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.