oral presentations should notify the contact person before September 30, 2003, and submit a brief statement of the general nature of the comments they wish to present, and the names and addresses of proposed participants.

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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: August 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–22580 Filed 9–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science. This meeting was announced in the **Federal Register** of August 14, 2003 (68 FR 48614). The amendment is being made to reflect a change in the date and time, agenda, and procedure portions of the meeting. Due to administrative complications, all topics previously announced will be discussed on September 17, 2003. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Hilda Scharen, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 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 12539. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2003, FDA announced that a meeting of the Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science would be held on September 17 and 18, 2003. On page 48614, in the second column, the agenda portion of the meeting is amended to read as follows:

Date and Time: The meeting will be held on September 17, 2003, from 8:30 a.m. to 5 p.m.

Agenda: On September 17, 2003, the subcommittee will discuss the following topics: (1) Quality by design and how it is distinct from approaches that attempt to test in quality; and (2) define principles by which risk management is integrated into decisionmaking.

Procedures: Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m.

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: August 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–22628 Filed 9–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0385]

Draft ''Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information;'' 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 Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information'' dated September 2003. The draft guidance document provides recommendations to applicants on preparing and using comparability protocols for changes in chemistry, manufacturing, and controls of products in approved marketing applications. The guidance applies to comparability protocols that applicants would submit in biologics license applications (BLAs) or supplements to these applications for therapeutic recombinant deoxyribonucleic acid (DNA) derived protein products, naturally derived protein products, plasma derivatives, vaccines, allergenics and therapeutic DNA plasmids. The guidance also applies to new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), or supplements to these applications for protein drug products, and certain peptides that are not sufficiently characterizable (i.e., complex mixture of small peptides).

DATES: Submit written or electronic comments on the draft guidance by December 4, 2003, to ensure their adequate consideration in preparation of the final guidance. 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 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; or 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; or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or Stephen K.

Moore, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430; or Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information'' dated September 2003. The draft document applies to comparability protocols that would be submitted in BLAs, or supplements to these applications, for therapeutic recombinant DNA derived protein products, naturally derived protein products, plasma derivatives, vaccines and allergenics, therapeutic DNA plasmids and NDAs, ANDAs and investigational new drugs (INDs) for protein drug products, and not sufficiently characterizable peptide products (e.g., complex mixture of small peptides).

The draft guidance does not pertain to comparability protocols for human blood and blood components intended for transfusion and for further manufacture, somatic cell therapy, and gene therapy vectors (except therapeutic DNA plasmids). It also does not pertain to vaccines for veterinary use because these are regulated by the U.S. Department of Agriculture.

The draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the guidance was approved under OMB control numbers 0910–0001, 0910–0032, and 0910–0338.

The 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 this topic. 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

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of 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 at *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cvm/guidance/published.htm*.

Dated: August 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–22577 Filed 9–3–03; 10:00 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice; 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 ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' In the draft guidance, the agency describes a formal, two-tiered dispute resolution process intended to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP) that arise during FDA inspections of pharmaceutical manufacturers.

DATES: Submit written or electronic comments on the draft guidance by March 3, 2004. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collection of information by November 4, 2003.

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; the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448; or Communications Staff (HFV–12), Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance and on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the collection of information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary Jane Mathews, Center for Drug Evaluation and Research (HFD–3), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–2847.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' The guidance was drafted as part of the FDA initiative ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products.

The agency formed the Dispute Resolution Working Group comprising representatives from the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The working group met weekly on issues related to the dispute resolution process and met with stakeholders in December 2002 to seek their input.