

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Medical Devices 101: 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 (ORA), Southwest Regional Office (SWRO), in cosponsorship with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Medical Devices 101: An Educational Forum." This public workshop, presented previously on February 9, 2007, is intended to provide an overview on FDA's medical device requirements to entrepreneurs, startup companies, and small businesses.

Date and Time: The public workshop will be held on October 26, 2007, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA SWRO, 4040 North Central Expressway, 9th floor conference room, Dallas, TX.

Contact Person: 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@fda.hhs.gov.

Registration: FMDIC has a \$75 early registration fee. The early registration fee for government officials is \$50 and for students is \$25 with positive identification. Early registration ends October 12, 2007. After October 12, 2007, registration is \$100 for the public at large, \$75 for government officials, and \$50 for students with positive identification. To register online, please visit

<http://www.fmdic.org/>. As an alternative, you may mail your registration information including name, title, organization or company name, physical address, telephone and fax numbers, and e-mail address, along with a check or money order for the appropriate amount payable to the FMDIC, to William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843-3120. The available space will be filled in order of receipt of registration with appropriate fees. Seats are very limited; please submit registration as soon as possible. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site may be available based on space availability on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$99 payable to FMDIC. The registration fee will be used to offset expenses associated with this event including lunch, refreshments, and course materials.

If you require special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 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. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at an estimated cost of 10 cents per page.

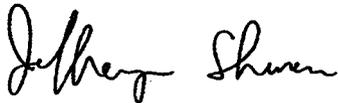
SUPPLEMENTARY INFORMATION: The workshop, previously presented on February 9, 2007 (72 FR 968, January 9, 2007), is being held in response to the interest in the topics discussed from small medical device entrepreneurs and startup manufacturers in the Dallas District area. FDA presents this workshop in cosponsorship with FMDIC 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 Quality System Regulation. The following topics will be broadly covered at the workshop: (1) Medical device classification; (2) establishment registration; (3) device listing; (4) premarket notification; (5) premarket approval; (6) quality system regulation; (7) labeling; (8) recalls, removals, and

corrections; (9) medical device reporting; (10) tracking; and (11) postmarket surveillance.

Dated: 8/15/07
August 15, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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