

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#### Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling; Availability; Reopening of Comment Period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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until June 21, 1999, the comment period for the draft guidance for industry entitled "Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling" that appeared in the **Federal Register** of January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**ADDRESSES:** Copies of the draft guidance for industry are available on the Internet at "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 Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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,