DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Meeting of the National Human Research Protections Advisory Committee

AGENCY: Office of Public Health and Science, Office for Human Research Protections.

ACTION: Notice of July 30–31, 2001 Meeting.

SUMMARY: Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Human Research Protections Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below. Individuals planning on attending the meeting and who want to ask questions must submit their requests in writing in advance of the meeting to the contact person listed below.

DATES: The Committee will hold its next meeting on July 30–31, 2001. The meeting will convene from 8:30 a.m. to its recess at approximately 5:30 p.m. on July 30 and resume at 8:30 a.m. to 5:00 p.m. EST on July 31.

ADDRESSES: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, (301)468–4972.

FOR FURTHER INFORMATION CONTACT: Ms. Kate-Louise Gottfried, Executive Director, National Human Research Protections Advisory Committee, Office for Human Research Protections, 6100 Executive Boulevard, Room 310B (MSC 7507), Rockville, Maryland 20892–7507, (301)496–7005. The electronic mail address is kg123a@nih.gov.

SUPPLEMENTARY INFORMATION: The National Human Research Protections Advisory Committee was established on June 6, 2000 to provide expert advice and recommendations to the Secretary of HHS, Assistant Secretary for Health, the Director, Office for Human Research Protections, and other departmental officials on a broad range of issues and topics pertaining to or associated with the protection of human research subjects.

The draft agenda for the Committee's July meeting is below. Updates to this agenda will be posted on the NHRPAC website at http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm.

Draft Agenda

Monday July 30, 2001

8:30–8:45am HHS&Human Subject Protection, Arthur Lawrence, Ph.D., Acting Principal Deputy Assistant, Secretary for Health [15 minutes]
8:45am–9:15am The Perilous Intersection of Protection, Human Research Subjects and Conflicts, of Interest, Michael Wood, M.D., President and CEO The Mayo Foundation [30 minutes]
9:15am–9:30 Welcome: Overview of Meeting Mary Faith marshall, Ph.D. Chairperson NHRPAC [15 minutes]
9:30am–10:00am Final Review & Approval of NHRPAC Response to Financial Relationships Interim Guidance Mark Barnes, J.D. Chair, Working Group [30 minutes]
10:00am–12:30pm Update: Children's Workgroup Alan Fleischman, M.D. Chair, Working Group [2 hours, 30 minutes]
[10:30am–10:45am] BREAK [15 minutes]
12:30–1:30pm LUNCH—On your own
1:30pm–3:30pm The Office for Human Research Protectiosn (OHRP) [2 hours]
Introduction Greg Koski, Ph.D., M.D. Director, OHRP [10 minutes]
Education Jeffrey Cohen, Ph.D. Director, Division of Education [15 minutes]
Assuance George Gasparis, Acting Director, Division of Assurances and Quality Improvement [15 minutes]
Compliance Kristina Borror, Ph.D. Division of Compliance [15 minutes]
International Melody Lin, Ph.D., Deputy Director and Director, Office for International Activities [10 minutes]
Policy, Irene Stith-Coleman, Ph.D., Director, Office of Policy, Planning, and Special Projects [10 minutes]
3:30pm–3:45 BREAK [15 minutes]
3:45–5:30 Update and Discussion: Third Parties: Research Subjects? Mary Kay Pelias, J.D., Ph.D. Chair, Working Group [1 hour, 45 minutes]
5:30pm–5:pm Closing Comments/ ADJOURN [15 minutes]

Tuesday, July 31, 2001

8:30 am–8:45 am The Honorable Diane DeGette, Congresswoman, Colorado [15 minutes]
8:45 am–9:15 am Human Subject Protections, General Accounting Office (GAO), Marcia G. Crosse, Ph.D., Assistant Director, Health Care—Public Health Issues [30 minutes]
9:15 am–9:45 am National Bioethics Advisory Committee (NBAC), Marjorie Speers, Ph.D., Acting Executive Director, NBAC [30 minutes]
9:45 am–10:45 am HIPAA and the Privacy Regulation: The Implications for Research, Julie Kaneshiro, M.P.P., Policy Analyst, OSP, National Institutes of Health [1 hour]
10:45 am–11:00 am BREAK [15 minutes]
11:00 am–12:30 pm Informed Consent & Decisional Capacity Overview, Mary Faith Marshall, Jeremy Sugarman, MD, MPH, MA, Director, Center for the Study of Medical Ethics and Humanities, Professor of Medicine and Philosophy, Duke University Medical Center, Don Rosenstein, M.D., Chief Psychiatry Consultation-Liaison Service, National Institute of Mental Health, Adil Shamoo, Ph.D., Department of Biochemistry and Molecular Biology, University of Maryland School of Medicine, Jim McNulty, President, Depressive/Manic Depressive Association of Rhode Island [1 hour, 30 minutes]
12:30 pm–1:30 pm LUNCH—on your own [1 hour]
1:30 pm–2:30 pm Informed Consent (Continued) [1 hour]
2:30 pm–4:30 pm Update: Social Science, Felice Levine, Ph.D., Executive Officer, American Sociological Association; Jeffrey Cohen, Ph.D., Director, Education, OHRP [2 hours]
[3:00 pm–3:15 pm] BREAK
4:30 pm–5:00 pm Recap of Meeting & Action Items, Mary Faith Marshall, Ph.D., Chairperson, NHRPAC
5:00 pm ADJOURN

Kate-Louise Gottfried,

Executive Director, National Human Research Protections Advisory Committee.

[FR Doc. 01–17070 Filed 7–6–01; 8:45 am]

BILLING CODE 4150–28–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Community Coalition Development Projects for African American Communities, Program Announcement 01033

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease

Control and Prevention (CDC) announces the following meeting.

NAME: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Community Coalition Development Projects for African American Communities, PA#01033, meeting.

TIMES AND DATE: 9 a.m.–1 p.m., July 23, 2001 (Open); 1 p.m.–2 p.m., July 23, 2001 (Closed); 8:30 a.m.–4:30 p.m., July 24, 2001 (Closed); 8:30 a.m.–8:45 a.m., July 25, 2001 (Open); 8:45 a.m.–4:30 p.m., July 25, 2001 (Closed)

PLACE: The Westin Atlanta North at Perimeter, 7 Concourse Parkway, Atlanta, GA 30328.

STATUS: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92–463.

MATTERS TO BE DISCUSSED: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 01033.

CONTACT PERSON FOR MORE INFORMATION: Elizabeth A. Wolfe, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 8 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639–8025.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 2, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

[FR Doc. 01–17042 Filed 7–6–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0269]

Draft Guidance for Industry on the Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format.'' The agency has initiated a comprehensive effort to improve the format and content of prescription drug labeling. FDA intends to carefully coordinate development and implementation of these labeling initiatives to minimize the potential burden for manufacturers and other affected parties.

DATES: Submit written comments on the draft guidance by October 9, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 1–888–CBERFAX, or Voice Information System at 800–835–4709 or 301–827–1800. Send one self-addressed, adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Janet M. Jones, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or

Toni Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format.'' As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. Recently the agency published a proposed rule to revise the overall format of prescription drug labeling (65 FR 81082, December 22, 2000). Among other things, the agency proposed reordering the sections of the labeling based on the importance of the information to practitioners and the frequency with which practitioners refer to a section. Also, the agency proposed creating a ''highlights'' section and an index.

FDA is working on a proposed rule to revise the current requirements for the pregnancy subsection of labeling (see the notice (62 FR 41061, July 31, 1997) announcing a 21 CFR part 15 hearing to discuss the category requirements, and the notice (64 FR 23340, April 30, 1999) announcing a meeting of a public advisory committee to discuss possible changes to pregnancy labeling).

The agency also is developing guidance documents that focus on the content of certain labeling sections. The first draft guidance, ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics,'' was made available for public comment on June 21, 2000 (65 FR 38563). This draft guidance, ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format,'' is the second guidance document on the content and format of individual labeling sections. Among other things, this draft guidance discusses what studies to include in the Clinical Studies section, how to describe those studies, and how to present clinical study data in graphs and tables. The agency also is trying to raise awareness, with this draft guidance, of the implications for product promotion of information contained in the Clinical Studies section. This section exists in the current labeling and is expected to continue to exist when the proposed rule to revise the format for prescription drug labeling is made final.

At this time, FDA is also developing guidances for the Adverse Reactions, Clinical Pharmacology, and Warnings/Precautions sections of the labeling. The draft guidance for the Adverse Reactions section was made available for public comment on June 21, 2000 (65 FR 38563). The agency expects to publish draft guidances for the Clinical Pharmacology and Warnings/Precautions sections for comment in the