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/dmqrp/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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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

identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea P. Latish, Center for Devices and Radiological Health (HFZ–330), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4611.

SUPPLEMENTARY INFORMATION:

I. Background

The SMDA amended section 303(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 333(f)) to authorize FDA to impose CMP actions for all violations of the act involving medical devices except for current good manufacturing practice (CGMP) and medical device report violations that do not constitute a significant or knowing departure from such requirements or a risk to public health, filth violations in devices that are not otherwise defective, and minor violations for tracking and reports of corrections and removals. Thus, FDA has considerable latitude when applying CMP to violations involving devices.

FDA has developed a package of three documents that set forth the agency's policy concerning the application of civil money penalties for violations of the act involving medical devices. The three draft guidance documents are: ''Application of the Safe Medical Devices Act Civil Money Penalty Policy,'' ''Safe Medical Devices Act Civil Money Penalty Fee Matrix,'' and ''Safe Medical Devices Act Civil Money Penalty Decision Tree.''

The ''Application of the Safe Medical Devices Act Civil Money Penalty Policy'' outlines the use of the CMP for CGMP and premarket notification (510(k)) violations for chronic and repeat violators, and for less significant violations. It also discusses the relationship between CMP and seizure or injunction. The ''Safe Medical Devices Act Civil Money Penalty Decision Tree'' outlines whether the evidence and information collected justifies pursuing a CMP case. It is not an all-inclusive list of every issue that should be considered, but rather a series of questions to guide FDA's decision. The ''Safe Medical Devices Act Civil Money Penalty Fee Matrix'' is a procedure for calculating the penalty amount that will be assessed. The schedule set forth in the matrix covers the statutory factors that FDA is required to evaluate under the SMDA in determining the appropriateness of the case. The matrix will help to ensure consistency in the assessment of a CMP.

FDA is making these three draft guidance documents available to all FDA Regional and District Directors for the purposes of advising field personnel. FDA is announcing the availability of these documents to the public in order to advise persons who may be affected by FDA's policy and to obtain comment on whether the policy should be revised.

This guidance package of three documents takes into consideration the Presidential Memorandum, dated April 21, 1995, and the Small Business Regulatory Enforcement Fairness Act of 1996, both of which allow monies spent on corrective actions to be deducted from the fine imposed. CMP action, therefore, can provide noncompliant firms with a financial incentive to come into compliance.

The final CMP rule governing the procedures to be used in CMP matters was published in the **Federal Register** of July 27, 1995 (60 FR 38612), and is codified at 21 CFR part 17.

This draft guidance represents the agency's current thinking on the use of CMP recommendations made under the SMDA. 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, regulations, or both. This draft guidance is issued as a Level 1 draft guidance consistent with good guidance practices.

II. Electronic Access

In order to receive ''Guidance for FDA Staff on Civil Money Penalty Policy'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1124) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. 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''. ''Guidance for FDA Staff on Civil Money Penalty Policy'' will be available at ''http://www.fda.gov/cdrh/oc''.

III. Comments

Interested persons may, on or before September 7, 1999, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 1999.

Linda S. Kahan.

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

[FR Doc. 99–14405 Filed 6–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, June 14, 1999, 7:00 PM to June 16, 1999, 5:00 PM, Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852 which was published in the **Federal Register** on May 20, 1999, 64 FR 27585:

This is not an open meeting. The meeting is closed to the public.

Dated: June 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–14502 Filed 6–7–99; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.