**FOR FURTHER INFORMATION CONTACT:** Robert E. Osterberg, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–5482 or M. David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry and reviewers entitled ''Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' When selecting the starting dose in an initial clinical trial for a new molecular entity (NME), one can only rely on the safety data generated in nonclinical studies since, by definition, there are no human data. The draft guidance describes a method by which a starting dose may be selected for an initial clinical trial that is not expected to result in significant toxicity, but that will allow reasonably rapid attainment of phase I trial objectives (e.g., assessment of the NME's tolerability, pharmacodynamic and/or pharmacokinetic profile). The draft guidance establishes a consistent terminology for discussing the starting dose and a strategy for selecting a maximum recommended safe starting dose based on no-observed-adverse-effect levels in animals. Common conversion factors for deriving human equivalent doses from animal data are provided, and factors to be considered in determining reasonable safety margins are discussed in detail. The draft guidance also addresses the use of the nonclinical pharmacologically active dose and systemic exposure data in selection of a maximum recommended clinical starting dose. Comments on dose escalation are outside the scope of this draft document.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on estimating a maximum safe starting dose in initial clinical trials for therapeutics in adult healthy volunteers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 8, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–906 Filed 1–15–03; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following advisory committee meeting. The meeting will be open to the public.

*Name:* Advisory Committee on Training in Primary Care Medicine and Dentistry.

*Date and Time*: February 10, 2003; 8:30 a.m.–4:30 p.m., February 11, 2003; 8 a.m.–2 p.m.

*Place:* The Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

*Purpose*: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. This meeting will be devoted to drafting the third report of the Advisory Committee which will be submitted to Congress and the Secretary of the Department of Health and Human Services in November 2003. The third report will focus on disparities in health care and their implications for primary care medical education.

*Agenda*: The meeting on February 10 will begin with welcoming and opening comments from the Chair and Executive Secretary of the Advisory Committee. A plenary session will follow in which the Advisory Committee members will work to draft various sections of the third report. The Advisory Committee will also divide into two workgroups to further develop the report.

On February 11 the Advisory Committee will meet in plenary session to discuss performance measures for programs under section 747 of the Public Health Service Act and methods of disseminating Advisory Committee recommendations. The Advisory Committee will discuss its role and provide an opportunity for public comment.

**FOR FURTHER INFORMATION CONTACT:** Anyone interested in obtaining a roster of members or other relevant information should write or contact Stan Bastacky, D.M.D., M.H.S.A., Acting Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A–21, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6326. The web address for information on the Advisory Committee is *http://bhpr.hrsa.gov/medicine-dentistry/actpcmd*.

Dated: January 10, 2003.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 03–1021 Filed 1–15–03; 8:45 am]

**BILLING CODE 4165–15–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; Comment Request; the Ethical Problems Encountered by Nurses and Social Workers: Implications for Job Satisfaction and Retention

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Department of Clinical Bioethics, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection:* Title: The Ethical Problems Encountered by Nurses and Social Workers:

Implications for Job Satisfaction and Retention. Type of Information Collection Request: new. Need and Use of Information Collection: The purposes of the study are (1) to identify common ethical problems experienced by nurses and social workers in health care settings; (2) to identify the relationships between selected individual and organizational factors and perceptions of ethical stress, job satisfication and retention; and (3) to identify the availability of ethics support services. The findings will provide valuable information concerning: (1) The extent to which ethical problems and stress are contributing to a shortage of health care providers; (2) the importance of ethics related content in nurses' and social workers' education; and (3) the importance of ethics support services. Frequency of Response: Once. Affected Public: Individuals; academic institutions; business or other for-profit; not-for-profit organizations. Type of Respondents: Registered nurses and social workers. The annual reporting burden is as follows: Estimated Number of Respondents: 2,700; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: .33; and Estimated Total Annual Burden Hours Requested: 891. The annualized cost to respondents is estimated at: $59,400. There are no capital costs to report. There are no operating or maintenance costs to report.

*Request for Comment:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans, contact Connie Ulrich, RN, PhD, Principal Investigator, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, Building 10, Room 1C118, Bethesda, MD 20892, or call non-toll-free number (301) 451–8338 or E-mail your request, including your address to: *culrich@cc.nih.gov*.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 9, 2003.

**David K. Henderson,**

*Deputy Director, Warren G. Magnuson Clinical Center, National Institutes of Health.*

**Ezekiel Emanuel,**

*Director, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health.*

[FR Doc. 03–938 Filed 1–15–03; 8:45 am]

**BILLING CODE 4140–01–M**

## 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 National 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Host-Tumor Cell Interactions in Myeloma.

*Date:* January 28, 2003.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate to review and evaluate grant applications.

*Place:* National Institutes of Health, 6116, Executive Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* William D. Merritt, PhD, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8034, MSC 8328, Bethesda, MD 20892–8328, 301–496–9767.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(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: January 7, 2003.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–930 Filed 1–15–03; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of 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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, 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 in advance of the meeting.

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

*Name of Committee:* National Cancer Advisory Board, Ad Hoc Subcommittee on Confidentiality of Patient Data.

*Dates:* February 10–12, 2003.

*Open:* February 10, 2003, 7:15 p.m. to 8:15 p.m.

*Agenda:* To discuss activities related to the Ad Hoc Subcommittee on Confidentiality of Patient Data.

*Place:* Bethesda Hyatt Hotel, 1 Metro Place, Bethesda, MD 20892.

*Contact Person:* Ms. Mary McCabe, Executive Secretary, National Cancer Institute, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, MD 20892, (301) 496–6404.

*Name of Committee:* National Cancer Advisory Board.

*Open:* February 11, 2003, 8:30 a.m. to 12:05 p.m.