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. 4,989,724) 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:

3. The date an exemption under section 505 of the act (21 U.S.C. 355) became effective (21 U.S.C. 355): 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.

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.


Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.

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


Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 98–19031 Filed 7–17–98; 8:45 am]
BILLING CODE 4160–01–F

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, 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]
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 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.

Agency: 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™ (valrubin 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–Güerin (BCG) immunotherapy and for whom cystectomy is contraindicated. On September 2, 1998, the committee will discuss: (1) NDA supplement 17–970/5–040 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 20–571/5–08 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 20–451/5–003 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).