

5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) 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 QUADRAMET® (samarium sm 153 EDTMP). QUADRAMET® is indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance radionuclide bone scan. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for QUADRAMET® (U.S. Patent No. 4,898,724) from The Dow Chemical 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 November 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the

approval of QUADRAMET® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for QUADRAMET® is 2,844 days. Of this time, 2,189 days occurred during the testing phase of the regulatory review period, 655 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) became effective (21 U.S.C. 355):* June 16, 1989.

The applicant claims January 28, 1986, as the date the investigational new drug application (IND) for QUADRAMET® (IND 33,240) became effective for purposes of regulatory review period determination. Applicant also states the notice of clinical investigation exemption was submitted on May 16, 1989. However, FDA records indicate that the IND effective date was June 16, 1989, which was 30 days after FDA receipt of IND 33,240.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* June 13, 1995.

FDA has verified the applicant's claim that the new drug application (NDA) for QUADRAMET® (NDA 20,570) was initially submitted on June 13, 1995.

3. *The date the application was approved:* March 28, 1997. FDA has verified the applicant's claim that NDA 20,570 was approved on March 28, 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 1,412 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 15, 1998, 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 January 13, 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: June 23, 1998.

**Thomas J. McGinnis,**

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98-19027 Filed 7-16-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Nonprescription Drugs Advisory Committee: Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Nonprescription Drugs Advisory Committee. This meeting was announced in the **Federal Register** of June 26, 1998 (63 FR 34902). The amendment is being made to cancel the entire session on July 28, 1998. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Rhonda W. Stover or Angie Whitacre, 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 12541.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 26, 1998 (63 FR 34902), FDA announced that a meeting of the Nonprescription Drugs Advisory Committee would be held on July 28 and 29, 1998.

1. On page 34902, in the third column, the "Date and Time" portion is amended to read as follows:

*Date and Time:* The meeting will be held on July 29, 1998, 8:30 a.m. to 5 p.m.

2. On page 34902, beginning in the third column, the "Agenda" portion is amended by removing the first paragraph.

3. On page 34903, in the first column, under the "Procedure" portion, in the ninth line, "July 28 and 29" is corrected to read "July 29".

Dated: July 10, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98-19031 Filed 7-17-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Nucleic Acid Testing for Hepatitis C Virus (HCV) and Other Viruses in Blood Donors; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Nucleic Acid Testing for Hepatitis C Virus (HCV) and Other Viruses in Blood Donors. The topic to be discussed is the exploration of the current state of technology and implementation of nucleic acid testing for screening blood donors.

**Date and Time:** The workshop will be held on Wednesday, September 16, 1998, 8:30 a.m. to 5 p.m.

**Location:** The workshop will be held at the Parklawn Bldg., 3d floor, conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857.

**Contact:** Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843.

**Registration:** Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Friday, September 4, 1998. Registration at the site will be done on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

**Agenda:** The public workshop is intended to discuss nucleic acid testing that currently is the most sensitive method available to further reduce disease transmission by blood transfusion in the early window phase of infection. Nucleic acid testing is being implemented for blood donor screening by testing plasma pools, and

pool testing may be useful by serving as an interim measure until screening of individual blood donations is technologically feasible.

Regulatory and scientific topics to be discussed at the workshop include donor testing issues, pooling strategies, and test validation and reference materials for standardization of various nucleic acid technologies.

**Transcripts:** Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: July 9, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-19110 Filed 7-16-98; 8:45 am]

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## 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 September 1, 1998, 8:30 a.m. to 5:30 p.m., and September 2 and 3, 1998, 8 a.m. to 5:30 p.m.

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

**Contact Person:** Karen M. Templeton-Somers, 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 12542. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On September 1, 1998, the committee will discuss: (1) New drug

application (NDA) 20-893 Metaret™ (suramin hexasodium for injection), Parke-Davis Pharmaceutical Research, indicated for the treatment of patients with hormone refractory prostate cancer; and (2) NDA 20-892 Valstar™ (valrubicin 40 milligrams/milliliter), Anthra Pharmaceuticals, Inc., indicated for intravesical use in the treatment of patients with biopsy-proven carcinoma *in situ* of the urinary bladder who are refractory to bacille Calmette-Guérin (BCG) immunotherapy and for whom cystectomy is contraindicated. On September 2, 1998, the committee will discuss: (1) NDA supplement 17-970/S-040 Nolvadex® (tamoxifen citrate), Zeneca Pharmaceuticals, indicated for the prevention of breast cancer in women at high risk; and (2) biologics license application (BLA) 98-0369 Herceptin™ (trastuzumab), Genentech, Inc., indicated for the treatment of patients with metastatic breast cancer who have tumors which overexpress HER2. On September 3, 1998, the committee will discuss: (1) NDA supplement 20-571/S-08 Camptosar™ (irinotecan hydrochloride injection), Pharmacia & Upjohn, indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following a 5-FU-based therapy; and (2) NDA supplement 20-451/S-003 Photofrin® (porfimer sodium) for injection, QLT PhotoTherapeutics, Inc., indicated for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer.

**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 August 14, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., on September 1, 1998, and between approximately 8:15 a.m. and 8:45 a.m., on September 2 and 3, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 14, 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).