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FDA is announcing the availability of a draft guidance for industry and reviewers entitled ''Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers.''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 The draft guidance describes a method by which a starting dose may be selected for an initial clinical trial that is not expected to result in significant toxicity, but that will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 The draft guidance establishes a consistent terminology for discussing the starting dose and a strategy for selecting a maximum recommended safe starting dose based on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 The draft guidance also addresses the use of the nonclinical pharmacologically active dose and systemic exposure data in selection of a maximum recommended clinical starting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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on estimating a maximum safe starting dose in initial clinical trials for therapeutics in adult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persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance.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

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

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: