

# DRUG & COSMETIC ESTABLISHMENT REGISTRATION, PRODUCT LISTING & AMOUNT REPORTING: ELECTRONIC SUBMISSIONS

## Regulatory Services— US

The U.S. Food and Drug Administration has moved to electronic submissions for both Drug, and most recently, Cosmetic Facilities and products. This includes Establishment/Facility registration, product listing, and amount reporting (Drugs and Biologics).

For both Drugs and Cosmetics, establishment and listing submissions can be made through FDA's Electronic Submissions Gateway (ESG), utilizing Structured Product labeling (SPL) tools, or through FDA Direct. The SPL Xforms and FDA Direct Portal both create establishment registration and product listing files that conform to FDA's data standards established for electronic submission of establishment registrations and product listings.

These systems both allow for secure electronic transmission of establishment registration and product listing information to FDA but do require some setup. **toXcel** is well versed with both the FDA Direct and ESG requirements, as well as the pros and cons of each transmission method.

FDA has also implemented amount reporting requirements for listed human and animal drugs and Human biological products. These submissions are made annually by manually inputting data or utilizing CSV file templates submitted through FDA's NextGen Portal. **toXcel** is also familiar with the NextGen Portal setup and submission options and can assist companies in complying with these reporting annual reporting requirements.

**toXcel** can help identify which submission methods best suit your company's needs. We can interface directly with FDA as your company's transaction partner and can electronically create and submit establishment registration, product listing, and annual reporting forms on your behalf. **toXcel** is ready to assist registrants with their product stewardship and marketing goals and continually remains informed on ever-changing FDA procedures, news, and updates.

For further information, contact Alan Katz at 703-754-0248 extension 8111 or by email at [Alan.Katz@toxcel.com](mailto:Alan.Katz@toxcel.com).

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