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.