ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC) is announcing a public workshop entitled ''Quality Systems Educational Forum: Production and Process Controls.'' This public workshop is intended to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

Date and Time: The public workshop will be held on April 23, 2004, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Crowne Plaza Dallas Market Center Hotel, 7050 I–35 Stemmons Freeway, Dallas, TX 75247. Directions to the facility are available at the FMDIC Web site at *http://www.fmdic.org.*[1]

Contact Person: David Arvelo or Sue Thomason, 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 and ends March 26, 2004. Registration is $175 from March 27 to April 9, 2004. 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.

[1]FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

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

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.

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, 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 outreach activities 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) The production and process control subsystem of the QSR, (2) FDA 483 trends and applicable regulations, (3) the business friendly approach, (4) software validation, (5) process validation, (6) product acceptance including techniques and purchasing controls, and (7) device history records.

Dated: February 26, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4785 Filed 3–3–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Drug Abuse, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDA.

Date: May 12, 2004.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Intramural Research Program, National Institute on Drug Abuse, NIH, Johns Hopkins Bayview Campus, Bldg. C, 2nd Floor Auditorium, Baltimore, MD 21224.

Contact Person: Stephen J. Heishman, PhD, Research Psychologist, Clinical Pharmacology Branch, Intramural Research Program, National Institute on Drug Abuse, National Institutes of Health, DHHS, 5500 Nathan Shock Drive, Baltimore, MD 21224, (410) 550–1547.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: February 26, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–4795 Filed 3–3–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as