

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**The Essentials of Food and Drug Administration Device Regulations: A
Primer for Manufacturers and Suppliers; Public Workshop**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Philadelphia District, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a public workshop on FDA device regulations. This 1 1/2-day public workshop for start up and small device manufacturers and their suppliers will include both industry and FDA perspectives and a question and answer period.

Date and Time: The public workshop will be held on Tuesday, October 11, 2005, from 8:30 a.m. to 5:30 p.m. and Wednesday, October 12, 2005, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at The Wyndham Philadelphia at Franklin Plaza, 17th and Race St., Philadelphia, PA 19103, 215-448-2000. For further hotel information and driving directions, go to <http://www.wyndham.com/hotels/PHLFP>. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact:

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For AdvaMed: Krystine McGrath, 202-434-7237, FAX: 202-783-8750, *kmcgrath@advamed.org*; or Dia Black, 202-434-7231, FAX: 202-783-8750, e-mail: *dblack@advamed.org*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of \$350 per person to the AdvaMed contacts (see *Contact*). The registration fee for FDA employees is waived. To register via the Internet go to *http://www.advamed.org/philadelphia*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Payment forms accepted are major credit card (MasterCard, Visa, or American Express) or company check. If you wish to pay by check contact Krystine McGrath (see *Contact*). For more information on the meeting, or for questions on registration, contact Krystine McGrath or Dia Black (see *Contact*). Attendees are responsible for their own accommodations.

The registration fee will be used to offset the expenses of hosting the workshop, including meals (breakfasts and a lunch), refreshments, meeting rooms, and training materials. It also includes a networking reception on Tuesday, October 11, 2005. 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 Judy Summers-Gates at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The “Essentials of FDA Device Regulations: A Primer for Manufacturers and Suppliers” workshop 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 workshop 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 workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- The quality system regulations and inspections;
- Complaints, medical device reporting, 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 of regulatory responsibility;

- Reimbursement and medical rechnology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

Dated: SEP 30 2005

September 30, 2005.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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