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Dated: March 6, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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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 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. 00–5835 Filed 3–9–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0892]

Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''PET Drug Applications —Content and Format for NDA's and ANDA's.'' The draft guidance is intended to assist manufacturers of certain positron emission tomography (PET) drugs in submitting new drug applications (NDA's) or abbreviated new drug applications (ANDA's) in accordance with a notice entitled ''Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications'' published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the draft guidance and the collection of information provisions by June 8, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http:/www.fda.gov/cder/guidance/index.htm and at http:/www.fda.gov/cder/regulatory/pet. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.