MEMORANDUM

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

DATE:

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: New Drug Application – Annual Reports
Abbreviated New Drug Applications – Annual Reports

Regulatory Citation: 21 CFR 314;
Effective Date: April 01, 2004

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

On March 29, 2004, CDER will begin accepting NDA annual reports in electronic format as described in the guidance document Providing Regulatory Submissions in Electronic Format - Annual Reports for NDAs and ANDAs. This guidance is available on the FDA web site at the following address: http://www.fda.gov/cder/guidance/4840dft.pdf

Previously, CDER had posted guidance on submitting an annual report in electronic format in Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions. This is the preferred method for submitting electronic submissions. Applicants who have begun submitting their applications using this guidance document should continue to follow that guidance when submitting their annual reports. Applicants who have not yet begun filing their annual reports electronically may submit them following either guidance.

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