MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

2233 '03 AUG 26 P2:24

DATE: August 26, 2003

FROM: Linda Burek, Director
Office of Information Technology
CDER, HFD-070

SUBJECT: Docket 92S-0251 - Transmittal

TO: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR Part 11.2(b) (2), and on behalf of the Center for Drug Evaluation and Research (CDER), please find attached notification of CDER's readiness to accept electronic regulatory submissions for:

Submission: Investigational New Drug Applications
New Drug Applications
Abbreviated New Drug Applications
Master Files
Annual Reports
Promotional material

Regulatory Citation: 21 CFR 312; 21 CFR 314;
Effective Date:

Please add the attached notification to the official docket 92S-0251.

On September 1, 2003, CDER will begin a pilot program of accepting fully electronic submissions using the eCTD specifications. CDER has posted the technical specifications for preparing and testing these electronic submissions on the Internet at http://www.fda.gov/cder/regulatory/ersr/ectd.htm.
Sponsors and applicants wishing to provide submissions following the eCTD specifications should contact CDER prior to creating or sending an eCTD submission at esub@cder.fda.gov to inform us of your plans. You will need to send in a sample submission prior to sending in the official submission to ensure that you have the processes properly worked out. When sending an e-mail please include the following:

- Contact Person Name - This will be the main contact during the sample eCTD submission phase.
- Contact Person's Company Name

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- Contact Person's Mailing Address
- Contact Person's Phone Number
- Contact Person's Email Address
- Date When You Plan To Submit An Application

A technical representative from the FDA will contact you and assign a number to be used in preparing the sample, as well as arrange a time to test the sample.

Once the sample eCTD submission has been created, it should be submitted to FDA for testing. This is a sample submission only and is not considered an official submission for review purposes. Your cover letter should clearly indicate that it is a test eCTD submission. You should leave the regulatory transmittal forms (e.g., form 1571, 356h, 2252) blank.

You should send one copy of the electronic sample submission to the CDER Central Document Room (CDR) at the address provided by FDA's technical representative.

Once received, FDA will test the sample submission. It will be processed to ensure that it conforms to the FDA eCTD Specifications. These tests include but are not limited to DTD validation, verification of file checksums, verification of the presence of the modified file, and identification of missing files.

The contents of the sample eCTD submission will NOT be reviewed by an FDA reviewer. The FDA will provide the participant with a report highlighting the errors found during the initial processing of the sample eCTD submission.

The participant should correct all errors identified by the FDA. The revised sample eCTD submission should use the next higher sequence number, i.e., no submission should use the same submission sequence number as a previous submission. The revised submission should be resubmitted.

Once a sample submission has been processed successfully by FDA, the sponsor or applicant may then update their submission with the actual application or DMF number, completed regulatory forms and any other pertinent data and submit the electronic submission using the eCTD specifications to CDER's Central Document Room as an official regulatory submission.