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