submitted, except that individuals may submit one copy.

Dated: June 23, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–19089 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

Grassroots Regulatory Partnership Meeting; Southwest Region Device Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southwest Region, and Center for Devices and Radiological Health) is announcing a free public meeting as a followup to a meeting held in April 1995. The FDA office of the Southwest Region will meet with interested persons in the Southwest Region to address specific issues related to the medical device industry, Southwest Region, and FDA. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of this agency, and to create local partnerships.

DATES: The public meeting will be held on Friday, August 25, 1995, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Denver West Hotel, 360 Union Blvd., Lakewood, CO.

FOR FURTHER INFORMATION CONTACT: Virlie Walker, FDA Denver District, Bldg. 20, Entrance W–10, Denver Federal Center, Sixth and Kipling Sts., Denver, CO 80255–0087, 303–236–3018, FAX 303–236–3099.

SUPPLEMENTARY INFORMATION:

Those persons interested in attending this meeting should FAX their comments and registration by Monday, August 21, 1995, including name, firm name, address, and telephone number to 303–236–3099. There is no registration fee for this meeting, but advance registration is required. Space is limited and all interested parties are encouraged to register early.

Dated: July 27, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–19058 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0226]

Current Issues in AIDS Clinical Trials; Notice of a Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on current issues in acquired immune deficiency syndrome (AIDS) clinical trials. The workshop will be followed by a joint meeting of subcommittees of the Antiviral Drugs Advisory Committee and the National Task Force on AIDS Drug Development, announced elsewhere in this issue of the **Federal Register**. The workshop will enable experts in the field of AIDS clinical trials, interested representatives of industry, and interested members of the public to exchange ideas regarding clinical trials of drugs for the treatment of AIDS. While the workshop is not intended to result in consensus among participants or to contribute to the formulation of agency policy, discussions regarding current issues in AIDS clinical trials may provide assistance to pharmaceutical sponsors in designing appropriate study protocols and expediting drug development.

DATES: The public workshop will be held on Wednesday and Thursday, September 6 and 7, 1995, from 8:30 a.m. to 5 p.m. Registration must be received by August 18, 1995.

ADDRESSES: The public workshop will be held at the National Institutes of Health, William H. Natcher Conference Center, 45 Center Dr., 2BC–02, Bethesda, MD. Written comments may be submitted at any time to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. A transcript and summary of the workshop will be available from the Docket Management Branch (address above) and from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Heidi C. Marchand or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0104. Persons interested in attending this meeting should FAX their registration to one of the individuals named above at 301–443–9216, including the participant's name; organization name, if any; address; and telephone number. There is no registration fee for any part of this workshop, but advance registration is required. Interested parties are encouraged to register early because space is limited.

SUPPLEMENTARY INFORMATION:

Current Federal regulations allow for the accelerated approval of drugs intended to treat serious and life-threatening diseases, including AIDS and human immunodeficiency virus (HIV)-related diseases, on the basis of clinical trials showing that the drugs have an effect on surrogate endpoints. Following approval, FDA may require that the drug applicant study the drug further to verify the clinical efficacy of the product by performing clinical trials designed to demonstrate therapeutic benefit by clinical endpoints. In AIDS, the clinical endpoints that have been considered meaningful are survival and disease progression as manifested by the development of AIDS-defining opportunistic infections.

One of the major challenges facing developers of HIV therapeutics is the successful design and conduct of the clinical trials intended to provide the data needed to confirm the clinical benefit of drugs that have received accelerated approval. Study design issues include, but are not limited to, choice of patient population, control groups, treatment modifications on study, and analysis of heterogeneous endpoints. Study conduct issues include efficient recruitment of volunteers and retention of study subjects in trials long enough to gather sufficient endpoint data. These studies are being designed and conducted in the context of a rapidly changing world of new information and treatment strategies and increasing reliance on the use of surrogate markers to make treatment decisions.

The goal of this workshop is to discuss critical issues in the conduct of clinical trials in HIV in accelerated approval matters and to suggest strategies to overcome identified obstacles so that new drugs and information on the best use of these new drugs can be made available more quickly.

A transcript and summary of the workshop will be available from the Freedom of Information Office (address above) approximately 10 business days after the workshop at a cost of 10 cents per page.

Interested persons may submit, at any time, to the Dockets Management Branch (address above) comments on the workshop. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the workshop will remain open until October 31, 1995. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (address above) by October 31, 1995.

Dated: July 28, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–19087 Filed 8–2–95; 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:

Joint Subcommittee Meeting of the National Task Force on AIDS Drug Development and the Antiviral Drugs Advisory Committee on Clinical Trial Design Issues

Date, time, and place. September 8, 1995, 8:30 a.m., Auditorium, William H. Natcher Conference Center, National Institutes of Health, 45 Center Dr., 2BC.02, Bethesda, MD.

Type of meeting and contact person. Open committee discussion, 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 p.m.; Heidi C. Marchand or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0104, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602, or Antiviral Drugs Advisory Committee, code 12531.

General functions of the committees. The National Task Force on AIDS Drug Development shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers, and provides options for the elimination of these barriers. The Antiviral Drugs Advisory 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 subcommittee. Those desiring to make formal presentations should notify a contact person before August 25, 1995, 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 subcommittee discussion. The subcommittee will hear summary presentations from discussions held during the public workshop on current issues in AIDS clinical trials to be held on September 6 and 7, 1995, (announced elsewhere in this issue of the **Federal Register**) and discuss recommendations on the scientific design of AIDS clinical trials.

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, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page.