

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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10/18/05  
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Center *J. COLE*

[Docket No. 2003D-0367]

**Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.” This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), investigational new drug applications (INDs), master files, advertising material, and promotional labeling using the electronic common technical document (eCTD) specifications. The submission of these documents in electronic format should improve the agency’s efficiency in processing, archiving, and reviewing them.

**DATES:** Submit written or electronic comments on agency guidances at any time.

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**ADDRESSES:** Submit written requests for single copies of the 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 telephone requests to 800-835-4709 or 301-827-1800. Submit written comments on the 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, e-mail: [levinr@cder.fda.gov](mailto:levinr@cder.fda.gov), 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 guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.” This document provides guidance to industry regarding submission of marketing applications (NDAs, ANDAs, BLAs), INDs, and related submissions (master files, advertising, and promotional labeling) in electronic

format based on the International Conference on Harmonisation eCTD specifications.

In the **Federal Register** of August 29, 2003 (68 FR 52044), FDA made available a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions” and gave interested persons an opportunity to submit comments by October 28, 2003. The agency considered received comments as it finalized this guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on providing applications and related submissions in electronic 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.

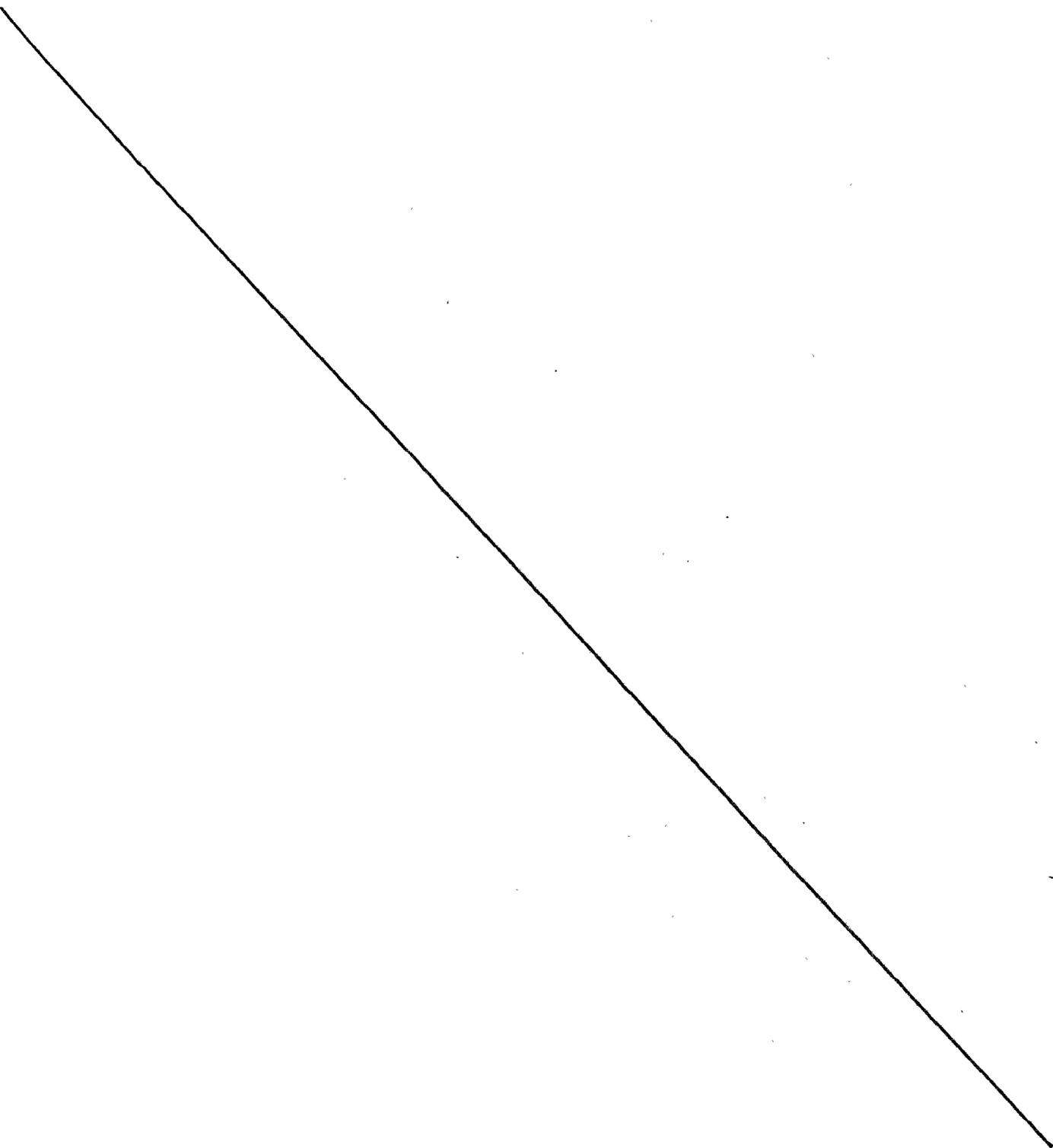
## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 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. Paperwork Reduction Act of 1995**

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 collections of information in this guidance have been approved under OMB control number 0910–0014 (until January 31, 2006), OMB control number 0910–0001 (until May 31, 2008), and OMB control number 0910–0338 (until September 30, 2008).



IV. 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>.

Dated: 10/12/05  
October 12, 2005.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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