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.

[FR Doc. 01–16471 Filed 6–29–01; 8:45 am]

BILLING CODE 4160–01–S

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:

Why a guidance document and not a regulation?

Two comments stated that FDA should issue a regulation instead of a guidance document to establish procedures to resolve scientific disputes.

FDA believes that it is not required to issue a regulation concerning the Dispute Resolution Panel procedures. The relevant section of FDAMA required a regulation only in those cases where no other statutory provision or a codified regulation provided a right of review of the matter in controversy. At the time of FDAMA's enactment, FDA already had a wide range of dispute resolution mechanisms in place, including § 10.75, ''Internal agency review of decisions.'' That regulation permits any interested person to obtain review of any FDA decision. To implement the dispute resolution section of FDAMA, FDA amended § 10.75 to make it clear that a scientific controversy may be brought before an advisory panel or committee in appropriate circumstances. The agency concluded that a new regulation was not required. However, each center prepared guidance setting forth procedures tailored to meet the needs of persons affected by the different processes used by each center. CDRH published a general guidance on dispute resolution within the center, ''Medical Device Appeals and Complaints'' (February, 1998), chartered and staffed the Dispute Resolution Panel in 2000, and is issuing this guidance to facilitate use of that Panel. Furthermore, FDA believes it is important to develop experience under the final guidance before considering whether it might be useful, even though not required, to issue a regulation at some point in the future. The guidance permits both CDRH and industry greater flexibility in resolving a particular controversy than a regulation would.

B. Independence of the Process

One comment argued that the Dispute Resolution Panel should have final authority to reverse FDA decisions rather than just make recommendations to the CDRH Director. Another comment believed a Dispute Resolution Panel recommendation to the CDRH Director should stand unless the decision would be unlawful or pose a significant threat to public health.

The legislative history indicates that the purpose of section 562 of the act is ''to assure that the regulated industry receives a fair and impartial hearing and that the FDA *receives sound recommendations and advice*'' (H. Rept. 105–310 at 373 (October 7, 1997)) (emphasis added). Congress intends and expects any panel that reviews disputes will provide ''recommendations and advice,'' and that FDA must retain the final decisionmaking responsibility. The Dispute Resolution Panel will provide an important independent source of additional analysis and additional views that FDA will then use in making a final decision.

Two comments focused on the independence of the process related to the role of CDRH officials in deciding whether a request for Dispute Resolution Panel review would be granted or denied.

FDA is responding to these comments by strengthening the independence of the CDRH Ombudsman in that process. The Ombudsman will have authority to grant requests for Dispute Resolution Panel reviews, in consultation with the panel chair, without obtaining the approval of the Center Director, a Deputy Center Director, or anyone else in CDRH, although he would not be precluded from discussing the request with them to get background information about the dispute that would be helpful in making the decision to grant or deny review. However, if the Ombudsman wishes to deny a request for Dispute Resolution Panel review, the Ombudsman will consult with, and obtain the concurrence of, the appropriate Deputy Center Director.

C. Thresholds for Review of Scientific Disputes

Two comments objected to statements in the draft guidance to the effect that a request for Dispute Resolution Panel review must primarily concern a scientific controversy regarding an FDA ''decision or action.'' The comments prefer an approach that would permit disagreements to be brought to the Dispute Resolution Panel ''early'' in the product review process, such as disagreements about the reasonableness of FDA data requirements, before there was an actual decision or action by the agency.

FDA agrees that there may be some early disputes that would be appropriate for, and could benefit from, a review by the Dispute Resolution Panel and has revised the guidance to include such examples.

D. Timeliness of the Process

Several comments were concerned that the process described in the draft guidance will not ensure timely review of disputes.

FDA has revised the guidance to streamline the process and tighten some of the timeframes for processing and reviewing disputes. In most cases, CDRH expects matters accepted for Dispute Resolution Panel review to receive a final decision within 90 to 120 days of receipt of the request. Practical and administrative constraints preclude developing a timeframe shorter than this.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the Dispute Resolution Panel procedures for resolving scientific disputes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000.) This guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

As the agency gains experience with the Dispute Resolution Panel process, this guidance document may be revised from time to time.

III. Electronic Access

In order to receive ''Resolving Scientific Disputes Concerning The Regulation Of Medical Devices'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1121) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Paperwork Reduction Act of 1995

The information collection provisions contained in this guidance have been approved by the Office of Management and Budget (OMB) under OMB control number 0910–0467.

V. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 15, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16472 Filed 6–29–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4653–N–09]

Notice of Proposed Information Collection for Public Comment: Notice of Funding Availability and Application Kit and Reporting Forms for the Hispanic-Servicing Institutions Work Study Program (HIS–WSP)

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The soliciting public comments on the subject proposal.

DATES: *Comments Due Date*: August 31, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB Control Number and be sent to: Reports Liaison Officer, Office of Policy Development and Research, U.S. Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships—telephone (202) 708–1537. This is not a toll-free number. Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Ms. Karabil.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction act of 995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected entities concerning the proposed information collection to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of information to be collected; and (4) minimize the burden of collection of information on those who are to respond; including through the use of appropriate technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: Notice of Funding Availability and Application Kit and Reporting Forms for the Hispanic-Serving Institutions Work Study Program (HSI–WSP).

Description of the need for the information and proposed use: The information is being collected to select grantees in this statutorily-created competitive grant program (if it is ever funded again by the Congress). More importantly, the information is being used to monitor the performance of grantees to ensure that they meet statutory and program goals and requirements.

Members of the affected public: Certain Hispanic-serving institutions of higher education: 40 applicants and 30 grantees.

Estimation of the total number of hours needed to prepare the information collection including the number of respondents, frequency of response, and hours of response: Information pursuant to submitting applications will be submitted once. Information pursuant to grantee monitoring requirements will be submitted once a year.

The following chart details the respondent burden on an annual basis:

	Number of respondents	Total annual responses	Hours per response	Total hours
Application	40	40	40	1,600
Annual Reports	30	30	6	180
Final Reports	30	15	8	120
Recordkeeping	30	15	5	75
Total				2,050