The reporting burden for § 100.2(d) is insignificant because enforcement notifications are seldom submitted by States requesting the agency take enforcement action under the act against a particular food. Over the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343–1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications.

Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 310(b) of the act.

Dated: May 28, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–14458 Filed 6–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting for Representatives of Health Professional Organizations; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting with representatives of health professional organizations. The public meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. The two primary topics on the agenda for this meeting will be managing risks from medical product use and pediatric clinical studies.

DATES: The public meeting will be held on Tuesday, June 15, 1999, from 1:30 p.m. to 3:30 p.m.

ADDRESSES: The public meeting will be held at the Holiday Inn Bethesda, 8210 Wisconsin Ave., Bethesda, MD.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6630.

Those persons interested in attending this meeting should call Betty Palsgrove at 301–827–6618 to register. Registration may also be transmitted by FAX 1–800–344–3332 or 301–443–2446. Please include the name and title of the person attending, the name of the organization, address, and telephone number. There is no registration fee, however, space is limited. Persons will be registered in the order in which calls are received.

SUPPLEMENTARY INFORMATION: The purpose of the public meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff. It will also provide an opportunity for informal discussion on these topics of particular interest to health professional organizations.

The scheduled presenters for this meeting will be Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER) and M. Diane Murphy, Director, Office of Drug Evaluation IV, CDER.

Dated: June 2, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–14404 Filed 6–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Imaging 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: Medical Imaging 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 June 28 and 29, 1999, 8 a.m. to 5 p.m.

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

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12540. Please call the Information Line for up-to-date information on this meeting.

Agenda: Section 121 of FDA's Modernization Act of 1997 directs FDA to establish appropriate procedures for the approval of positron emission tomography (PET) drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355). At this meeting, FDA will present its findings on the safety and effectiveness of three PET drugs: (1) Fludeoxyglucose F 18 Injection, (2)Ammonia N 13 Injection, and (3) Water 0 15 Injection, for particular indications based on review of published literature. The committee will discuss the safety and effectiveness data on these three drugs. FDA also will discuss its proposed procedures for obtaining marketing approval for these three PET drugs.

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 18, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m., June 28, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 18, 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. 99–14403 Filed 6–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance 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: 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