

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0368]

DMB

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Certifier	<i>Prodeon</i>

Draft Guidance for Industry on Submitting Marketing Applications According to the ICH/CTD Format; General Considerations; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Submitting Marketing Applications According to the ICH/CTD Format; General Considerations." This guidance provides general guidance on how to organize new drug applications (NDAs), abbreviated new drug applications (ANDAs) and biologics license applications (BLAs) based on the International Conference on Harmonisation (ICH) M4 guidance on organizing the Common Technical Document (CTD) for the registration of pharmaceuticals for human use.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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 the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels to assist the 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug

Administration, 1451 Rockville Pike, Rockville, MD 20857, 301-594-5400; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug

Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Submitting Marketing Applications According to the ICH/CTD Format; General Considerations." This guidance is intended to supplement the ICH M4 guidances on quality, safety, and efficacy, which were signed off at step 4 of the ICH process in October 2000. Final versions of the M4 guidances on organizing the CTD will be available soon. This general considerations guidance applies to NDAs, ANDAs, and BLAs for both new molecular entities and nonnew molecular entities and all related presubmissions, supplements, and amendments.

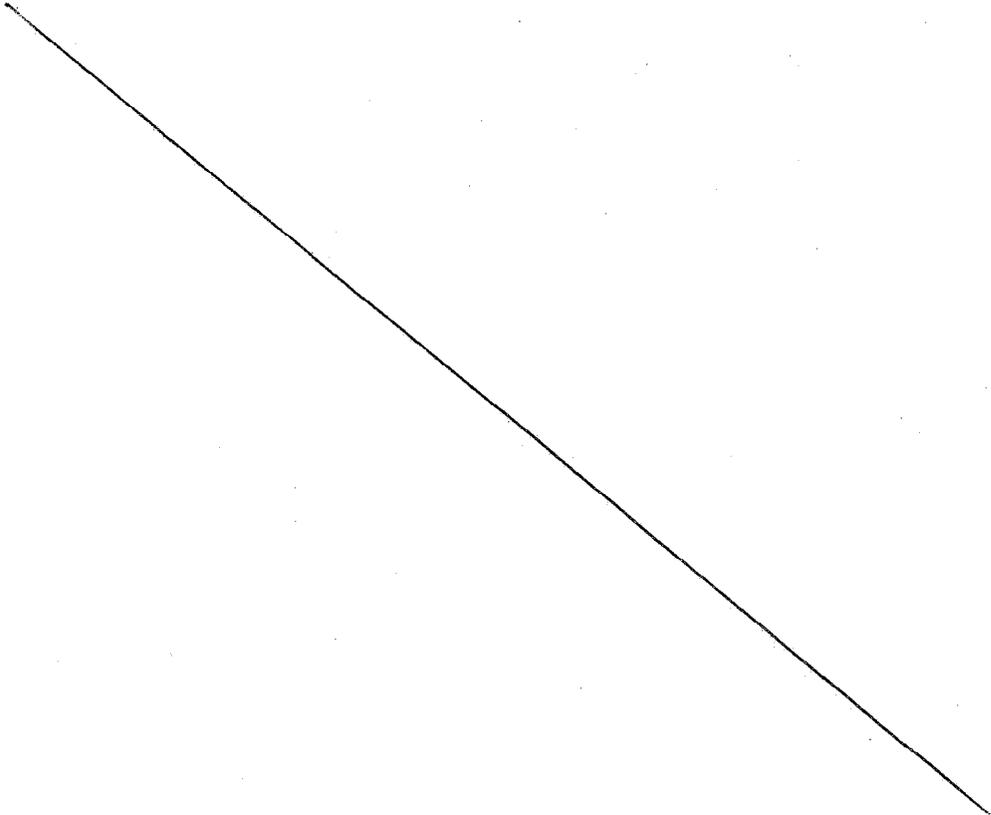
This guidance provides some general information on the organization and format of the CTD as well as recommendations for completing module 1, which contains administrative and prescribing information specific to each regulatory authority. The content of documents in the CTD is provided in other FDA guidance documents. When finalized, this guidance will supersede the "Guidelines on Formatting, Assembling, and Submitting of New Drug and Antibiotic Applications," issued in February 1987.

This level 1 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 general considerations for submitting marketing applications according to the ICH/CTD format. 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 (address above) written 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

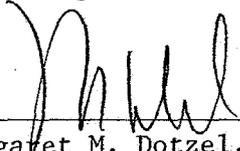


III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 8/28/01

August 28, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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