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]

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, 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 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]

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.

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-Gũerin (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).

Dated: July 9, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–19030 Filed 7–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0393]

National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guide entitled ''National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish.'' The guide was developed cooperatively by FDA and the Interstate Shellfish Sanitation Conference (ISSC) with the intent of replacing the existing NSSP Manuals of Operation, Parts I and II. The guide contains a Model Ordinance for ensuring that only safe and sanitary shellfish are offered for sale in interstate commerce. Language contained in the Model Ordinance has been codified for easy adoption into law or regulation by State regulatory agencies. The guide also includes documentation supportive of the codified language of the Model Ordinance, including: The NSSP's history, public health reasons and explanations specific to the guidelines contained in the Model Ordinance, NSSP guidance documents, suggested NSSP forms, shellfish policy setting documents, pertinent Federal regulations, and references to the public health reasons and explanations. These supportive materials aid in ensuring consistent and uniform implementation of a national shellfish safety program.

DATES: Comments on the guide may be submitted at any time.

ADDRESSES: Submit written comments on the guide to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guide entitled ''National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish'' to the contact person in the nearest regional office listed in the **SUPPLEMENTARY INFORMATION** section of this document. Send two self-addressed adhesive labels to assist in processing your requests. An electronic version of the guide is available on the World Wide Web at (http/www.issc.org).

FOR FURTHER INFORMATION CONTACT: Paul W. DiStefano, Office of Seafood, Center for Food Safety and Applied Nutrition (HFS–417), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3150, FAX: 202–418–3198, e-mail: ''pdistefa@bangate.fda.gov'', or the contact person in the nearest regional office as listed in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION: Copies of the guide entitled ''National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish'' can be obtained from the nearest regional office as follows:

FDA Addresses	Contact Person
Stoneham District Office, State Programs Branch, One Montvale Ave., Stoneham, MA 02180	David G. Field
New York Regional Office, 850 Third Ave., Brooklyn, NY 11232–1593	Jerry H. Mulnick
Baltimore District Office, Investigations Branch, 900 Madison Ave., Baltimore, MD 21201	Al A. Ondis
Atlanta Regional Office, State Cooperative Programs, 60 Eighth St. NE., Atlanta, GA 30309	James A. Casey
Charleston Resident Post, 334 Meeting St., rm. 505, P.O. Box 21077, Charleston, SC 29413	Donald Hesselman
Tallahassee Resident Post, Hobbs Federal Bldg., 227 North Bronough St., suite 4150, Tallahassee, FL 32301	Marc B. Glatzer
Baton Rouge Resident Post, 5353 Essen Lane, suite 220, Baton Rouge, LA 70809	John E. Veazey
Detroit District Resident Post, 1560 East Jefferson Ave., Detroit, MI 48207	Nicholas L. Majerus
Dallas Regional Office, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247	David A. Blevins
Seattle District Office, 100 Second Ave., suite 2400, Seattle, WA 98104	Tim E. Sample
Shellfish Safety Team (HFS–628), 200 C St. SW., Washington, DC 20204	Stanley D. Ratcliffe

FDA is the Federal agency responsible for administration of the NSSP. The NSSP is a voluntary program in which State shellfish control agencies, the shellfish industry, FDA, and other Federal agencies participate. The NSSP, which has been in existence since 1925, addresses the sanitary control of fresh and frozen molluscan shellfish (oysters, clams, mussels, and scallops) offered for sale in interstate commerce. To promote uniform administrative and technical controls, the NSSP has developed and maintained recommended shellfish control practices for adoption by member States. These control practices, which were initially published as the NSSP Manuals of Operation, Parts I and II, are contained in the guide ''NSSP Guide for the Control of Molluscan Shellfish.''

In 1982, interested State officials and members of the shellfish industry formed the ISSC to provide a structure wherein State regulatory authorities could meet on a regular basis to discuss ways to improve shellfish sanitation and safety. FDA and the ISSC entered into a memorandum of understanding (MOU) that was published in the **Federal Register** of March 30, 1984 (49 FR 12751), agreeing, among other things, that FDA would provide technical assistance to the ISSC. The ISSC in turn would help FDA develop or revise program criteria and guidelines in the NSSP Manuals of Operation. Based on the MOU, and in cooperation with the ISSC, FDA periodically publishes revisions of the NSSP