or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Surgical Instrument Marking Tape Survey

The mandate of FDA's Center for Devices and Radiological Health under the authority of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301–395) and regulations contained in Title 21 of the Code of Federal Regulations includes the approval and adequate labeling of medical devices. Section 903(b)(2)(c) of the act (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to medical devices.

The regulatory status of adhesive-backed, colored tape on medical devices is under review by FDA. The tape is frequently applied to medical devices, particularly surgical instruments, to facilitate sorting. It may be considered an accessory to medical devices used in surgical treatment as defined by 21 CFR 878.4800.

There are two case reports in the literature in which adverse events are attributed to the use of adhesive-backed, colored tape to mark surgical instruments (*Journal of Oral Maxillofacial Surgery*, 41:687–688, 1983; and *British Journal of Surgery*, 74:696, 1987). Two additional adverse event reports have been submitted to FDA.

The purpose of the survey is to estimate the proportion of the population at risk from this practice, and to determine if use of operating room nurse managers as proxies for sampling health care facilities for this purpose is effective. In addition, data will be collected to identify tape durability, extent of use, and whether there are any practices or procedures for marking surgical instruments and/or any human factors that could be altered to better protect the public health. Labeling information will also be collected.

The proposed randomized survey will be a one-time data collection effort. Completion of the survey is voluntary, and anonymity of individuals and institutions will be protected. Survey results will be available to participants upon request.

The only respondent burden will derive from the time needed to respond to survey questions. This will occur on a one-time basis. The length of the screening portion (questions 1 to 7) is estimated at 5 minutes, and the full survey length is estimated at an additional 25 minutes. Burden estimates are based on the need to have 308 surveys returned to achieve a statistically significant sampling.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening Questions Only (30%)	92	1	92	0.083	7.63
Complete Survey (70%)	216	1	216	0.50	108
TOTAL	308	-	-	-	115.63

There are no capital costs or operating and maintenance costs associated with this survey.

Dated: August 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–22441 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Antiviral Drugs Advisory Committee

Date, time, and place. September 26, 1996, 1 p.m. and September 27, 1996, 8:30 a.m., Holiday Inn—Gaithersburg, Goshen Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, September 26, 1996, 1 p.m. to 3 p.m.; open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; open committee discussion, September 27, 1996, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 4:30 p.m.; Rhonda W. Stover, 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 Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531. Please call the hotline for information concerning any possible changes.

General functions of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 20, 1996, 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 required to make their comments.

Open committee discussion. On September 26, 1996, the committee will discuss data relevant to the approved drug, saquinavir (Invirase™, Hoffmann-La Roche), for use in combination with nucleoside analogues for the treatment of human immunodeficiency virus (HIV) infection. On September 27, 1996, the committee will discuss data relevant to new drug application 20–705, delavirdine (Rescriptor®, Pharmacia and Upjohn Co.) for use in the treatment of HIV infection.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion 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. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: August 27, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–22485 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F

Bioresearch; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Nashville District Office, and the Center for Drug Evaluation and Research) is announcing a free public workshop on FDA regulatory requirements for the bioresearch industry. The workshop is designed to assist the industry in complying with regulations for clinical investigators, institutional review boards, and sponsor-monitors.

DATES: The public workshop will be held on Tuesday, September 24, 1996, from 8:45 a.m. to 4:45 p.m.

ADDRESSES: The public workshop will be held at the University of Alabama—Birmingham, University Hospital, 620 South 19th St., Spain Wallace Bldg., Margaret Cameron Spain Auditorium, rm. S100, Birmingham, AL.

FOR FURTHER INFORMATION CONTACT: William H. Oates, FDA's Nashville District Office, 296 Plus Park Blvd., Nashville, TN 37217, 615–781–5374 ext. 118, FAX 615–781–5391.

Those persons interested in attending this meeting should FAX their registration, including name(s), firm name, address, telephone and FAX numbers, and any specific questions to William H. Oates (address above) by September 13, 1996. There is no registration fee for this workshop. Space is limited, therefore, interested parties are encouraged to register early.

SUPPLEMENTARY INFORMATION: FDA's survey of the bioresearch industry shows that many of these firms are either unaware of applicable regulations and guidelines or not in compliance with applicable requirements. This workshop is designed to assist the bioresearch industry in complying with applicable regulations.

Dated: August 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–22442 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F