

AMB

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0526]

Draft Guidance for Industry on Drug Product: Chemistry, Manufacturing, and Controls Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Drug Product: Chemistry, Manufacturing, and Controls Information." This draft guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug products that should be submitted in original new drug applications (NDAs) and abbreviated new drug applications (ANDAs). The draft guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 150 days after date of publication in the Federal Register]*.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Upinder Atwal, Center for Drug Evaluation and Research (HFD-623), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301-827-5848, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-435-5681.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Drug Product: Chemistry, Manufacturing, and Controls Information.” This draft guidance addresses the information to be submitted in NDAs and ANDAs for drug products to ensure continued product quality (i.e., identity, strength, quality, purity, and potency). Recommendations are provided on the information that should be included for: (1) Description and composition of the drug product, (2) manufacture, (3) control of excipients, (4) control of drug products, (5) reference standards or materials, (6) container closure systems, and (7) stability. Information is also provided on the type of pharmaceutical development information that should be included in an NDA or ANDA. 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 Documentation for the Manufacture and Controls for Drug Products” (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 number 0910–0001.

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 CMC information for drug 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.

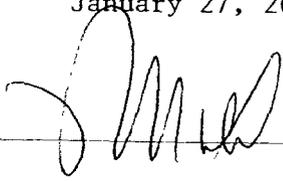
II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen 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 document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

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Margaret M. Dotzel
Assistant Commissioner for Policy

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