

Radiological Health (HFZ-017), 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 105, at least 7 days in advance of the meeting.

Dated: August 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-21207 Filed 8-19-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 9, 2002, from 10:30 a.m. to 5 p.m., and September 10, 2002, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, ext. 143, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 9, 2002, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an endovascular graft placed percutaneously to treat infrarenal abdominal aortic aneurysms as an alternative to surgery. On September 10, 2002, the committee will discuss, make recommendations, and vote on a supplement to a PMA for a double disk occluder indicated for closure of patent foramen ovale in patients at risk for recurrent cryptogenic stroke or transient ischemic attack. Background

information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the September 9, 2002, session will be posted on September 6, 2002; material for the September 10, 2002, session will be posted on September 9, 2002.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 30, 2002. On both days, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of each topic and for approximately 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 30, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 12, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Affairs.

[FR Doc. 02-21210 Filed 8-19-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonprescription Drugs Advisory Committee with members from the following committees: Anesthetic and Life Support Drugs Advisory Committee, Arthritis Advisory Committee, Cardiovascular and Renal Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee, and Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19 and 20, 2002, from 8 a.m. to 5 p.m.

Location: Hilton, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Sandra Titus or LaNise Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 19, 2002, the committee will discuss safety issues related to the use of acetaminophen. The primary area for discussion will focus on potential hepatotoxicity related to the use of acetaminophen in both over-the-counter (OTC) and prescription (RX) products. On September 20, 2002, the committee will discuss safety issues related to the use of aspirin and other OTC nonsteroidal anti-inflammatory drugs (NSAIDs). The primary areas for discussion will focus on potential gastrointestinal bleeding and renal insufficiency related to the use of these products.

In rulemaking, the agency has proposed aspirin and acetaminophen as category I ingredients for safety and effectiveness. Other NSAIDs and combination products are marketed under new drug applications. The agency continues to believe that these ingredients are safe and effective in the prescription and OTC products currently on the market when properly used. The advisory committee will discuss whether labeling or other