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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0314]

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Certifier D. Hawkins

"Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format--Investigational New Drug Applications (INDs);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format--Investigational New Drug Applications (INDs)" dated March 2002. The document is intended to provide guidance to sponsors on the design, development, organization, and submission in electronic format of an IND to the Center for Biologics Evaluation and Research (CBER). This guidance finalizes the draft guidance that was announced in the FEDERAL REGISTER on June 1, 1998 (63 FR 29741).

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

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, cb0123

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1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the guidance document 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>.

FOR FURTHER INFORMATION CONTACT:

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Center for Biologics Evaluation and Research (HFM-17),  
Food and Drug Administration,  
1401 Rockville Pike,  
Rockville, MD 20852-1448,  
301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format--Investigational New Drug Applications

(INDs)" dated March 2002. The agency has developed this guidance to assist sponsors on the design, development, organization, and submission in electronic format of INDs to CBER. The guidance announced in this notice finalizes the draft "Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products" dated May 1998 (63 FR 29741, June 1, 1998).

This document reflects CBER's experience with the electronic IND pilot program and incorporates knowledge gained from development of the electronic marketing applications guidance document entitled "Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format--Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Applications (NDA)]" November 12, 1999 (64 FR 61647), revised. The agency also incorporated suggestions and recommendations from sponsors in developing a table of contents driven navigational system. However, this guidance does not address the scientific, clinical, and regulatory requirements for preparing an IND submission. These requirements can be found in title 21 of the Code of Federal Regulations, part 312 (21 CFR part 312). Part 312 must be followed in the preparation of any IND.

FDA currently is working on electronic submissions in the Common Technical Document (CTD) format developed by the International Conference on Harmonization (ICH). As FDA develops guidance on electronic CTD submissions, CBER intends to harmonize this guidance with the CTD guidance. This guidance describes how sponsors may submit electronic INDs to CBER. Sponsors may continue to submit INDs in paper form.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

## II. Comments

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see ADDRESSES) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy.

Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

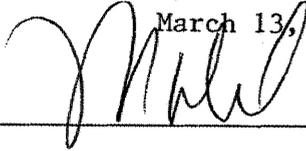
III. Electronic Access

Persons with access to the Internet may obtain the document

at either <http://www.fda.gov/cber/guidelines.htm> or  
<http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 3/13/02

March 13, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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Dawn P. Hawkins