

Name of Committee: National Mammography Quality Assurance 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 July 12, 1999, 9 a.m. to 6 p.m.

Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss problematic issues encountered during the early phases of implementation of the final regulations and continue the discussion of the proposed Mammography Quality Standards Act (MQSA) compliance guidance. This guidance is being updated continually in response to questions that FDA receives from the public. The committee will also receive updates on the issues of States as Certifying Bodies under MQSA and Voluntary Stereotactic Accreditation Programs. The draft MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at "<http://www.fda.gov/cdrh/dmgrp/guidance.html>". Additional information regarding guidance updates may be obtained by calling the Information Line.

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 June 14, 1999. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 14, 1999, 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.

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

Dated: May 28, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99-14406 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Arthritis 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 and the Arthritis Advisory Committee.

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

Date and Time: The meeting will be held July 20, 1999, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sandra L. Titus or Kathleen R. Reedy, 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 July 20, 1999, the committees will jointly consider an over-the-counter, new drug application (NDA) 21-070, Flexeril® (cyclobenzaprine HCl, 5 milligrams tablets, three times a day, Merck and Co.), proposed to treat muscle spasms.

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 July 12, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 20, 1999. Time allotted for each presentation may be limited. Those desiring to make formal

oral presentations should notify the contact person before July 12, 1999, 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.

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

Dated: May 28, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 99-14402 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1273]

Medical Devices; Draft Guidance for FDA Staff on Civil Money Penalty Policy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for FDA Staff on Civil Money Penalty Policy." The civil money penalty (CMP) policy is intended for use by all FDA Regional and District Directors for the purpose of advising their field personnel when considering potential CMP recommendations under the Safe Medical Devices Act of 1990 (SMDA).

DATES: Written comments concerning this draft guidance must be received by September 7, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for FDA Staff on Civil Money Penalty Policy" 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 adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Written comments concerning this guidance must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be