Regulatory Alert: FDA Processing Delays

Some clearance and release delays have been associated with the national rollout of PREDICT, a component of the U.S. Food and Drug Administration (FDA) automated system intended to assess the risk of FDA regulated commodities. FedEx Express and FedEx Trade Network are working with FDA at local, regional, and national levels to improve processing and speed releases for these shipments.

Under PREDICT a low risk shipment with all required data present is more likely to receive a fast, fully automated release; shipments with higher risk scores and/or missing data are more likely to be delayed while secondary, manual reviews take place.

Under PREDICT the FDA requires “Affirmation of Compliance” codes for certain commodities in order to receive a fully automated release. Affirmation of Compliance codes primarily apply to medical devices, electronic components, medical and non-medical radiation-emitting products, and parts and components of these commodities. The most recent data from FDA show medical devices and drugs have the lowest rate of fully automated release.

FDA advises that entry filers should provide accurate, consistent, and complete data for FDA regulated merchandise, including:

- Consistent, accurate identifiers for firms
- Accurate Product Codes
- All relevant affirmations of compliance

Shipments missing any required data for FDA declaration will be delayed while information is secured from customer. Shipments missing Affirmation of Compliance information may be submitted to FDA but will not receive fully automated release.

PREDICT/ Affirmations of Compliance

PREDICT = Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting

Affirmations of Compliance = data elements submitted voluntarily to FDA to expedite the entry review process.

Example:

- New drug application number
- Device “510(k) clearance” number
- National drug code (NDC)
- Radiological health product report accession number.

FDA will not accept import declaration with missing data. Import declaration may be submitted without Affirmation of Compliance codes, but will not receive automated release.

To expedite entry screening by PREDICT, importers and entry filers must provide:

- Consistent, accurate identifiers for firms
- Accurate product codes
- All of the relevant affirmations of compliance

Exporters to the U.S. should review U.S. import requirements with U.S. importer for inclusion of all required data on shipment documentation.

U.S. importers should identify all required data for FDA declaration, advise foreign suppliers to include data for each FDA regulated item on shipment documentation and submit product data to FedEx Express /FedEx Trade Networks for inclusion on Clearance Profile Guide for use with future shipments.

Content Intended For FedEx Express Customers Only
Advisory References:
FDA PREDICT Overview:
http://www.fda.gov/ForIndustry/ImportProgram/ucm172743.htm

FDA Affirmation of Compliance Codes, letter to the industry
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm271180.htm