

# **ACE/ITDS: FDA Implementation Update and Tips for Drug Importers**

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# Disclaimer

**This presentation is intended only to provide a general overview. It is not intended to be comprehensive nor does it constitute legal advice.**

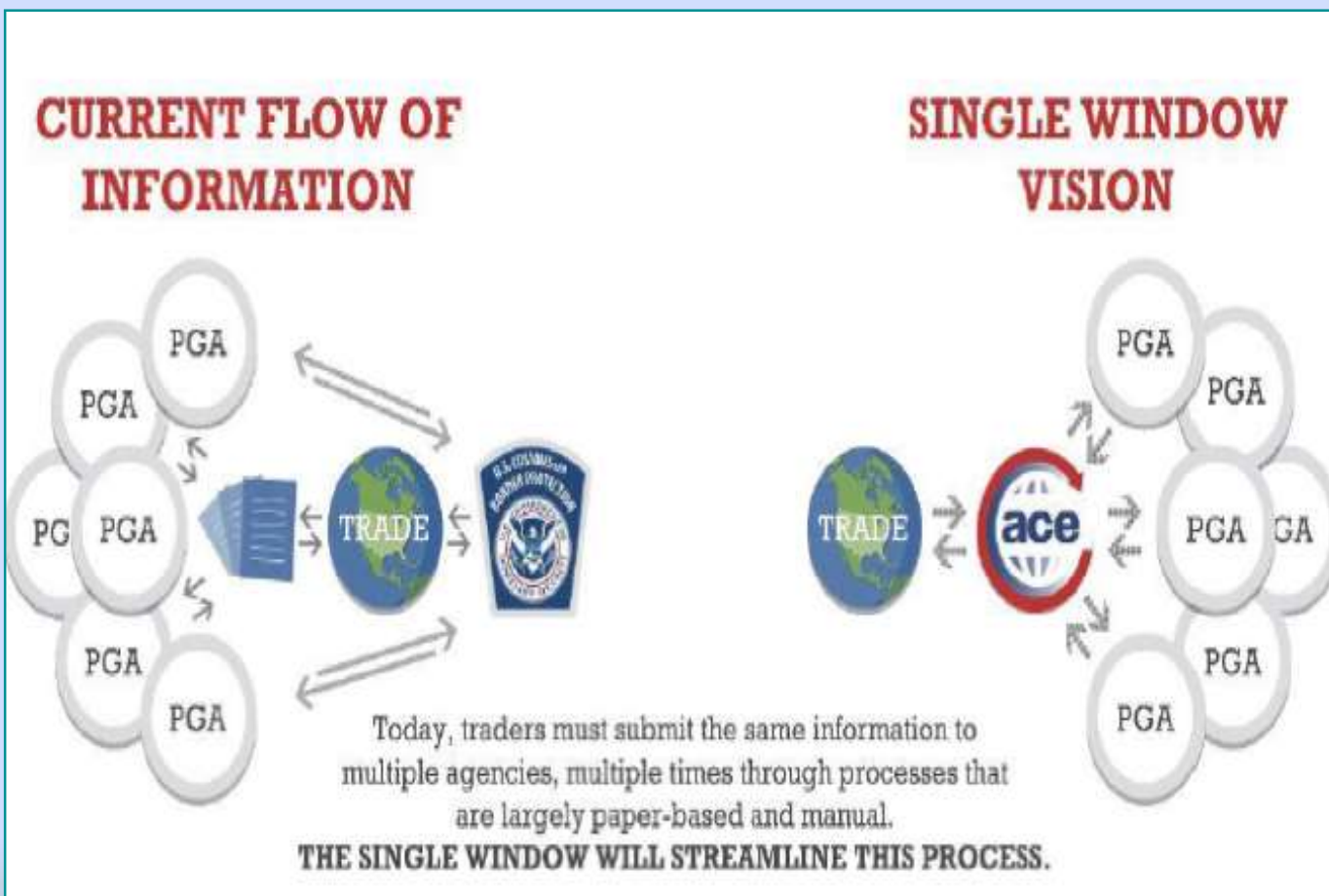
# Objectives

- Introduction to ACE/ITDS
- Overview of ACE implementation - FDA's perspective
- Basic requirements for importing drugs
- Tips for transmitting drug information in ACE

# What is ACE/ITDS?

- The Automated Commercial Environment/ International Trade Data System is a single access point through which industry can electronically submit information for all government agencies involved in international trade.
- FDA is one of 46 Partner Government Agencies (PGAs) working with U.S. Customs and Border Protection (CBP) to implement ACE/ITDS.

# What is ACE/ITDS?



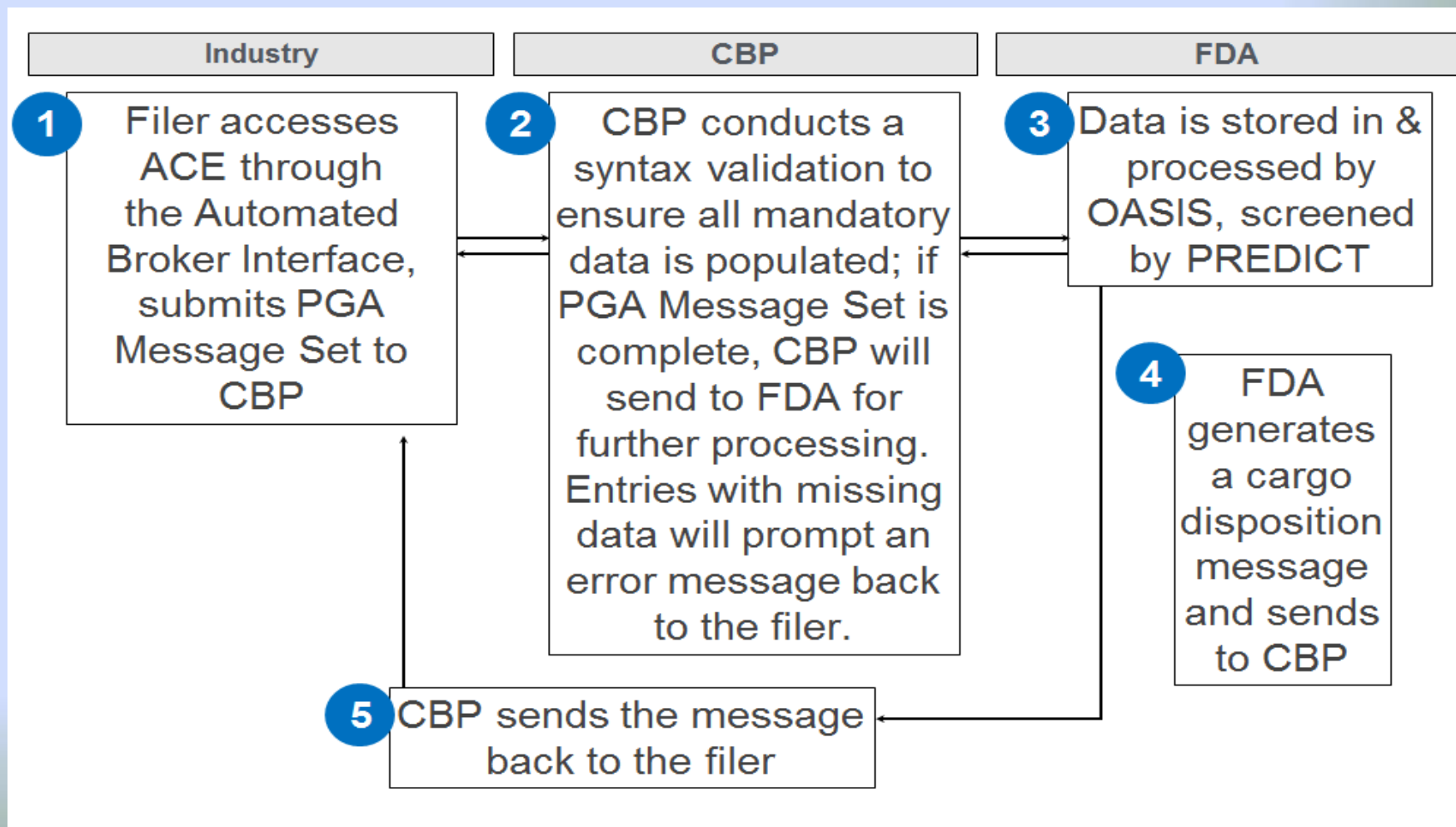
# Executive Order 13659

- “...to reduce supply chain barriers to commerce while continuing to protect our national security, public health...”
- “...the Federal Government must increase efforts to improve the technologies, policies, and other controls governing the movement of goods across our national borders.”
- By December 31, 2016, PGAs must have capabilities, agreements, and other requirements in place to use ITDS and supporting systems, such as ACE

# FDA's Efforts to Implement ACE/ITDS

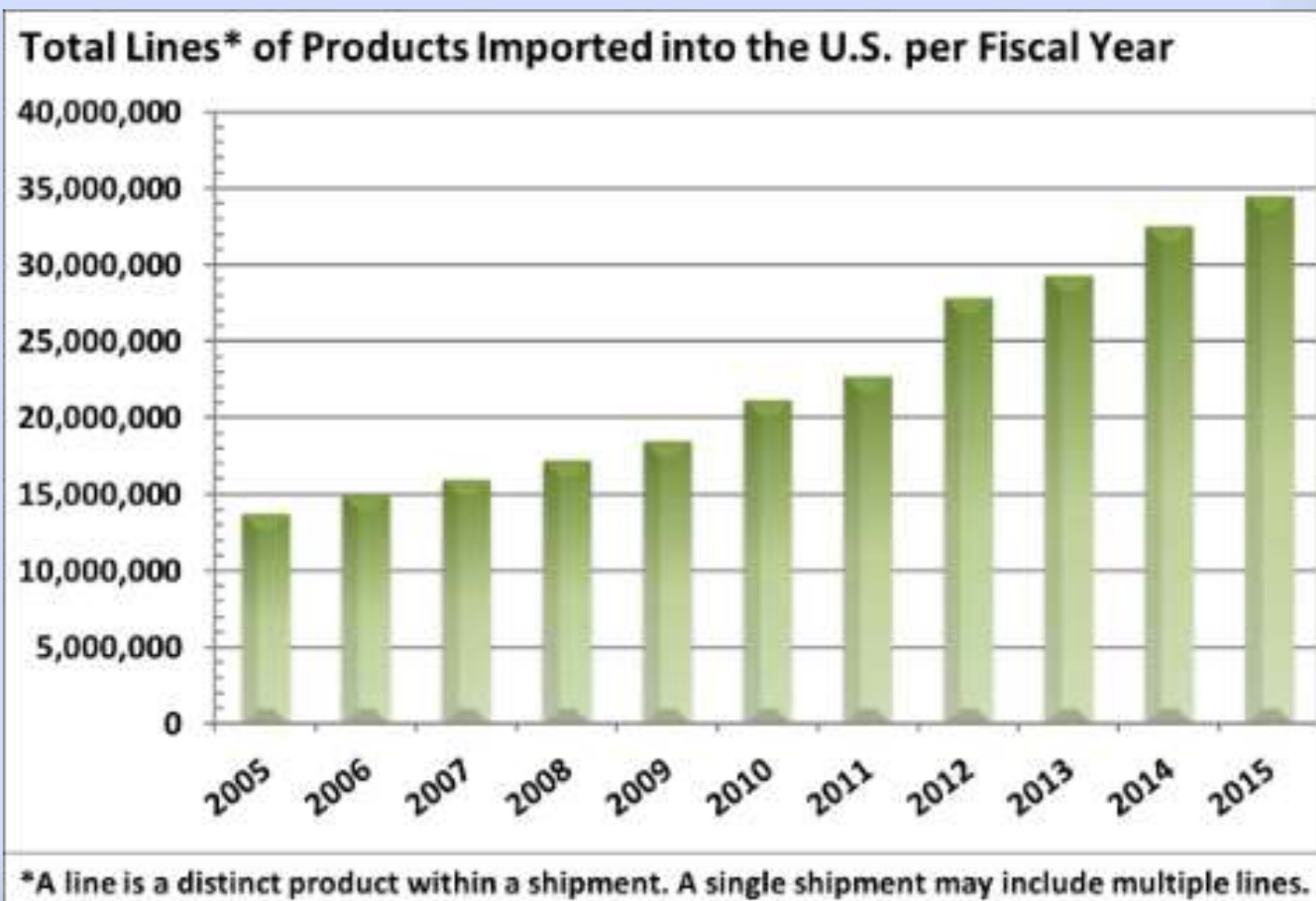
- **August 27, 2015:** FDA participates in National Customs Automation Program test (FDA ACE Pilot)
- **May 2, 2016:** FDA ACE Pilot ends
- **July 1, 2016:** Notice of Proposed Rulemaking (NPRM) published
- **August 30, 2016:** Comment period ends
- **Currently:** FDA reviewing comments submitted to public docket

# FDA ACE Process






# Imports of FDA-Regulated Products

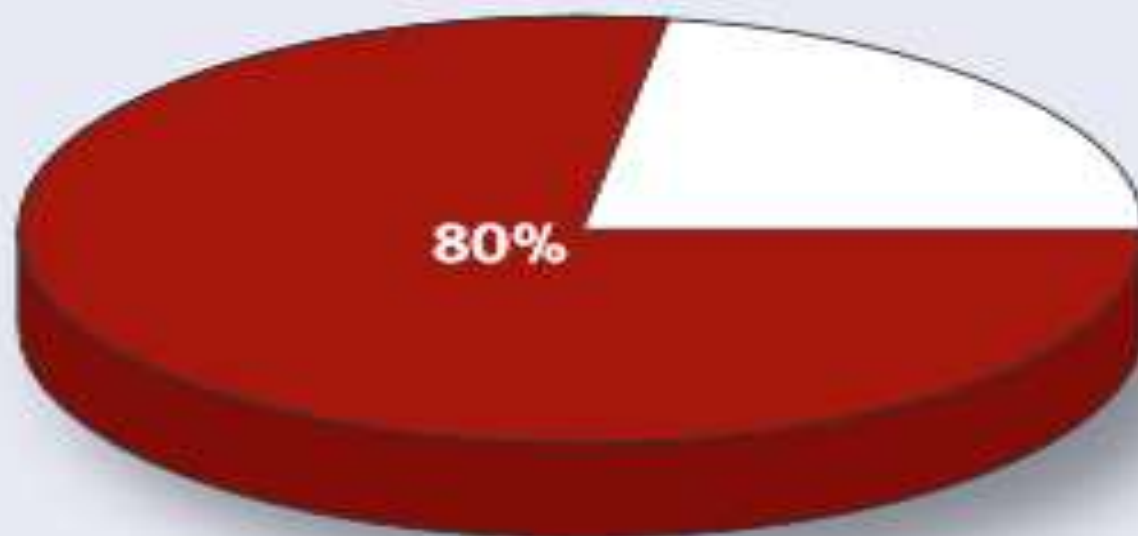


# Globalization and Drugs

**Origin of APIs for drugs in the U.S. market, 1998**

Volume: percent

 Foreign-produced



# What is a Drug?

- “[A]rticles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”
- “[A]rticles (other than food) intended to affect the structure or any function of the body of man or other animals”
- Components



# Drug Imports

Under 801(a) of FDCA, a drug is subject to refusal if it appears from examination or otherwise that it is:

- manufactured, processed, or packed under insanitary conditions
- forbidden or restricted in sale in the country in which it was produced/exported
- **is adulterated, misbranded or in violation of sec. 505 of the FDCA**

# Drug Imports and 801(a)(3)

- Adulteration (sec. 501)
  - Includes failure to comply with cGMPs
- Misbranding (sec. 502)
  - False or misleading labeling
  - Labeling lacks adequate directions for use
  - Foreign manufacturer has not registered as an establishment or listed its drugs in U.S. commerce per section 510
- Violation of sec. 505
  - “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective”

## ACE: Tips for Importing Drugs

- Name, Address (and DUNS # if known) for:
  - Manufacturer, Shipper, Importer, Delivered-to Party
- Provide correct FDA Product Code
- Provide correct Intended Use Code
- FDA strongly encourages transmission of:
  - API information for imported finished dosage form drugs
  - Accurate product description (e.g., API, brand or trade name)

# ACE: Drug Affirmations of Compliance

- Affirmations of Compliance (required based on intended use)
  - REG (Establishment Registration Number)
  - DLS (Drug Listing Number)
  - DA (Drug Application Number)
  - IND (Investigational New Drug Application Number)

# Drug Entry Review

- FDA receives electronic transmission of entry from CBP and reviews entry (District Level, per 21 CFR 1.94)
  - Release
  - Detain without physical examination
    - Import Alerts
  - Request more information through
    - Documents (submitted through ITACS)
    - Field exam and/or sample collection
  - Refuse



# ACE: Key Points for Drug Importers

- Know your products and supply chain
- Know the statutory and regulatory requirements that apply to your products
- Give your brokers the accurate and complete information to file an entry in ACE

# Resources

## **ACE Support**

- 24/7 help desk to assist industry with the transition to ACE
- Contact FDA at [ACE\\_Support@fda.hhs.gov](mailto:ACE_Support@fda.hhs.gov)

## **FDA ACE/ITDS Webpage**

[www.fda.gov/ForIndustry/ImportProgram/ucm456276.htm](http://www.fda.gov/ForIndustry/ImportProgram/ucm456276.htm)

## **CDER Import/Export Compliance Branch Webpage:**

[www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm)

## **ORA Import Basics Webpage**

[www.fda.gov/ForIndustry/ImportProgram/ImportBasics/default.htm](http://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/default.htm)

# QUESTIONS?



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