PREDICT: A risk-based tool for regulated products
U.S. FDA’s Regulatory Programs

• The Food Drug & Cosmetic Act established FDA as the regulatory body which ensures the safety and efficacy of the following products:
  – Foods
  – Drugs
  – Biologics
  – Medical devices
  – Radiation emitting electronics
  – Cosmetics
  – Veterinary products
  – Tobacco products
FDA TBT Measures

• FDA requires that all products covered under the FD&C meet the same technical requirements, whether imported or produced domestically.

• This includes imports of drugs, medical devices, cosmetics, tobacco, and food which carries nutrition facts labels.
Single Window

• A single, harmonized data set collected electronically by CBP

• Early validation of exporter’s paperwork results in better data quality and quicker admissibility decisions

• Coordinated, consolidated status messaging across agencies
Import Volume

Total Lines* of Products Imported into the U.S. per Fiscal Year

*A line is a distinct product within a shipment. A single shipment may include multiple lines.
PREDICT

• All imported products that FDA regulates are electronically screened before they enter the United States
PREDICT

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

• Method: Replaced the admissibility portion of FDA’s legacy electronic screening process.
PREDICT - Methods

- Verification of applicable regulatory requirements, e.g. registration, approval status, etc.
- Automated data mining and pattern discovery
- Automated review of administrative requirements
- Open source intelligence

www.fda.gov
PREDICT – Improved Targeting

• Evaluate shipments on the basis of risk factors and surveillance requirements.
• Facilitate automated releases, giving border inspectors more time to evaluate higher risk lines.
• For consignments not automatically admitted, identify risk factors for border inspectors to consider in determining disposition.
PREDICT - Risk Factors

• Inherent risk of the product

• Results of field exams and analytical testing of previous entries from the same producer or country.

• Results of facility inspections (foreign and domestic)

• Accuracy of import and registration documents
Additional Information

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