

MEMORANDUM

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

DATE: February 8, 2002

SUBJECT: Docket 925-0251 – Transmittal

FROM: Ralph Lillie, Director
Office of Information Technology
CDER, HFD-070

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: Advertisements and Promotional Labeling
Regulatory Citation: 21 CFR 314.81(b)(3)(i)
Effective Date: 2/8/2002

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

A draft guidance document entitled, "Providing Regulatory Submissions in Electronic Format – Prescription Drug Advertising and Promotional Labeling," has been issued by FDA to aid those submitting records electronically. See 66 FR 21, January 31, 2001. FDA is considering comments that it has received from the public on this draft guidance and will issue a final guidance on this topic. This draft guidance should be used for electronic submission of Advertising and Promotional Labeling.