

determine what and where tests are available; (3) predicting the impact of proposed regulatory changes on laboratory services, the government can respond to requests for information from

a position of more complete knowledge and understanding than the partial information currently available; and (4) monitoring the changes in laboratory testing as our health care delivery

systems moves toward managed care. The total annual burden hours are 1,228.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Contact questionnaire	1,178	1	0.25
Mail survey	1,178	1	0.50
Telephone follow-up	1,178	1	0.25
On-site QC	100	1	0.50

Dated: August 25, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing an amendment to the notice of meeting of the Oncologic Drugs Advisory Committee which is scheduled for September 18 and 19, 1997. This meeting was announced in the **Federal Register** of August 14, 1997 (62 FR 43539). The amendment is being made to: (1) Remove the second agenda item scheduled on September 19, 1997; (2) change the starting and ending times of the meeting on September 19, 1997; and (3) reschedule the time allotted for oral presentations from the public on September 19, 1997. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Jannette O'Neill-Gonzalez or Robinette Taylor, 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1997 (62 FR 43539), FDA announced that a meeting of the Oncologic Drugs

Advisory Committee would be held on September 18 and 19, 1997. This amendment is to provide an update to the information provided earlier pertaining to the September 19, 1997, meeting day. There are no changes for the September 18, 1997, meeting day. On page 43540, beginning in column 1, portions of the notice pertaining to the September 19, 1997, meeting day are amended to read as follows:

Date and Time: The meeting will be held on September 19, 1997, from 8:30 a.m. to 12:50 p.m.

Agenda: On September 19, 1997, the committee will discuss: NDA 20-826, Paxene® (paclitaxel, Baker-Norton Pharmaceuticals, Inc.), "indicated after failure of first line or subsequent systemic chemotherapy for the treatment of advanced AIDS-related Kaposi's Sarcoma."

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 September 4, 1997. Oral presentations from the public will be scheduled between approximately 8:35 a.m. and 9:05 a.m. on September 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 1997, 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: August 25, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

X-ray Assemblers Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following workshop: X-ray Assemblers Workshop. This workshop is being sponsored by FDA's Southeast Region and the radiological health programs within the Southeast Region (Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, and the Virgin Islands). The topics to be discussed are the update on the x-ray assemblers' responsibilities under the diagnostic x-ray performance standard; State rules and regulations on diagnostic x-ray standards; completing the form, FDA-2579 (Report of Assembly of a Diagnostic X-ray System); and inspections of x-ray assemblers. The purpose of the workshop is to provide x-ray assemblers with an update on assemblers responsibilities under the diagnostic x-ray performance standard; review the various State regulations; and provide technical training in the area of assembler inspections and completion of the form, FDA-2579.

Date and Time: The workshop will be held on Thursday, September 25, 1997, 8 a.m. to 4:30 p.m.

Location: The workshop will be held at the Medical Forum Bldg., 950 22d Street North, Birmingham, AL.

Contact: R. Thomas Trout, Regional Radiological Health Representative, Southeast Region, Food and Drug Administration (HFR-SE19), 60 Eighth Street NE., Atlanta, GA 30309, 404-347-4001, ext. 5248, FAX 404-347-4349.

Registration: Send registration information (name, title, firm name, address, telephone, and fax number) to the contact person by September 18,