the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*.

FOR FURTHER INFORMATION CONTACT: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration,1451 Rockville Pike, Rockville, MD 20852, 301–594–5476.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for reviewers entitled ''Integration of Study Results to Assess Concerns About Human Reproductive and Developmental Toxicities.'' This draft guidance describes a process for estimating human reproductive and development risks as a result of drug exposure. The integration process is intended to estimate the likelihood a drug will increase the risk of adverse human reproductive or developmental effects. The process is based on the evaluation of a complete set of reproductive and general toxicology studies conducted in animals, pharmacokinetics, and the absorption and distribution of metabolic elimination (ADME) studies conducted in animals and humans. The evaluation also compares animal and human drug-induced pharmacodynamic responses, drug metabolism and disposition, drug-induced pharmacologic and toxic effects, and drug exposures in animal studies versus those at the highest recommended dose in humans.

An earlier version of this integration tool was presented in a public meeting announced on May 4, 1999 (64 FR 23844), and held on June 24, 1999. The draft integration tool, slides from the presentations at the meeting, and comments received subsequent to the meeting were placed on the FDA Web site and in docket number 99N–2079. This draft guidance incorporates modifications as a result of the public meeting and comments submitted to the public docket.

The type and extent of the available toxicology data may vary depending on the biologic actions of the product, test systems available for studying the compound, and other factors. In some instances, the data may not include all desirable reproductive toxicology, general toxicology, pharmacokinetics, and ADME studies. Such limitations of the available data may preclude use of the integration process (e.g., often the case for biologic products). However, even if the integration process cannot be used, the product should be evaluated to the greatest extent possible in accordance with sound scientific principles and the considerations described in this document.

For purposes of this draft guidance, all reproductive risks are divided into one of two broad categories of toxicity—reproductive and developmental toxicity, which are further subdivided into seven classes of toxicity. The three classes of reproductive toxicity include: Effects on fertility, parturition, and lactation. The four classes of developmental toxicity include: Mortality, dysmorphogenesis (structural alterations), alterations to growth, and functional toxicities. For a given drug, each class of toxicity should ordinarily be assessed individually.

The criteria presented in the draft guidance are derived from a limited sample of pharmaceuticals where the clinical outcomes are reasonably well defined. The Center for Drug Evaluation and Research (CDER) believes that using specific criteria and benchmark values to assess the potential to increase risk to humans for adverse reproductive and developmental outcomes will result in a more unbiased and uniform evaluation. CDER also believes this approach will help identify specific areas of additional information about a pharmaceutical that would be useful in more fully defining risk and allow specific analysis of areas of disagreement that influence the risk evaluation. CDER is particularly interested in comment on the appropriateness of the values used to define levels of increased risk for products with positive signals for reproductive or developmental toxicity and on experience in applying the outlined evaluation approach using information that may exist in public and commercial domains.

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 ''Integration of Study Results to Assess Concerns About Human Reproductive and Developmental Toxicities.'' 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 (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 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: November 1, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–28258 Filed 11–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0195]

Draft ''Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations'' dated November 2001. The draft guidance document, when finalized, is intended to provide information to assist FDA staff in creating and implementing effective collaborations consistent with relevant legal, ethical, and policy considerations. FDA and its stakeholders use collaborations to take advantage of and amplify the unique resources possessed by each to address a variety of public health issues. The draft guidance document enumerates factors that FDA employees should consider, and the procedures they should follow, when planning a leveraged collaboration.

DATES: Submit written or electronic comments on the draft guidance to

ensure their adequate consideration in preparation of the final document by February 11, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of ''Guidance for FDA: The Leveraging Handbook, An Agency Resource for Effective Collaborations'' dated November 2001 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER-FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document 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*.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations'' dated November 2001. ''Leveraging'', as used by FDA, describes formal or informal relationships or agreements with others outside FDA that enhance the agency's ability to meet its public health mission. Leveraged collaborations between FDA and non-FDA partners, such as industry, academia, consumer groups, scientific experts, public health providers, States, and other government agencies, are not new to the agency. For many years, FDA has used collaborations to accomplish a wide variety of tasks related to fulfilling its public health mission. FDA is careful to structure its collaborations so that the agency's regulatory independence, impartiality, and integrity are preserved. Successful collaborations used by FDA and its partners range in size and complexity from simple daylong workshops and training sessions to the creation of cooperatively administered centers that provide critical product-related safety information and expertise, i.e., the National Center for Food Safety and Technology, the Joint Initiative for Food Safety and Nutrition, and the Product Quality Research Institute. Other collaborations involve conducting research to improve the safety, efficacy, purity, or potency of regulated products and convening experts to evaluate emerging public health issues and to recommend actions that should be taken to address the issues.

FDA held two public meetings that were announced in the **Federal Register** to discuss ways in which FDA could improve and increase collaborations with outside organizations (65 FR 8365, February 18, 2000). The meetings were held on March 23, 2000, at Stanford University, and on April 12, 2000, at Duke University. More than 300 people attended the meetings and more than 25 leveraging proposals were presented to the agency. FDA is currently reviewing the proposals. To review the transcripts of the meetings, you can visit the FDA Dockets Management Branch Web site at *http://www.fda.gov/ohrms/dockets/dockets/00n0001/00n0001.htm*.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the formation and implementation of leveraged collaborations between FDA and outside organizations. 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 requirement of the applicable statutes and regulations.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by February 11, 2002. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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 draft guidance document at either *http://www.fda.gov/oc/leveraging/handbook.html* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 31, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–28386 Filed 11–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 2001:

Name: Council on Graduate Medical Education (COGME).

Date and Time: December 5, 2001, 8:30 a.m.–4:30 p.m., December 6, 2001, 8:30 a.m.–12 p.m.

Place: Holiday Inn, Capitol, Columbia Ballroom, 550 C Street, SW., Washington, DC 20024.

The meeting is open to the public.

Agenda: The agenda for the first day, December 5, will include: Welcome and opening comments from the Acting Administrator, Health Resources and Services Administration; the Associate Administrator for Health Professions; and the Acting Executive Secretary of COGME. There will be a panel of speakers on the topic of ''Models of Health Care Delivery.'' The afternoon agenda includes a presentation on ''Substitutability in the Physician Workforce.'' The Council's three workgroups will convene. They are: Workgroup on Diversity, Workgroup on Graduate Medical Education Financing, and Workgroup on Workforce.

The agenda for the second day, December 6, will include reports from the three workgroup chairs. Work will continue on COGME's Final Report. There will be a discussion on plans for future work and new business.

Anyone requiring information regarding the meeting should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Acting Executive Secretary, Council on Graduate Medical Education, Division of Medicine and Dentistry, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone (301) 443–6326,