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Draft Guidance for Industry on Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols—Chemistry, Manufacturing, and Controls Information.''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DATES: Submit written or electronic comments on the draft guidance by [*insert date 120 days after date of publication in the* **Federal Register**]. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard 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 Dockets Management Branch 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/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/cvm/guidance/published.htm.

Dated: February 19, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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