by the Department of Health and Human Services (DHHS) and the Department of Justice with regard to safety, abuse potential, risk management, risk communication, and quantitative evaluation of spontaneous reports, and recommends actions to be taken by DHHS with regard to marketing, investigation, and control of such drugs or other substances.

**Criteria for Members**

Persons nominated for membership on the committees described previously in this document must have adequately diversified research and/or clinical experience appropriate to the work of the committee in such fields as anesthesiology, surgery, internal medicine, infectious disease, asthma, rheumatology, microbiology, pediatrics, ophthalmology, cardiology, clinical/medical oncology, hematology, radiology, nuclear medicine, biostatistics, epidemiology, dermatopathology/immunodermatology, dermatology, psychopharmacology, neurochemistry, neuropharmacology, endocrinology, obstetrics and gynecology, reproductive endocrinology, gastroenterology, pharmacology, clinical pharmacology, hepatology, virology, pharmaceutical manufacturing, bioavailability and bioequivalence research, pharmacokinetics, neurology, psychiatry, psychology, neuropharmacology, neuropathology, pulmonary disease, allergy, immunology, clinical immunology, safety, abuse potential, risk management, risk communication and quantitative evaluation of spontaneous reports or other appropriate areas of expertise.

The specialized training and experience necessary to qualify the nominee as an expert suitable for appointment is subject to review, but may include experience in medical practice, teaching, research, and/or public service relevant to the field of activity of the committee. The term of office is up to 4 years.

**Criteria for Consumer-Nominated Members**

FDA currently attempts to place on each of the committees described previously in this document one voting member who is nominated by consumer organizations. These members are recommended by consumer organizations which have the responsibility for screening, interviewing, and recommending candidates with appropriate scientific credentials. Candidates are sought who are aware of the consumer impact of committee issues, but who also possess enough technical background to understand and contribute to the committee's work. This would involve, for example, an understanding of research design, benefit/risk and the legal requirements for safety and efficacy of the products under review, and considerations regarding individual products. The agency notes, however, that for some advisory committees, it may require such nominees to meet the same technical qualifications and specialized training required of other expert members of the committee. The term of office for these members is up to 4 years. Nominations for all committees listed previously in this document are invited for consideration for membership as openings become available.

**Nomination Procedure**

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Nominations shall specify the committee for which the nominee is recommended. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict on interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 5, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 02–17477 Filed 7–10–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Drug Safety and Risk Management Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Drug Safety and Risk Management Advisory Committee (formerly Drug Abuse Advisory Committee).

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on July 17, 2002, from 8 a.m. to 5 p.m.

*Location*: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person*: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–021), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (for Express delivery: 5630 Fishers Lane, Room 1093, Rockville MD 20857), 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss ways to improve the usefulness of consumer medication information (CMI) distributed with prescriptions being filled at the nation's pharmacies. Findings of a recent FDA-sponsored study(www.fda.gov/ohrms/dockets/ac/acmenu.htm) showed that CMI is currently being distributed with more than 85 percent of prescriptions and that scientific accuracy of the materials is high, but the usefulness of materials is variable due largely to omissions of important risk and benefit information. The committee will consider: (1) Potential causes of insufficiencies in CMI, including current practices of the parties involved in developing and processing CMI and pharmacy practices that may affect the distribution and content of CMI, and (2) potential interventions to address causes of CMI insufficiencies in the current system, and scientific methods to assess and monitor whether effective communication of key information to patients is occurring.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 15, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 15, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly L. Topper by July 15, 2002.

FDA regrets that it was unable to publish this notice 15 days prior to the Drug Safety and Risk Management Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Drug Safety and Risk Management Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15–day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2).

Dated: July 5, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 02–17402 Filed 7–10–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02D–0258]**

### Draft Revised Guidance for Industry on Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry entitled ''Bioavailability and Bioequivalence for Orally Administered Drug Products—General Considerations.'' FDA's Biopharmaceutics Coordinating Committee determined that a revision of the guidance was necessary as a result of experience with implementation of the guidance, input from the Advisory Committee for Pharmaceutical Science at a meeting held on November 28 and 29, 2001, and changes in agency thinking based on new data. This revision should provide better guidance to sponsors conducting bioavailability (BA) and bioequivalence (BE) studies for orally administered drug products.

**DATES:** Submit written or electronic comments on the draft revised guidance by August 12, 2002. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this draft revised 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 one self-addressed adhesive label to assist that office in processing your requests. Submit written comments 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft revised guidance for industry entitled ''Bioavailability and Bioequivalence for Orally Administered Drug Products—General Considerations.'' This document is intended to provide information to sponsors and/or applicants planning to include BA and BE information for orally administered drug products in investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and their supplements. This draft revises the guidance published as a final guidance in the **Federal Register** on October 27, 2000 (65 FR 64449). It is being revised as a result of changes in agency thinking based, in part, on input from the Advisory Committee for Pharmaceutical Science, experience with the guidance, and comments from industry. This draft revision of the guidance does the following: (1) Changes recommendations for the use of replicate and nonreplicate study designs for extended-release products and includes recommendations regarding dissolution methods development (section III, Methods to Document BA and BE), (2) changes to the use of only the average BE approach for BE comparisons, (section IV, Comparison of BA Measures in BE Studies), (3) clarifies the definitions of proportionality (section V, Documentation of BA and BE) in the documentation of BA and BE in response to comments from industry, (4) changes recommendations regarding waivers of BE studies (subsection V.C.2, Waivers of In Vivo BE Studies (Biowaivers)) in certain situations, and (5) makes other changes such as use of the more general term ''modified release'' as opposed to ''extended'' or ''delayed release'' (subsections V.D.2 and V.D.3) and minor corrections to citations of the regulations. This draft revision should provide better guidance to sponsors conducting BA and BE studies for orally administered drug products.

This draft revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft revised guidance, when finalized, will represent the agency's current thinking on submitting BA and BE information to INDs, NDAs, and ANDAs. 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.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the draft revised 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. This draft revised 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.

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

Dated: June 28, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–17403 Filed 7–10–02; 8:45 am]

**BILLING CODE 4160–01–S**