and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Omnicef® Oral Suspension (cefdinir). Omnicef® Oral Suspension is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of specific microorganisms in specified conditions. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Omnicef® Oral Suspension (U.S. Patent No. 4,935,507) from Warner–Lambert Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 14, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Omnicef® Oral Suspension represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Omnicef® Oral Suspension is 2,745 days. Of this time, 2,406 days occurred during the testing phase of the regulatory review period, while 339 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: June 1, 1990. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 1, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 31, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Omnicef® Oral Suspension (NDA 50–749) was initially submitted on December 31, 1996.

3. *The date the application was approved*: December 4, 1997. FDA has verified the applicant's claim that NDA 50–749 was approved on December 4, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,213 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 16, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12654 Filed 5–19–99; 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's regulatory issues.

Date and Time: The meeting will be held on June 17, 1999, 8 a.m. to 5 p.m. and June 18, 1999, 8 a.m. to 3 p.m.

Location: DoubleTree Hotel, 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 20852–1448, 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 June 17, 1999, in the morning, the committee will discuss and provide recommendations on inadvertent contamination of plasma pools for fractionation: Risk issues. In the afternoon, the committee will discuss strategies for insuring compliance in the plasma fractionation industry, and the supply and demand of plasma derivatives. On June 18, 1999, the committee will hear informational presentations on the blood action plan and the device action plan, discuss and provide recommendations on the topic of deferral of blood donors at risk of malaria, and discuss and provide comments on the topic of HTLV supplemental tests.

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 7, 1999. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m.; 1:30 p.m. and 2 p.m.; and 4 p.m. and 4:30 p.m. on June 17, 1999, and between 10:30 a.m. and 11 a.m. and 2 p.m. and 2:30 p.m. on June 18, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 7, 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 14, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–12793 Filed 5–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices 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 23, 1999, 8 a.m. to 6 p.m., and June 24, 1999, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Salons C, D, and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 23, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an endovascular graft for the treatment of abdominal aortic aneurysms. Subsequently, the committee will discuss, make recommendations, and vote on a PMA for an endovascular graft for the treatment of abdominal aortic or aorto-iliac aneurysms. On June 24, 1999, the committee will discuss, make recommendations, and vote on a PMA for a prosthetic heart valve. Subsequently, the committee will discuss, make recommendations, and vote on a PMA for a dual-chamber defibrillator for the treatment of atrial and ventricular tachyarrhythmias.

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 13, 1999. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on June 23, 1999 and June 24, 1999. Near the end of committee deliberations on both days, a 30-minute open public hearing will be conducted for interested persons to address issues specific to the topics before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 13, 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 14, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–12792 Filed 5–19–99; 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). At least one portion of the meeting will be closed 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's regulatory issues.

Date and Time: The meeting will be held on June 7 and 8, 1999, 8 a.m. to 5:30 p.m.

Location: Town Center Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Karen M. Templeton–Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20057, 301–827–7001, 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: The committee will discuss: (1) The use of time-to-progression as the primary endpoint in breast cancer drug trials; and (2) new drug application (NDA) 21–010, epirubicin hydrochloride for injection, Pharmacia and Upjohn Co., indicated for use as a component of adjuvant therapy in patients with evidence of axillary-node-tumor involvement following resection of primary breast cancer (Stage II & III). Epirubicin is indicated for the therapy of patients with locally advanced or metastatic breast cancer. On June 8, 1999, the committee will discuss: (1) NDA 50–718/S–006, Doxil® (doxorubicin HCl liposome injection), Alza Corp., indicated for the treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel- and platinum-based chemotherapy regimens and who may also be refractory to topotecan. Refractory is defined as a patient having progressive disease while on treatment, or within 6 months of completing treatment; and (2) NDA 20–221/S–012, Ethyol® (amifostine) for injection, U.S. Bioscience, Inc., indicated for use to reduce the incidence and severity of radiation induced xerostomia.

Procedure: On June 7, 1999, from 10:30 a.m. to 5:30 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 May 28, 1999. Oral presentations from the public will be scheduled between approximately 10:45