

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0571]

Draft Guidance for Industry on Drug Substance; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Drug Substance: Chemistry, Manufacturing, and Controls Information.” This draft guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug substances that should be submitted to support original new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), and abbreviated new animal drug applications (ANADAs). The draft guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 180 days after date of publication in the **Federal Register***].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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. 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Steve Miller, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2392, or

Chris Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, 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 “Drug Substance: Chemistry, Manufacturing, and Controls Information.” This draft guidance provides recommendations on the drug substance information to be submitted in NDAs, ANDAs, NADAs, and ANADAs to ensure continued drug substance and drug product quality (i.e., the identity, strength, quality, purity, and potency). Recommendations are provided on the information that

should be included for: (1) Nomenclature, structure, and general drug substance properties, (2) manufacture, (3) characterization, (4) control of drug substance, (5) reference standards or materials, (6) container closure system, and (7) stability. The draft guidance is structured to facilitate the preparation of applications submitted in CTD format. The draft guidance, when finalized, will replace the guidance entitled “Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substance” (February 1987).

This 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 these topics. 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 copies of any 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. 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 document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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