U.S. FOOD & DRUG ADMINISTRATION

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

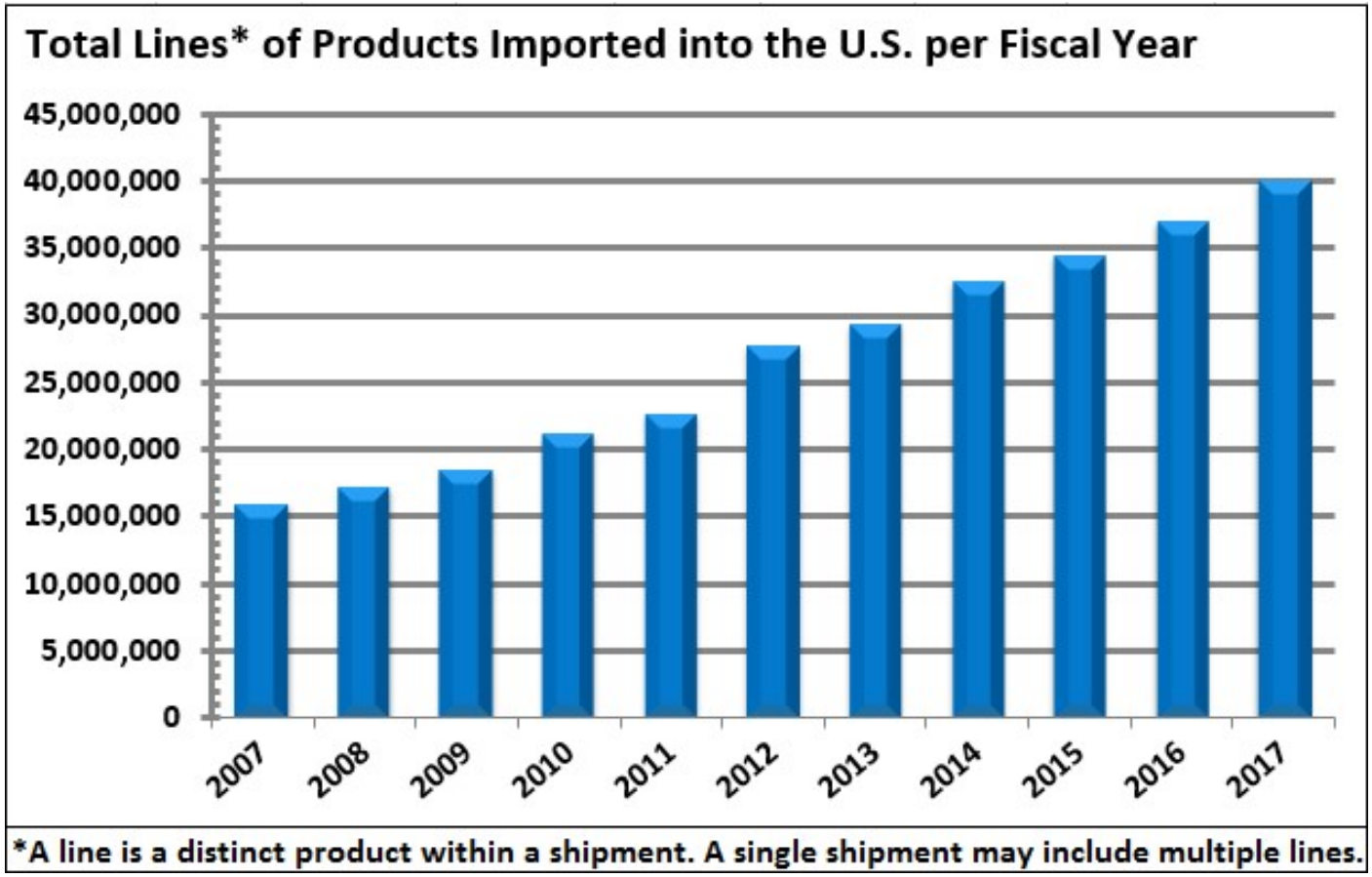
FDA TBT Measures

- 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



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

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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