

day before the meeting at: www.fda.gov/ohrms/dockets/ac/acmenu.htm.

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 February 25, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 4, 2003, and between approximately 8:30 a.m. and 9 a.m. and 11:30 a.m. and 12 noon on March 5, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2003, 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 LaNise Giles at 301-827-7001 at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the March 4, 2003, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Arthritis 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: February 13, 2003.

Linda Arey Skladany,

Associate Commissioner for External Affairs.
[FR Doc. 03-4350 Filed 2-24-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0061]

Draft Guidance for Industry on Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Comparability Protocols—Chemistry, Manufacturing, and Controls Information." This draft document provides recommendations to applicants on preparing and using comparability protocols for postapproval changes in chemistry, manufacturing, and controls (CMC) information.

DATES: Submit written or electronic comments on the draft guidance by June 25, 2003. 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; or 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 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 that office in processing your requests. Submit phone requests to 800-835-4709 or 301-827-1800. 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Stephen Moore, Center for Drug Evaluation and Research (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,

301-827-6430, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20892, 301-435-5681, 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 guidance for industry entitled "Comparability Protocols—Chemistry, Manufacturing, and Controls Information." This draft guidance applies to comparability protocols that would be submitted in 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, except for applications for protein products. Well-characterized synthetic peptides submitted in these applications are included within the scope of this guidance. This draft guidance also applies to comparability protocols submitted in drug master files (DMFs) and veterinary master files (VMFs) that are referenced in these applications. A separate guidance will address comparability protocols for proteins as well as for peptide products outside the scope of this guidance that are submitted in these applications. This separate guidance will also address comparability protocols for products submitted in biologics license applications (BLAs).

This 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 this guidance was approved under OMB control numbers 0910-0001 and 0910-0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on "Comparability Protocols; Chemistry, Manufacturing, and Controls Information". 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 (see