

ELECTRONIC SUBMISSION OF DRUG ESTABLISHMENT REGISTRATION & DRUG LISTING



As of June 1, 2009, the U.S. Food and Drug Administration ceased accepting paper-based forms (FDA forms 2656 and 2657) for drug establishment registration and drug product listing. In order to improve Agency effectiveness and accuracy of submissions, FDA replaced its former paper-based system with structured product labeling (SPL) using extensible markup language (XML) tools known as Xforms. Xforms for old paper-based NDC labeler code requests, drug establishment listings, and drug listings are now electronically created as SPL Xforms and submitted by means of FDA's Electronic Submissions Gateway (ESG).

The ESG allows secure transmission of drug establishment registration and drug listing Xforms to FDA reviewers. In order to submit SPL Xforms for drug establishment and drug listing, registrants must first become an approved transaction partner with FDA's ESG. Following registration with the ESG, a registrant can submit initial listing files and updates as required. **toXcel** is well established with the FDA's ESG and experienced in the creation of SPL Xforms.

The structured product labeling Xforms are XML-based files in which drug establishment registration and drug listing files are built which, when electronically transmitted to FDA via the ESG, conform to FDA's data standards established for electronic submission of drug establishment and drug listing.



toXcel can interface with FDA's ESG as your company's transaction partner and can electronically create and submit your company's SPL Xforms for drug establishment registration and drug listing. **toXcel** is ready to assist registrants with their product stewardship and marketing goals and continually remains informed on ever-changing FDA SPL news and updates.