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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique (QSIT); Public Workshops; Addendum

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an additional workshop in the series of FDA/Industry Exchange Workshops that were conducted in 1999. The original list of workshops was published in the **Federal Register** of September 10, 1999. Topics for discussion include: Development of Quality Systems Inspection Technique (QSIT), Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventive Action, Design Controls, and Industry Perspective QSIT. This additional workshop will enhance the medical device community's understanding of QSIT, and the device industry's establishment of effective quality systems, thereby preventing regulatory problems during inspections.

Date and Time: The meeting will be held on Wednesday, March 29, 2000, 8:30 a.m. to 4:30 p.m.

Location: The meeting will be held at Carlsbad: Four Seasons Resort—Aviara, 7100 Four Seasons Point, Carlsbad, CA 92009, 760-603-6800.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with \$140 to the registrar by Monday, March 20, 2000. Fees cover refreshments, organization and site cost, and materials. Space is limited, therefore interested parties are encouraged to register early. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please inform the registrar at least 7 days in

NM-1

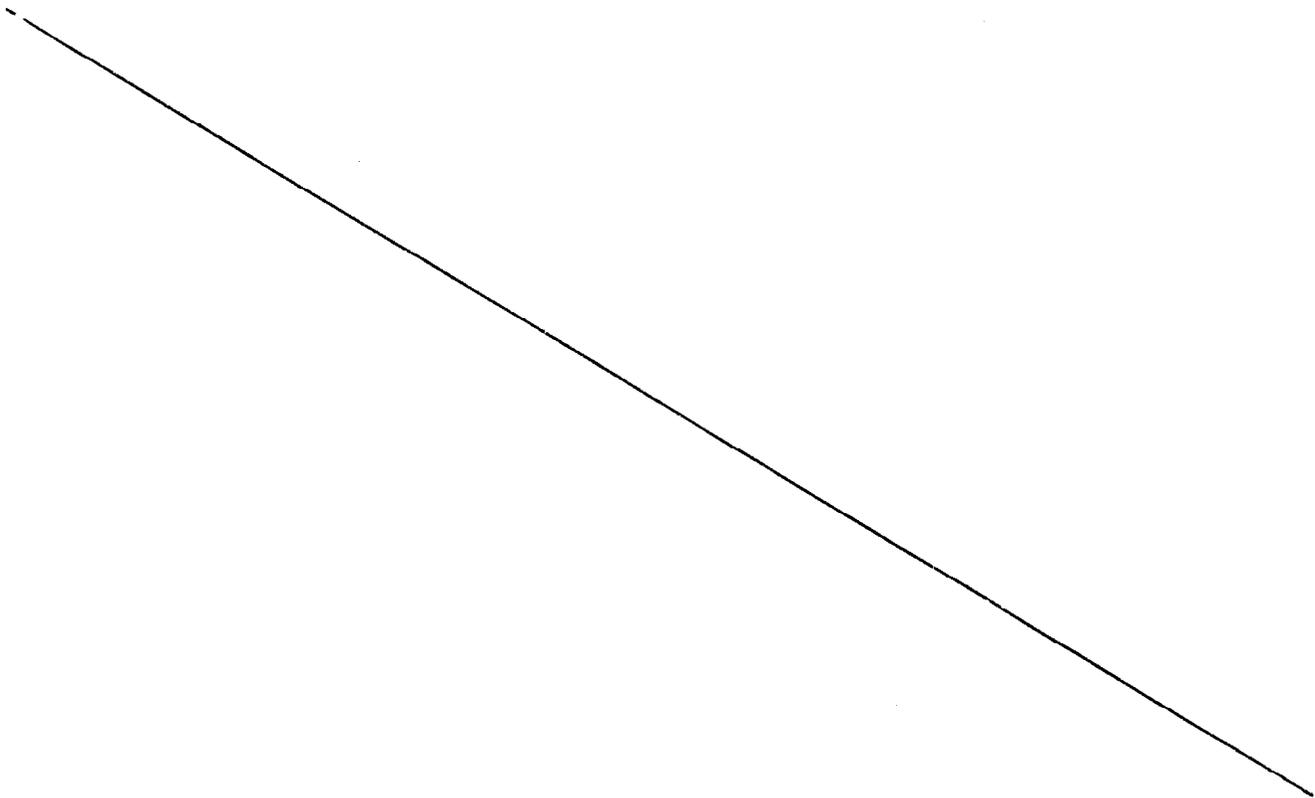
advance of the workshop. A sample registration form is provided at <http://www.fda.gov/cdrh/meetings/qsitmeetca.html>.

Contact: Marcia Madrigal, FDA, Pacific Region (HFR PA-150), 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217, 510-637-3980.

Registrar and cosponsor: Joyce W. Williams, San Diego Regulatory Affairs Network (SDRAN), c/o Arena Pharmaceuticals, Inc., 6166 Nancy Ridge Dr., San Diego, CA 92121, 858-453-7200, ext. 227, FAX 858-453-7210, e-mail: jwilliams@arenapharm.com.

SUPPLEMENTARY INFORMATION: In the fall of 1999, FDA field offices began using the QSIT nationwide as the tool for medical device inspections. QSIT was developed using a collaborative effort with stakeholders and tested in the three districts. The original list of workshops was published in the **Federal Register** of September 10, 1999 (64 FR 49192).

This additional workshop further implements the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) through working more closely with stakeholders and ensuring access to needed scientific and technical expertise.



It also implements a Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) goal of providing outreach activities by Government agencies directed to small businesses.

Dated: March 6, 2000



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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