DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Conducting Successful Clinical Trials Under Good Clinical Practice Regulations to Facilitate the Product Approval Process; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA), Los Angeles District Office, in cooperation with the Southern California Pharmaceutical Discussion Group (SCPDG) and the Association of Clinical Research Professionals, is announcing a workshop intended to give clinical investigators and clinical research staff an opportunity to learn and discuss requirements and expectations for clinical research intended to support new product applications to FDA.

Date and Time: See Table 1 following the ''*Location*'' section of this document.

Location: See Table 1 below.

TABLE 1.

Meeting Address	Date and Local Time	FDA Contact Person
SAN DIEGO: Marriott Mission Valley Inn, 8757 Rio San Diego Dr., San Diego, CA, 619–692–3800	Monday, May 10, 1999, 8 a.m. to 5:30 p.m.	Sandi R. Velez
LOS ANGELES: Westin Bonaventure Hotel, 404 South Figueroa St., Los Angeles, CA, 213–624–1000	Wednesday, May 12, 1999, 8 a.m. to 5:30 p.m.	Do.
TUSCON: Plaza Hotel and Conference Center, 1900 East Speedway Blvd., Tucson, AZ, 520–327–7341	Friday, May 14, 1999, 8 a.m. to 5:30 p.m.	Do.

Contact: Sandi R. Velez, Los Angeles District Office, Office of the District Director (HFR–PA200), 19900 MacArthur Blvd., Irvine, CA 92612–2445, 949–798–7698, FAX 949–798–7715.

Registration: Space is limited. Preregistration and confirmation are required by April 28, 1999. Registration forms may be obtained from the contact listed previously. There is a $150 registration fee payable to SCPDG. The registration fee and form should be sent to Eileen Ohlander at 2525 Dupont Dr., RD–3C, Irvine, CA 92613, FAX 714–246–6220. The registration fee will cover actual expenses including refreshments, lunch, materials, and some speaker expenses. Parking fees are not included in the registration fee. Walk-ins will be accepted, provided space is available. Walk-in registration for each workshop is scheduled between 7:30 a.m. and 8 a.m. on the morning of each workshop.

If you need special accommodations due to a disability, please contact Sandi R. Velez at least 7 days in advance.

Dated: April 16, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10012 Filed 4–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 6 and 7, 1999, 8:30 a.m. to 5 p.m.

Location: CDER Advisory Committee Conference Room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Igor Cerny, or Tony Slater, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or by e-mail at CERNY@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and provide FDA with advice about the agency's development and publication of a list of bulk drug substances that may be used in pharmacy compounding that do not have a United States Pharmacopeia or National Formulary monograph and are not components of FDA-approved drugs. Specifically, the committee is likely to address the following drug substances as candidates for the bulk drugs list: 4-aminopyridine, 3,4-diaminopyridine, betahistine dihydrochloride, chloramine-T, cyclandelate, dinitrochlorobenzene, diphenylcyclopropenone, hydrazine sulfate, mild silver protein, monosodium asparate, pentylenetetrazole, peruvian balsam, and squaric acid dibutyl ester.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 23, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. for dinitrochlorobenzene, diphenylcyclopropenone, and squaric acid dibutyl ester, and between approximately 2:45 p.m. and 3:15 p.m. for 4-aminopyridine, 3,4-diaminopyridine, and betahistine dihydrochloride on May 6, 1999; and between approximately 10:15 a.m. and 10:45 a.m. for mild silver protein, cyclandelate, and monosodium asparate, and between approximately

2:45 p.m. and 3:15 p.m. for hydrazine sulfate on May 7, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 1999, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 16, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–10076 Filed 4–19–99; 11:05 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1266]

Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 21, 1999, the comment period for the draft guidance for industry entitled ''Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling'' that appeared in the **Federal Register** of January 28, 1999 (64 FR 4434). FDA is taking this action in response to several requests for an extension and to allow interested parties additional time to submit comments.

DATES: Written comments may be submitted by June 21, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–730), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3225.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 28, 1999, FDA published a notice announcing the availability of a draft guidance for industry entitled ''Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.'' The draft guidance is intended to clarify for prescription drug manufacturers, relabelers, and distributors FDA's position regarding placing the therapeutic equivalence code on approved FDA product labels and labeling. The January 28, 1999, notice invited interested persons to submit written comments on the draft guidance within 60 days.

The agency has received several requests to extend the comment period on the draft guidance. The agency has decided to reopen the comment period on the draft guidance until June 21, 1999, to allow the public more time to review and comment on its contents.

Interested persons may, on or before June 21, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10010 Filed 4–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovative Approaches to Clinical Trials Informatics.

Date: April 19, 1999.

Time: 1:00 PM to 3:00 PM.

Agenda: To review and evaluate contract proposals.

Place: 6130 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Wilna A. Woods, PHD, Deputy Chief, Special Review, Referral and Research Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Rockville, MD 20852, (301) 496–7903.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 15, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–10057 Filed 4–21–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Director's Consumer Liaison Group, April 19, 1999, 9:00 AM to April 29, 1999, 5:00 PM, Natcher Building, Conference Room B, 45 Center Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on April 13, 1999, 64 FR 18036.

The meeting will be held from April 19, 1999, 8:30 AM to April 20, 1999,