From: Margo Burnette, Director
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CDER, HFD-070

Subject: Docket 92S-0251 – Transmittal

To: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR part 112(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(l), 314.94(d), 601.14(b), and 314.81(b)

Effective date: October 31, 2005

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

Memorandum 31 to docket 92S-0251 (dated September 21, 2004) announced the Center's readiness to accept content of labeling in either PDF or XML format

This notification updates Memorandum 31 by eliminating the use of PDF as an acceptable format for the submission of content of labeling beginning October 31, 2005. Health Level Seven (HL7) Structured Product Labeling (SPL) in XML format is the only acceptable format for the submission of the content of labeling in electronic format. This applies to the content of labeling provided with original submissions, supplements, and annual reports.

The Agency has developed an automated system to process, review and archive the contents of labeling in electronic format using the HL7/SPL standard and implementation begins on October 31, 2005.

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

1992S-0251

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- 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