harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In the **Federal Register** of September 25, 2001 (66 FR 49029), FDA published a draft tripartite guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products.'' The notice gave interested persons an opportunity to submit comments by November 26, 2001. After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three regulatory agencies on February 7, 2002.

This guidance is an annex to an ICH guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products'' (66 FR 56332). It is intended to provide guidance on the application of bracketing and matrixing for stability studies conducted in accordance with the principles outlined in Q1A(R).

ICH Q1A(R) notes that, if justified, the use of two types of reduced stability study designs (i.e., bracketing and matrixing) can be applied to the testing of new drug substances and products, but ICH Q1A(R) provides no further guidance on the subject. This ICH Q1D guidance is intended to provide guidance on bracketing and matrixing designs. Specific principles are defined in this guidance for situations in which bracketing or matrixing can be applied and where bracketing or matrixing can be applied if additional justification is provided. Design factors and other considerations are presented, and potential risks of using reduced designs are discussed. Sample designs are also provided for illustrative purposes.

This guidance represents the agency's current thinking on reduced stability testing of new drug substances and products. 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 statues and regulations.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the 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 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 *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/publications.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 8, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–904 Filed 1–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0492]

Draft Guidance for Industry and Reviewers on Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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.'' This draft guidance outlines a common process (algorithm) and terminology for deriving a maximum recommended starting dose for ''first in human'' clinical trials of new molecular entities in adult healthy volunteers. Described in the guidance is a method for using nonclinical data to select a maximum starting dose in adult humans that is not expected to result in significant toxicity. The goal is to ensure the safety of adult human volunteers in initial clinical trials.

DATES: Submit written or electronic comments on the draft guidance by March 17, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels 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. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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: