Drug Establishment Registration & Drug listing

Electronic Submissions

Regulatory Services— US

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. The old paper-based NDC labeler code requests, drug establishment listings, and drug product listings are now electronically created as SPL Xforms and submitted by means of FDA's Electronic Submissions Gateway (ESG).

The SPL Xforms are used to create XML-based drug establishment registration and drug product listing files that conform to FDA's data standards established of electronic submission of drug establishment and drug listing.

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.

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.

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