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.

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