determining whether a facility is exempt from payment of inspection fees under 42 U.S.C. 263b(r). A governmental entity is a mammography facility subject to inspection under section 354(g)(1) of the PHS Act (42 U.S.C. 263b(g)(1)), that meets either of the following criteria: (1) Is operated by any Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof; or (2) provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k *et. eq*., and at least 50 percent of the mammography screening examinations provided during the preceding 12 months were funded under that statute. The first notice of fees for facilities provides additional background relating to this definition (see 52 FR 14585).

VI. Billing and Collection Procedures

Within 30 days following inspection, FDA mails a bill to the inspected facility (governmental entities do not receive bills). The bill sets forth the type of inspection conducted (annual or followup), the fee to be paid, and the date payment is due (30 days after billing date). Inspection fees are billed to and collected from the party that operates the facility. If the facility is owned or controlled by an entity other than the operator, it is up to the parties to establish, through contract or otherwise, how the costs of facility inspections will be allocated.

If full payment is not received by the due date, a second bill is sent. At that time, interest begins to accrue at the prevailing rate set by the Department of the Treasury (currently, the prevailing rate is 13.75 percent), a 6 percent late payment penalty is assessed in accordance with 45 CFR 30.13, and a $20 administrative fee is assessed for each 30-day period that a balance remains due. If payment is not received within 30 days of a third and final bill, FDA may initiate action to collect unpaid balances (with interest and penalties), including the use of collection agencies and reporting of delinquencies to commercial credit reporting agencies.

Any questions or concerns about the billing and collection procedures may be addressed to Billing Inquiries c/o Mammography Quality Assurance Program, FA, P.O. Box 6057, Columbia, MD 21045–6057, 1–800–838–7715.

VII. Review and Appeals Procedures Regarding Qualifications as a Governmental Entity

FDA will review each declaration that a facility qualifies as a governmental entity. If FDA disallows a facility's claim that it is a governmental entity, a bill will be sent to the facility with payment due within 30 days.

If FDA determines that a facility is not a governmental entity, but the facility believes it qualifies for exemption under the definition of governmental entity set forth previously, the facility may appeal FDA's determination by explaining and certifying the basis for its belief in a letter directed to the FDA Ombudsman c/o Mammography Quality Assurance Program, FA, P.O. Box 6057, Columbia, MD 21045–6057, postmarked within 30 days of FDA's notice to the facility that the facility does not qualify as a governmental entity. The FDA Ombudsman will review a facility's claim that it is a governmental entity and will normally reach a decision within 60 days. If the Ombudsman determines that a facility does not qualify as a governmental entity, the Ombudsman shall provide a statement of the grounds for that determination. The Ombudsman's decision will constitute the agency's final decision on the matter. During the time required for the Ombudsman's review, FDA's efforts to collect the fee will be suspended and all time-related penalties held in abeyance.

VIII. Request for Comments

Although the MQSA does not require FDA to solicit comments on fee exemption, assessment and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views. FDA may consider altering its methodology of defining governmental entities, and assessing and collecting fees under the MQSA in future years. Each year's inspection experience provides additional data about differences among facilities and variations in costs by State, region, or other factors.

Interested persons may, on or before March 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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. Received comments and a full explanation of the costs included and the methodology employed in determining these fees are on file with the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–881 1–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Hematology and Pathology Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on January 28, 1998, 9:30 a.m. to 5 p.m.

Location: Parklawn Conference Center, conference rooms G and H, 5600 Fishers Lane, Rockville, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12515. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss a premarket approval (PMA) supplement for a computerized automated Papanicolaou (PAP) smear reader that is indicated for use as a primary screener to select a subpopulation of smears that will be designated for no further review.

Procedure: On January 28, 1998, from 10:30 a.m. to 11:30 a.m., the meeting is open to the public. 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 January 21, 1998. Oral presentations from the public will be

scheduled between approximately 10:30 a.m. and 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 21, 1998, 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.

Closed Committee Deliberations: On January 28, 1998, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will present to the committee confidential information regarding present or future issues.

FDA regrets that it was unable to publish this notice 15 days prior to the January 28, 1998, Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–882 Filed 1–9–98; 2:15 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices Panel of the Medical Devices 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). At least one portion of the meeting may be closed to the public.

Name of Committee: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on January 29, 1998, 8:45 a.m. to 6 p.m., and January 30, 1998, 8:45 a.m. to 1:30 p.m.

Location: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Salons F and G, Gaithersburg, MD.

Contact Person: Gail G. Gantt, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of http://www.fda.gov.cdrh for up-to-date information on this meeting.

Agenda: On January 29, 1998, the committee will discuss, make recommendations, and vote on one premarket approval application (PMA) for a wound dressing for use on diabetic foot ulcers and a second PMA for a wound dressing for use on venous stasis ulcers. On January 30, 1998, the committee will discuss, make recommendations, and vote on a PMA for a skin adhesive for wound edge approximation.

Procedure: On January 29, 1998 from 8:45 a.m. to 10 a.m and from 11 a.m. to 6 p.m., and on January 30, 1998, from 8:45 a.m. to 1:30 p.m., the meeting is open to the public. 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 January 22, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on January 29 and 30, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 22, 1998, 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.

Closed Presentation of Data: On January 29, 1998, from 10 a.m to 11 a.m. the meeting may be closed to permit discussion and review of trade secret and/or confidential information presented by the PMA sponsor(s) (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the January 29 and 30, 1998, General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–887 Filed 1–9–98; 1:52 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

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

Date and Time: The meeting will be held on January 30, 1998, 8 a.m. to 5 p.m.

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

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), 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 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the influenza virus vaccine formulation for 1998 and 1999. The committee will