FOR FURTHER INFORMATION CONTACT: Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 3, 1998 (63 FR 5562), FDA announced that a meeting of the Anti-Infective Drugs Advisory Committee would be held on February 19 and 20, 1998. This amendment is to provide an update to the information provided earlier pertaining to the February 19, 1998, meeting day. There are no changes for the February 20, 1998, meeting day. On page 5562, in the second column, the ''*Agenda*'' portion is amended to read as follows:

Agenda: On February 19, 1998, the committee will discuss new drug applications 50–747 and 50–748 quinupristin/dalfopristin (Synercid®, Rhone-Poulenc Rorer Pharmaceuticals, Inc.) for use in the treatment of vancomycin-resistant *Enterococcus faecium* (VREF) infections, complicated skin and skin structure infections, community-acquired pneumonia, hospital-acquired (nosocomial) pneumonia, and infections caused by *Staphylococcus aureus*.

Dated: February 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–4078 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood 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). The meeting will be open to the public.

Name of Committee: Blood 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 March 19, 1998, 8 a.m. to 6 p.m., and March 20, 1998, 8 a.m. to 3:30 p.m.

Location: DoubleTree Hotel, Plaza I, II and III, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 19, 1998, the Committee will hear an informational summary of the emerging infections plan of action and discuss and provide recommendations on the issue of the FDA proposal on plasma inventory hold. The committee will also discuss the comparison of infectious disease marker rates in paid versus volunteer donors. On March 20, 1998, the Committee will discuss and make recommendations on the issue of classification of blood bank software and the relative safety of solvent detergent-treated pooled plasma and single-donor plasma, donor retested. The meeting will conclude with an informational presentation on the FDA proposal for donor deferrals related to xenotransplantation.

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 March 9, 1998. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. and 4 p.m. and 5 p.m on March 19, 1998, and between approximately 9:30 a.m. and 10 a.m. and 1 p.m. and 1:30 p.m. on March 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 9, 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.

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

Dated: February 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–4075 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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: Oncologic Drugs 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 March 19 and 20, 1998, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers or Adele S. Seifried, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 19, 1998, the committee will discuss: (1) New drug application (NDA) supplement 20–509/S–005 Gemzar® (gemcitabine HCl), Eli Lilly and Co., indicated as a single agent or in combination with cisplatin for the first-line treatment of patients with locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer; and (2) NDA 20–896 Xeloda™ (capecitabine) tablets, Hoffman-La Roche Inc., indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of paclitaxel and an anthracycline-containing chemotherapy. On March 20, 1998, the committee will discuss: (1) NDA supplement 20–262/S–026 Taxol® (pacletaxel) injection, Bristol-Myers Squibb Pharmaceutical Research Institute, indicated as first-line therapy for the treatment of advanced carcinoma of the ovary; and (2) NDA supplement 20–262/S–024 Taxol® (pacletaxel) injection, Bristol-Myers Squibb Pharmaceutical Research Institute, indicated for the treatment of non-small cell lung cancer in patients who are not candidates for potentially curative and/or radiation therapy.

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 February 26, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m., on March 19, 1998, and 8 a.m. and 8:30 a.m. on March 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 26, 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.

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

Dated: February 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–4079 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0082]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Classification/ Reclassification; Restricted Devices; Analyte Specific Reagents'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 21, 1997 (62 FR 62243), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0361. The approval expires on January 31, 2001.

Dated: February 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–4080 Filed 2–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1897–N]

Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or After October 1, 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the update of Ambulatory Surgical Center payment rates effective for services on or after October 1, 1997. It implements section 1833(i)(2)(C) of the Social Security Act, which mandates an inflation adjustment to Medicare payment amounts for ambulatory surgical center (ASC) facility services during the years when the payment amounts are not updated based on a survey of the actual audited costs incurred by ASCs.

EFFECTIVE DATE: The payment rates contained in this notice are effective for services furnished on or after October 1, 1997.

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FOR FURTHER INFORMATION CONTACT: Joan Haile Sanow, (410) 786–5723.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that benefits under the Medicare Supplementary Medical Insurance (Part B) program include services furnished in connection with those surgical procedures that, under section 1833(i)(1)(A) of the Act, are specified by the Secretary and are performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center (ASC), in a rural primary care hospital, or in a hospital outpatient department. To participate in the Medicare program as an ASC, a facility must meet the standards specified under section 1832(a)(2)(F)(i) of the Act and the basic requirements for ASCs set forth in our regulations at 42 CFR 416.25.

Generally, there are two elements in the total charge for a surgical procedure: A charge for the physician's professional services for performing the procedure, and a charge for the facility's services (for example, use of an operating room). Section 1833(i)(2)(A) of the Act authorizes the Secretary to pay ASCs a prospectively determined rate for facility services associated with covered surgical procedures. ASC facility services are subject to the usual Medicare Part B deductible and coinsurance requirements. Therefore, Medicare pays participating ASCs 80 percent of the prospectively determined rate for facility services, adjusted for regional wage variations. This rate is intended to represent our estimate of a fair payment that takes into account the costs incurred by ASCs generally in providing the services that are furnished