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 Hilda Scharen at least 7 days in advance of the meeting.

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

Dated: September 24, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–22214 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0431]

Draft Guidance for Industry and the Food and Drug Administration; Current Good Manufacturing Practices for Combination Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practices for Combination Products.'' Once finalized, this guidance will provide guidance to industry and FDA staff on the applicability of current good manufacturing practices (CGMP) for combination products.

DATES: Submit written or electronic comments on the draft guidance by December 3, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Patricia Y. Love, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934, FAX 301–427–1935, e-mail: *patricia.love@oc.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practices for Combination Products.'' Combination products are defined under 21 CFR 3.2(e). This draft guidance document makes recommendations for achieving compliance with applicable CGMPs for the drug, device, or biological product constituent parts of a combination product. In addition, the draft guidance document makes recommendations for achieving compliance with applicable CGMPs for combination products where the constituent parts of a combination product are joined together. The applicable regulations include the CGMP regulations for finished pharmaceuticals, or drug products, and most biological products (21 CFR parts 210 and 211); the biological product regulations for biological products (21 CFR parts 600–680); and the quality system regulations for devices (21 CFR part 820).

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 CGMP for combination 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper 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 Division of Dockets Management 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/combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22205 Filed 9–29–04; 1:51 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0440]

Draft Guidance for Industry on Computerized Systems Used in Clinical Trials; 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 entitled ''Computerized Systems Used in Clinical Trials.'' This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999.

DATES: Submit written or electronic comments on the draft recommendations by January 3, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; to the Office of Health and Industry Programs,