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From: Margo Burnette, Director *PMC*  
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 the attached notification of CDER's readiness to accept electronic regulatory submissions for content of labeling

Regulatory citation: 21 CFR 314.50(i), 314.94(d), 601.14(b), and 314.81(b)

Effective date: September 24, 2004

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

On September 24, 2004, applicants may begin submitting the content of labeling in electronic format using the Health Level Seven (HL7) Structured Product Labeling (SPL) standard. This applies to the content of labeling provided with original submissions, supplements, and annual reports.

The Agency is developing an automated system to process, review and archive the contents of labeling in electronic format using the HL7/SPL standard with an expected implementation in fall 2005. During this transition period to the new system, content of the labeling may still be provided in PDF or XML format.

Applicants should provide the SPL content of labeling file as described in the document *SPL Implementation Guide for FDA Content of Labeling Submissions* available from HL7. Additional details on content of labeling submissions may be found in guidance to industry: *Providing Regulatory Submissions in Electronic Format – Content of Labeling*.

Documentation for creating and viewing SPL files may be found through the FDA web site at <http://www.fda.gov/oc/datacouncil/spl.html>. This site provides the following:

- Directions for obtaining the SPL standard and schema from HL7
- Links to the document *SPL Implementation Guide for FDA Content of Labeling Submissions*, the companion document to the HL7 SPL standard providing additional details on creating SPL files
- Link to the guidance to industry: *Providing Regulatory Submissions in Electronic Format – Content of Labeling*
- Stylesheet files for viewing SPL content of labeling files
- Sample SPL content of labeling files

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