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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Essentials of Food and Drug Administration Medical Device

Regulations: A Primer for Manufacturers and Suppliers; Public Seminar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public seminar.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health and Office of Regulatory Affairs, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a series of three seminars on FDA medical device regulations. These 2-day seminars, which are designed to address the training needs of startup and small device manufacturers and their suppliers, will include both industry and FDA perspectives and a question and answer period.

Dates: The seminars are planned for the following dates:

1. April 8 and 9, 2008, in Rosemont, IL 60018. Details about dates are posted on AdvaMed's Web site at: www.Advamedmtli.org/Chicago.¹

2. May 13 and 14, 2008, Bethesda, MD 20852. Details about dates are posted on AdvaMed's Web site at www.Advamedmtli.org/Bethesda.

3. June 17 and 18, 2008, Queens, NY. Details about dates are posted on AdvaMed's Web site at: www.Advamedmtli.org/New York.

Locations: The seminars are planned for the following locations:

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

1. April 8 and 9, 2008, Westin O'Hare, 6100 North River Rd., Rosemont, IL 60018. Details about location sites are posted on AdvaMed's Web site at: www.Advamedmtli.org/Chicago.

2. May 13 and 14, 2008, Marriott Bethesda North Conference Center, White Flint Auditorium, 5101 Marinelli Rd., North Bethesda, MD 20852. Details about location sites are posted on AdvaMed's Web site at: www.advamedmtli.org/Bethesda.

3. June 17 and 18, 2008, Crowne Plaza New York-LaGuardia, 104-04- Ditmars Blvd., East Elmhurst, NY 11369. Details about location sites are posted on AdvaMed's Web site at: www.advamedmtli.org/NewYork.

Contact: For FDA: William Sutton, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, 800-638-2041, ext. 125, FAX: 240-276-3151, e-mail: William.sutton@fda.hhs.gov.

For AdvaMed: Veronica Allen, 202-434-7231, FAX: 202-783-8750, e-mail: VAllen@AdvaMed.org.

Registration: The registration fee for a limited number of FDA employees is waived. Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$525 per person to AdvaMed, contact Veronica Allen, 202-434-7231, FAX: 202-783-8750. Payment forms accepted are major credit card (MasterCard, Visa, or American Express) or company check. If you wish to pay by check, contact Veronica Allen at VAllen@Advamed.org.

To register via the Internet, go to www.AdvaMed.org. The latest information on dates/venue sites will be posted on this Web site at: www.advamedmtli.org/Chicago, www.admedmtli.org/Bethesda, and

www.advamedmtli.org/NewYork (FDA has verified the Web site addresses, but is not responsible for changes to the Web sites after this document publishes in the **Federal Register**).

For more information on the meeting, or for questions on registration, contact Veronica Allen (see *Contact*).

Attendees are responsible for their own accommodations. For further hotel information and driving directions, go to the registration Web site.

The registration fee will be used to offset the expenses of hosting the conference, including meals (breakfast and a lunch), refreshments, meeting rooms, and training materials. It also includes a networking reception on the evening of the first day of each seminar.

Space is limited; therefore, interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Veronica Allen (see *Contact*) at AdvaMed as soon as possible.

SUPPLEMENTARY INFORMATION: The “Essentials of FDA Medical Device Regulations: A Primer for Manufacturers and Suppliers” seminar helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health by educating new entrepreneurs on the essentials of FDA device regulations. FDA has made education of the medical device community a high priority to assure the quality of products reaching the marketplace and to increase the rate of voluntary industry compliance with regulations.

The seminar helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders

and ensuring access to needed scientific and technical expertise. The seminar also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed at small businesses.

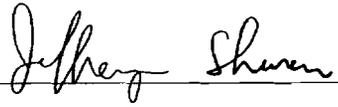
The following topics, as well as others, will be discussed at the seminar:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- Overview of the quality system regulation;
- Design controls;
- Documents, records, and change control;
- Purchasing controls and acceptance activities;
- Production and process control;
- Corrective and preventive actions;
- Complaints, medical device reports, corrections, and recalls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—Where do you go for assistance?
- General question and answer session;
- Manufacturers and suppliers—the chain regulatory responsibility;
- Reimbursement of medical technology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

MAR 27 2008

Dated: _____

March 27, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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