Mr. Marcus' request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 99N–2674 and sent to the Dockets Management Branch (address above). Mr. Marcus must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 306 of the act and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Dated: September 30, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–26938 Filed 10–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), is announcing an additional workshop in the series of FDA/Industry Exchange Workshops being conducted. The original list of workshops was published in the September 10, 1999 **Federal Register**. Topics for discussion include: Development of QSIT, Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventive Action, Design Controls, and Industry Perspective of 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, Time, and Location: The workshop will be held on November 30 from 8:30 a.m. to 4:30 p.m. local time in Englewood, CO at the location in the chart below.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with the correct payment amount to the Registrar. Fees cover refreshments, organization and site costs, and materials. Space is limited, therefore interested parties are encouraged to register early. Please arrive early to ensure prompt registration. If you need special accomodations due to a disability, please inform the Registrar at least 7 days in advance of the workshop. A sample registration form is provided at the end of this document.

Contact Person: Herman B. Janiger, U.S. Food and Drug Administration, Northeast Region, (HFRNE–17), 850 Third Ave., Brooklyn, New York 11232, 718–340–7000 ext. 5528.

SUPPLEMENTARY INFORMATION:

In the fall of 1999, FDA field offices will begin using the QSIT natiowide as the primary tool for medical device inspections. QSIT was developed using a collaborative effort with stakeholders and tested in the three districts. The additional workshop is scheduled as follows:

TABLE 1

Workshop Address	Date and Local Time	Deadline to Register and Fee	Registrar and Cosponsor	FDA Contact Person
ENGLEWOOD: Hilton Hotel, Denver Tech Center South, 7801 Orchard Rd., Englewood, CO 303–779–6161.	Tuesday, November 30, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, November 16, 1999, $170.00	Denise Rooney, Association of Food and Drug Officials, P.O. Box 3425, York PA 17402, 717–757–2888, FAX 717–755–8089	Brenda C. Baumert, Small Business Representative, Southwest Regional Office, 214–655–810, ext. 133.

The above 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 complies with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that requires outreach activities by Government agencies directed to small businesses. This notice announcing the workshops and a registration form may also be accessed at the CDRH website at http://www.fda.gov/cdrh/fedregin.html. The following information is requested for registration:

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REGISTRATION FORM

Quality System Inspection Technique (QSIT)

Regional Medical Device Workshop

Instructions: To register, complete this form and mail with registration fee to the Registrar for the workshop you wish to attend.

Date, _____

Location, _____

Fee enclosed, _____

Name, _____

Title, _____

Company, _____

Address, _____

Telephone, _____

Fax, _____

E-mail _____

Dated: October 6, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–26804 Filed 10–14–99; 8:45 am]

BILLING CODE 4160–01–C