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FDA

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 Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Veterinary Medicine (CVM), please find the attached notification of CBER's, CDER's and CVM's readiness to accept electronic regulatory submissions for drug establishment registration and drug listing.

Regulatory citation: 21 CFR 207

Effective date: July 10, 2008

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

Registrants and private label distributors should provide the National Drug Code Labeler Code request, drug establishment registration, and drug listing information in an SPL file as described in guidance entitled *Providing Regulatory Submissions in Electronic Format – Establishment Registration and Drug Listing.*

Documentation for creating and viewing SPL files may be found through the FDA website at http://www.fda.gov/oc/datacouncil/spl.html. Documentation includes:

- *Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing*;
- *Structured Product Labeling Validation Procedures for Drug Establishment Registration;*
- *Drug Listing* and *Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms.*