

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Workshop on Preclinical Testing for Endovascular Grafts**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

This notice announces the forthcoming workshop on preclinical testing for endovascular grafts, sponsored by the Food and Drug Administration (FDA). The meeting will be open to the public.

Date and Time: The meeting will be held on July 31, 2001, 9 a.m. to 6 p.m., and August 1, 2001, 9 a.m. to 5 p.m.

Location: Gaithersburg Holiday Inn, Walker-Whetstone Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: The workshop organizers are Megan Moynahan, 301-443-8517, ext. 171, mbm@cdrh.fda.gov, and Dorothy Abel, 301-443-8262, ext. 165, dba@cdrh.fda.gov, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

Agenda: The workshop will concern endovascular grafts used in the treatment of abdominal aortic aneurysms. The goal of the workshop is to find ways to improve how these grafts are tested. Participants of the workshop will first be asked to describe the environment to which these grafts are exposed. Then they will identify the failure modes of the grafts and examine how the devices have been tested to date. Finally, the participants will be asked to suggest ways to modify the testing of these devices by taking into consideration the graft environment.

Workshop participation is by invitation only and is therefore limited. However, the public may observe as audience members. Background information for the workshop will be available to the public on the Internet at <http://www.fda.gov/cdrh/meetings/073101workshop.html>.

Procedure: Members of the public who are interested in attending as audience members should contact the workshop organizers by July 13, 2001.

If you need special accommodations due to a disability, please contact either one of the contact persons listed above at least 7 days in advance.

Dated: June 25, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 99D-0239]

Medical Devices; Guidance on Resolving Scientific Disputes Concerning the Regulation of Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices." The guidance describes the role and operation of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee (the Dispute Resolution Panel), the types of controversies eligible for review by the Dispute Resolution Panel, and recommendations for submitting a request for review.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Les S. Weinstein, Center for Devices and Radiological Health (HFZ-5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-6220, ext. 119.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 404 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (section 562 of the Food, Drug, and Cosmetic Act (the act)

(21 U.S.C. 360bbb-1)) requires FDA to establish procedures for the review of scientific controversies where there is not already an existing right of review. Although FDA believes existing procedures, such as internal agency review of decisions under § 10.75 (21 CFR 10.75), provide for an appropriate review of most, if not all, disputes, the Center for Devices and Radiological Health (CDRH) is developing new procedures to ensure effective and timely review of scientific disputes. In fact, CDRH has recently taken significant steps to achieve this objective, including the appointment of its first CDRH Ombudsman and the establishment of an advisory Dispute Resolution Panel. CDRH is now announcing a final guidance document on the use of this new Dispute Resolution Panel to facilitate the fair and rapid resolution of scientific disputes.

This guidance supersedes the April 27, 1999 (64 FR 22617), draft guidance document entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel."

The Dispute Resolution Panel, chartered on August 18, 1999, has five standing members (including a nonvoting industry representative and a nonvoting consumer representative), and three additional temporary voting members appointed for each particular dispute. Standing members will have broad, crosscutting scientific, clinical, analytical, or mediation skills. Temporary members will be chosen based on their experience, expertise, or analytical skills relevant to the review of each particular dispute. FDA published a notice in the **Federal Register** of November 10, 1999 (64 FR 61352), requesting nominations for the Dispute Resolution Panel members. The five standing members have since been appointed, and the first meeting of the Dispute Resolution Panel, an open public session, was held on October 31, 2000; the Dispute Resolution Panel members heard presentations from FDA and the device industry on the role of this panel in dispute resolution.

A. Response to Comments on the Draft Guidance

Three comments were submitted concerning the April 27, 1999, draft guidance, two from medical device industry associations—Health Industry Manufacturers Association (now AdvaMed) and the Medical Device Manufacturers Association, and one from a device firm. CDRH's response to the significant comments follows: