MEMORANDUM

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

2003 SEP 12 10:15

DATE:

FROM: James Shugars, 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 Type: Investigational New Drug Applications
New Drug Applications
Biologics Licensing Applications
Abbreviated New Drug Applications
Master Files
Annual Reports

Regulatory Citation: 21 CFR 312; 21 CFR 314; 21CFR 600

Effective Date: January 01, 2008

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

Effective December 31, 2007, CDER is withdrawing Memorandum 6 (dated January 29, 1999), Memorandum 24 (dated July 09, 2002), and Memorandum 30 (dated March 31, 2004). After that date, electronic submissions to those submission types referenced above should in the format as described in Memorandum 27 (dated August 27, 2003), i.e., eCTD format (http://www.fda.gov/cder/guidance/7087rev.pdf).

Exceptions to this are as follows:

Exception for ongoing reviews:

Where there is an ongoing review of an original or supplemental application that has been submitted in accordance with one of the withdrawn memoranda, the

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submitter may continue to prepare submissions to the original or supplemental application according to the guidance originally used in preparing the application, e.g., "Providing Regulatory Submissions in Electronic Format – NDAs". If, while there is an ongoing review of a supplemental application, the submitter intends to prepare a new submission from the submission types listed above, they should follow the directions outlined in Memorandum 27.

Exception to Memorandum 27 for paper filers:

Submitters who submit in paper are occasionally requested, e.g., carcinogenicity datasets submitted to an IND, or required, e.g., Structured Product Labeling (SPL) to an NDA/BLA/ANDA, to submit material electronically. The guidance referenced by Memorandum 27, "Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications", states that once a sponsor or applicant submits following this guidance than all subsequent submissions to the application, including amendments and supplements, should follow this guidance. For paper filers, this is not applicable. Submitters would only be required to submit the electronic components in accordance with memorandum 27. All other submissions to the application may continue to be submitted in paper.

Submitters who wish to submit electronically but are currently unable to do so following Memorandum 27 may request a waiver that would permit them to continue to submit following the instructions contained in withdrawn Memoranda 6, 24, or 30.

The following information should be contained in an e-mail requesting a waiver should be sent to CDER's Electronic Submission Coordinator at esub@fda.hhs.gov.

- Contact Person Name - This will be the main contact
- Contact Person's Company Name
- Contact Person's Mailing Address
- Contact Person's Phone Number
- Contact Person's Email Address
- Relevant Submission Types and Numbers.
- A description of the submitters plan to become compliant with the guidance "Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications", including relevant timeframes.

The Electronic Submission Coordinator will contact the requestor concerning the status of the waiver request.

FDA is committed to the development and implementation of standards-based submission processes. Submitters who wish to submit electronically are strongly encouraged to do so in accordance with the eCTD specifications referred to by the guidance "Providing Regulatory Submissions in Electronic Format--Human

Pharmaceutical Applications and Related Submissions Using the eCTD Specifications" Submitters requesting waivers are encouraged to adopt these specifications at the earliest possible date.

To: FDA Dockets Management
Fax: 301-827-6870

From: Tim Mahoney
OIT-CDER
Director, Division of Applications Development and Services
301-827-3828

Date: September 12, 2007

Subject: 92S-0251

Note:

Attached please find a new memo for the 92S-0251 docket where CDER is requesting the removal of previous docket memos. Please contact myself or Gary Gensinger in CDER\OBPS if you have any questions.

Thanks,

Tim