FDA U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF REGULATORY AFFAIRS

Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

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PREDICT

Rolled out across the United States and all port of entries in 2012.

PREDICT

- **Purpose:** Improve import screening and targeting to prevent entry of adulterated, misbranded, or otherwise violative goods into the United States.

- **Method:** Replaced the admissibility portion of FDA's legacy electronic screening process.

PREDICT
Methods Include

- Automated data mining and pattern discovery
- Open source intelligence
- Automated queries of Center systems where relevant. (i.e. registration numbers, and or listings)

PREDICT Method Continue

- Improving targeting of entry lines by:
  - ✓Evaluate each line on a the basis of risk factors and surveillance requirements
  - ✓Facilitate the increase the number of automated releases by the system (i.e. System May Proceed), where by giving FDA more time to evaluate higher risk lines.
  - ✓For those lines not given a may proceed by the system, providing users with crucial information to make an admissibility decision.

PREDICT Screening Sources Include

- Results of field exams and sampling analyses of previous entries.
- Results of facility inspections (foreign and domestic)
- Inherent risk of the product
- Accuracy of product and facility coding by entry filers and importers

Additional Information

- FDA.gov
  - https://www.fda.gov/ForIndustry/ImportProgram/default.htm

Questions