therapy versus empiric therapy since widespread empiric use may decrease the drug's potential usefulness for treating MDR organisms. The agency encourages investigators, academicians, and members of the pharmaceutical industry with information relevant to the treatment of infections caused by MDR organisms, including current approaches to antimicrobial drug development, to respond to this notice.

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. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 (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: June 14, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–15942 Filed 6–21–96; 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:

Psychopharmacologic Drugs Advisory Committee

Date, time, and place. July 15, 1996, 8:30 a.m., Holiday Inn—Silver Spring, Main Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Kennerly Chapman, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 1901 Chapman Ave., rm. 200, Rockville, MD 20852, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Psychopharmacologic Drugs Advisory Committee, code 12544. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

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 must notify the contact person before July 10, 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. The committee will discuss the safety and effectiveness of Serlect® (sertindole), new drug application (NDA) 20–644, Abbott Laboratories, for use in the treatment of psychotic disorders.

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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: June 14, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–15943 Filed 6–21–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0067]

Guidance for Industry in Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis; Availability of Draft Guidance; Notice of Public Workshop on Juvenile Rheumatoid Arthritis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Discussion for Designing Clinical Programs for Developing Drugs, Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis (RA).'' On March 27, 1996, the agency held a public workshop to discuss the draft guidance. The agency is now announcing a second public workshop to discuss the draft guidance as it pertains to juvenile rheumatoid arthritis (JRA). The draft guidance was prepared by the Rheumatology Working Group comprised of members from: The Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. The workshop will enable experts in rheumatology clinical trials and interested representatives of industry, academia, and the public to exchange ideas on developing and assessing new treatment modalities for JRA and to discuss the types of claims that might be reasonably pursued, and evidence necessary to support such claims.

DATES: The public workshop will be held Tuesday, July 23, 1996, from 8 a.m. to 6 p.m. There is no registration fee for the workshop, but registration is requested before July 12, 1996. Interested parties are encouraged to register early because space is limited. Written comments on the draft guidance for consideration at the workshop should be submitted by July 12, 1996. The administrative docket will remain open until August 30, 1996, for the submission of written comments, data, information, or views on the draft guidance or the workshop.

ADDRESSES: The public workshop will be held at the Holiday Inn— Bethesda, Versailles III and IV, 8120 Wisconsin Ave., Bethesda, MD 20814. Persons interested in attending should Fax their registration to Rose E. Cunningham at 301–594–5493. The Fax should include the participant's name and title; organization name, if any; address; and telephone and Fax numbers.

A copy of the draft guidance document entitled ''Discussion for Designing Clinical Programs for Developing Drugs, Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis (RA)'' is available through CDER's Fax-on-Demand, 301–827–0577 or 800–342–2722, under the index ''Guidance to industry,'' document no. 0806. The agenda for the workshop is available as document no. 0504. The draft guidance, agenda, and registration are also available on the CDER Home Page on the World Wide Web at http://www.fda.gov/cder/jraworkshop.htm (these must be lower case). A transcript of the workshop will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 business days after the workshop at a cost of 10¢ per page.

Written comments on the draft guidance or the workshop should be submitted to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5470.