3) provides furniture, fixture, and equipment designs, and project management services for all CDC facilities; (4) provides record and guideline document support services to all BFO offices; and (5) maintains CDC Design Standards and Guidelines for use as basis of design for construction of new facilities, and modifications and renovations in CDC-owned facilities.

Facilities Maintenance & Engineering Office (CAJCD). (1) Operates, maintains, repairs, and modifies CDC's Atlanta area plant facilities and other designated CDC facilities throughout the United States (US) and Puerto Rico (PR), and conducts a maintenance and repair program for CDC's program support equipment; (2) develops services for new, improved, and modified equipment to meet program needs; (3) provides technical assistance, reviews maintenance and operation programs, and recommends appropriate action for all Atlanta area facilities and other designated CDC facilities throughout the US and PR; (4) provides recommendations, priorities, and services for new, improved, or modified equipment to meet program needs; (5) provides maintenance and operation of the central energy plant including structures, utilities production and distribution systems, and equipment; (6) conducts a program of custodial services, waste disposal, incinerations, disposal of biological waste, and other building services at all CDC Atlanta area facilities and other designated CDC facilities throughout the US and PR; (7) provides landscape development, repair, and maintenance at all CDC Atlanta area facilities and other designated CDC facilities throughout the US and PR; (8) provides hauling and moving services for CDC in the Atlanta area; (9) provides an Integrated Pest Management Program to control insect and rodents for CDC in Atlanta area facilities; (10) develops required contractual services and provides supervision for work performed in these areas; (11) establishes and maintains a computerized system for maintenance services, for stocking and ordering supplies, and replacement parts; (12) provides for pick-up and delivery of supplies and replacement parts; to work sites; (13) maintains adequate stock levels of supplies and replacement parts; (14) as needed, prepares designs and contract specifications, and coordinates completion of contract maintenance projects; (15) manages CDC's Energy Conservation Program for all CDC facilities; (16) reviews all construction documents for energy conservation goals and compliance with applicable CDC construction standards; (17) participates on all core teams and VE teams; (18) provides maintenance and inspection for fire extinguishers and fire sprinkler systems; (19) provides services for the procurement of natural gas; (20) develops and maintains a standard equipment list for all CDC facilities; (21) assists the Design Engineering Management Office and the Capital Improvements Management Office with facility-related issues; (22) provides building coordinators to interface with program personnel and all work to keep the building and equipment functioning; and (23) responsible for new building commissioning.

Real Property Management Office (CAJCE). (1) Conducts the real estate activities throughout CDC, including the acquisition of leased space, the purchase and disposal of real property for CDC nationwide (with emphasis on current and long-range planning for utilization of existing and future real property resources); (2) responsible for space assignment and utilization of all CDC space, both owned and leased, nationwide; (3) provides technical assistance in space planning to meet programmatic needs; (4) responsible for executing all easements for owned property; (5) administers day-to-day management of leased facilities and ensures contract compliance by lessors; (6) provides technical assistance and prepares contract specifications for all repair and improvement projects in leased space; (7) maintains liaison with the General Services Administration Regional Offices; (8) performs all functions relating to leasing and/or acquisition of real property under CDC delegation of authority for leasing, including direct lease actions; and (9) coordinates the relocation of CDC personnel within owned and leased space.

Dated: November 28, 2005.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 05–23689 Filed 12–6–05; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0535]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; MedWatch: Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''MedWatch: Food and Drug Administration Medical Products Reporting Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 27, 2004 (69 FR 77256), 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 0910–0291.

As requested by the agency, in addition to the approval of the revised forms, the existing forms are approved for continued use for the next 12 months to allow for the industry to make necessary changes to their computerized systems.

The approval expires on October 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23676 Filed 12–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of public workshop on FDA clinical trial statutory and regulatory requirements. This workshop was announced in the **Federal Register** of September 21, 2005 (70 FR 55405). The amendment is made to reflect a change in the *Location* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas TX 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *oraswrsbr@ora.fda.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2005 (70 FR 55405), FDA announced that a public workshop entitled ''Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements'' would be held on Wednesday, February 8, 2006. On page 55405, in the first column, the *Location* portion of the document is amended to read as follows:

Location: The public workshop will be held at the Renaissance Houston Hotel Greenway Plaza, 6 Greenway Plaza East, Houston, TX 77046, 713–629–1200, FAX: 713–629–4702.

Dated: November 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23675 Filed 12–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Risk Management, Corrective and Preventive Actions, and Training: An Educational Forum; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Region, Dallas District Office, in collaboration with the FDA Medical Device Industry Coalition (FMDIC) is announcing a public workshop entitled ''Risk Management, Corrective and Preventive Actions, and Training: An Educational Forum.'' This public workshop is intended to provide information about FDA's medical device quality systems regulation (QSR) to regulated industry, particularly small businesses.

Date and Time: The public workshop will be held on April 28, 2006, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at The Westin City Center, 650 North Pearl St., Dallas, TX 75201. Directions to the facility are available at the FMDIC Web site at *http://www.fmdic.org/*.

Contact Person: David Arvelo or Cassandra Davis, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952 or 214–253–4951, FAX: 214–253–4970, e-mail *oraswrsbr@ora.fda.gov*.

Registration: FMDIC has a $150 early registration fee. Early registration begins on February 1, 2006, and ends April 14, 2006. Registration is $175 from April 15, 2006, to April 28, 2006. To register online, please visit *http://www.fmdic.org/*. As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and e-mail, along with a check or money order for the appropriate amount payable to the FMDIC, to Dr. William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843–3120. Course space will be filled in order of receipt of registration with appropriate fees. Seats are limited; please submit registration form as soon as possible. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site will be done on a space-available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $175 payable to the FMDIC. The registration fee will be used to offset expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

If you need special accommodations due to a disability, please contact David Arvelo or Cassandra Davis at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. FMDIC and FDA present this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are, in part, to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the medical device QSR. The following topics will be discussed at the workshop: (1) Overview of the International Organization for Standardization (ISO) standard EN 14971, and residual risk, (2) incorporating risk management throughout the product lifecycle, (3) overview of a closed-loop corrective and preventive action (CAPA) system, (4) CAPA effectiveness, (5) overview of a training program, and (6) training program effectiveness.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.