TO: Director, Division of Dockets Management, HFA 305

FROM: Michael Fauntleroy, Director
CBER Electronic Submissions Program

Subject: Docket 92S-0251 – Transmittal

Pursuant to 21 CFR part 11.2(b)(2), and on behalf of the Center for Biologics Evaluation and Research (CBER), please find the attached notification of CBER's readiness to accept electronic regulatory submissions for content of labeling.

Regulatory citation: 314.50(l), 314.94(d), 601.14(b), 314.81(b).

Effective date: October 15, 2008

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

This notification establishes Health Level Seven (HL7) Structured Product Labeling (SPL) in XML as the only acceptable presentation in electronic format for the submission of the content of labeling beginning October 15, 2008. This applies to the content of labeling with original submissions, supplements, and annual reports. Content of labeling in SPL format is not required for annual reports unless there are changes from the currently approved SPL labeling.

Applicants should provide the SPL content of labeling file as described in the document, *Guidance for 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 SPL FDA Implementation Guide, the companion document to the HL7 SPL standard providing additional details on creating SPL files
- Link to the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Content of Labeling*
- Link to the *Guidance for Industry: Indexing Structured Product Labeling*
- Style sheet files for viewing SPL content of labeling files
- Sample SPL content of labeling files

Questions concerning content for CBER SPL submissions should be addressed to the appropriate CBER review division. Technical questions on SPL file format should be submitted to spl@fda.hhs.gov.