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.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 6, 1996 (61 FR 8961), FDA announced 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)'' also referred to as ''Draft Guidance for Industry in Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis.'' The agency also announced that it was holding a public workshop on March 27, 1996, to discuss the draft guidance. The agency is now announcing a second public workshop to discuss the draft guidance as it pertains to JRA.

New treatment modalities being developed for JRA may have beneficial effects that are different from traditional agents. However, uncertainty exists among experts in rheumatology clinical trials about the types of labeling claims that might be reasonably pursued for these agents and what evidence would be necessary to support such claims. In addition, there is a need to discuss endpoints for JRA trials, and whether functional/quality-of-life or radiographic claims are appropriate.

FDA, through its Rheumatology Working Group, has developed a draft guidance document for industry that provides an overview of some design problems that are encountered in JRA trials intended for product development. FDA is sponsoring a public workshop to provide an opportunity for experts in rheumatology clinical trials and interested representatives of industry, academia, and the public to discuss the working draft of the guidance document and to exchange ideas on developing and assessing new treatment modalities for JRA as well as the types of claims that might be reasonably pursued and the evidence necessary to support such claims.

After consideration of all data, information, or views submitted on the draft guidance at the workshop, FDA will issue a final guidance document and announce its availability with a notice published in the Federal Register.

Dated: June 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–15991 Filed 6–21–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: July 2, 1996.

Time: 3 p.m.

Place: Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: July 3, 1996.

Time: 3 p.m.

Place: Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 2087, Telephone: 301, 443–6470.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable materials and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: June 17, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–15931 Filed 6–21–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4056–N–02]

Office of the Assistant Secretary for Policy Development and Research; FY 1996 Funding Availability for the Community Outreach Partnership Centers (COPC) Program: Notice of Correction of Eligibility

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: FY 1996 funding availability; notice of correction.

SUMMARY: On May 16, 1996, HUD published a notice that announced the availability of $7.4 million for the Community Outreach Partnership Centers program. The purpose of this notice is to revise the eligibility criteria for first-round COPC grantees applying for Institutionalization Grants. The notice also revises the amount set aside for these grants.

DATES: The notice does NOT revise the application deadline of July 25, 1996, set forth in the May 16, 1996 Notice of Funding Availability (NOFA).

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships, U.S. Department of Housing and Urban Development, Room 8110, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1537; (TTY (202) 708–0770, or 1–800–877–8399). Other than the ''800'' number, these are not toll-free numbers.

SUPPLEMENTARY INFORMATION: On May 16, 1996, HUD published a notice that announced the availability of $7.4 million in funding for the Community Outreach Partnership Centers (COPC) program. The NOFA added a new type of grant under the program—Institutionalization Grants—for which only first-round (FY 1994) COPC grantees are eligible to compete. The NOFA placed two further conditions on eligibility for these grants. First, universities awarded Joint Community Development (JCD) grants are not eligible for Institutionalization Grants. Second, institutions of higher education that received grants as consortia in the first-round are required to apply again as consortia, with all current member institutions participating in the proposed Institutionalization Grant, and with the same lead applicant as the current COPC.

A problem has arisen with these two criteria, which unfairly eliminates a consortium from the competition. A consortium, composed of three universities, won a first-round grant.