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).

[FR Doc. 97–23183 Filed 8–29–97; 8:45 am]

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.

[FR Doc. 97–23121 Filed 8–29–97; 8:45 am]

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,

1997. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact R. Thomas Trout at least 7 days in advance.

Dated: August 26, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23243 Filed 8–27–97; 3:24 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0228]

Draft Guidance for Industry on Computerized Systems Used in Clinical Trials; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on the draft guidance entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials'' until November 3, 1997. FDA published a notice of availability of the draft guidance in the **Federal Register** of June 18, 1997 (62 FR 33094). FDA is reopening the comment period in response to requests for additional time to review the agency's draft guidance on the use of computerized systems in clinical trials.

DATES: Written comments may be submitted on the draft guidance document by November 3, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Office of Enforcement (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0425.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 18, 1997, FDA announced the availability of a draft guidance for industry entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' The draft guidance is intended to assist applicants who wish to use computer systems to generate, collect, maintain and transmit clinical data for submission to FDA in support of marketing or research applications. The notice invited interested persons to submit written comments on the draft guidance by August 18, 1997.

The agency received a number of requests for additional time to comment on the draft guidance and is reopening the comment period until November 3, 1997.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23180 Filed 8–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0333]

Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a position paper entitled ''Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants.'' The position paper is soliciting input from industry, users' groups, other regulatory agencies, and academia on FDA's approaches to improving the evaluation of liquid chemical sterilants and high level disinfectants.

DATES: Written comments by December 1, 1997.

ADDRESSES: Submit written requests for single copies of the position paper to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (toll free outside of MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the position paper to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the position paper and received comments are available for public examination in the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–0616.

SUPPLEMENTARY INFORMATION: FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a liquid chemical germicide medical device must submit a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) to FDA before introducing the device into interstate commerce. Regulations governing the general content and format of 510(k) submissions (part 807 (21 CFR part 807)) and other regulatory requirements are discussed in guidance documents available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (address above). The effective use of chemical germicides is important in preventing nosocomial infections. Comprehensive, scientifically sound criteria for the evaluation of chemical germicides is essential to help ensure that these agents are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, with the agency's evaluation criteria for chemical germicides in order to facilitate the assembly of necessary data, to maintain consistency of review, and to provide for a more efficient regulatory process. The purpose of this position paper is to solicit input from industry, users' groups, other regulatory agencies, and academia on FDA's approaches to improving the evaluation of liquid chemical germicides. The comments that FDA receives in response to this position paper will help it in assessing the current guidance and in developing the approach that will be used in future guidances for these products.