on the estimated number of examinations expected to be performed in a given year. If mammography examinations increase in number in subsequent years, which is expected for at least the foreseeable future, the annual burden and costs to meet this requirement will increase.

Included in the burden estimate is the FDA estimate for mammography lay summaries, which is the practice of notifying the patient in layman's terms of the results of the patient's mammography examination. FDA estimates that there are 9,800 facilities performing mammography in the United States. FDA also estimates that those facilities perform a total of 40 million mammography examinations in a year. In 90 percent of these cases, the notification to the patient can be established by a brief standardized letter to the patient. FDA estimates that preparing and sending this letter will take approximately 5 minutes. In the 10 percent of the cases in which there is a finding of ''Suspicious'' or ''Highly suggestive of malignancy,'' the facility is required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believes that this requirement can be met by a 5-minute call from the health professional to the patient.

Dated: October 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–27453 Filed 10–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 November 16 and 17, 2000, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 16 and 17, 2000, the committee will meet to discuss the following issues related to gene therapy clinical trials: (1) Product characterization, (2) preclinical models, and (3) long term followup.

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 November 9, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on November 16, 2000, and from 9 a.m. to 9:30 a.m. on November 17, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2000, 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: October 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27455 Filed 10–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; 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: Science Board to the Food and Drug Administration.

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 November 17, 2000, 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, CDER Advisory Committee Meeting Room, 5630 Fishers Lane, Rockville, MD 20857.

Contact Person: Susan Mackie Bond, Office of Science Coordination and Communication (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12603. Please call the Information Line for up-to-date information on this meeting.

Agenda: The board will meet to hear and to discuss the following issues: (1) Emerging science issues at FDA, (2) strategies for maintaining quality of science at FDA, and (3) programmatic peer review.

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 November 7, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 7, 2000, 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: October 18, 2000.

Linda S. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27456 Filed 10–25–00; 8:45 am]

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