

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Registration and Listing Grassroots Meeting for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Registration and Listing Grassroots Meeting for Medical Device Manufacturers. The topic to be discussed is FDA's intention to propose changes to the current medical device registration and listing process. This meeting is being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes manufacturers to register their establishments and list their devices, while ultimately reducing FDA's cost of maintaining the registration and listing system.

DATES: The meeting will be held on July 15, 1999, 8:30 a.m. to 12 m.; registration will begin at 8 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn Minneapolis West (Calhoun Ballroom), 9970 Wayzata Blvd., St. Louis Park, MN, 612-593-1918, FAX 612-593-0150.

FOR FURTHER INFORMATION CONTACT: Bryan H. Benesch, Office of Health and Industry Programs (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597 ext. 131, e-mail "BHB@CDRH.FDA.GOV".

For registration information: Rhonda L. Mecl, Supervisory Investigator, Minneapolis District Office, Food and Drug Administration, 240 Hennepin Ave., Minneapolis, MN 55401-1912, FAX 612-334-4134.

Those persons interested in attending the meeting should fax their registration including name, title, firm name, address, telephone, and fax number. There is no charge to attend this meeting, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Rhonda L. Mecl at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Over the past one and a half years, FDA has reviewed the entire registration and listing process to determine if the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of suggestions aimed at improving the registration and listing process for both FDA and industry. This meeting will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes. FDA has held three meetings on the same subject on April 20 and 21, 1999, in California (64 FR 12813, March 15, 1999) and on May 25, 1999, in Rockville, MD (64 FR 20006, April 23, 1999).

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the World Wide Web (WEB).

What are the advantages and disadvantages to industry and how would industry be affected if WEB submissions were mandated?

(2) Require that owners and parent companies register and list and take responsibility for the registration and listing of their establishments. What is the highest level in a company that should be responsible for registration and listing and how should this level be defined/described?

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), premarket approval, or product development protocol process.

(4) Because of the ease of submission through the WEB, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of the meeting will be available on CDRH's Registration and Listing Process Reengineering Team website approximately 20 working days after the meeting. The CDRH Registration and Listing Process Reengineering Team home page may be accessed at "<http://www.fda.gov/cdrh/grassroots/reglist.htm>".

Dated: June 13, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 99D-1878]

"Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (dated June 1999) entitled "Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)." The draft guidance is intended to provide recommendations for donor screening and supplemental testing for antibody to HCV, and notification of consignees and recipients of prior collections from a donor who later tests repeatedly reactive for antibody to HCV (including single antigen and multiantigen screening tests), notification of consignees and recipients of blood and blood components at increased risk for transmitting HCV. The draft guidance, when final, is intended to supersede the September 1998 guidance entitled "Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV."

DATES: Written comments on the draft guidance may be submitted at any time, however, comments should be submitted by August 23, 1999, to ensure their adequate consideration in preparation of the final document. Submit written comments on the