Importing FDA-Regulated Products in ACE

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What is ACE/ITDS?

The Automated Commercial Environment/ International Trade Data System is a single access point in which industry can electronically submit information on behalf of all government agencies involved in international trade.

Current Status

- FDA began processing ACE entries in August 2015; open to all ports and all product types
- 40K entries processed to date (100K) lines
- Facilitating onboarding of first-time ACE filers each day

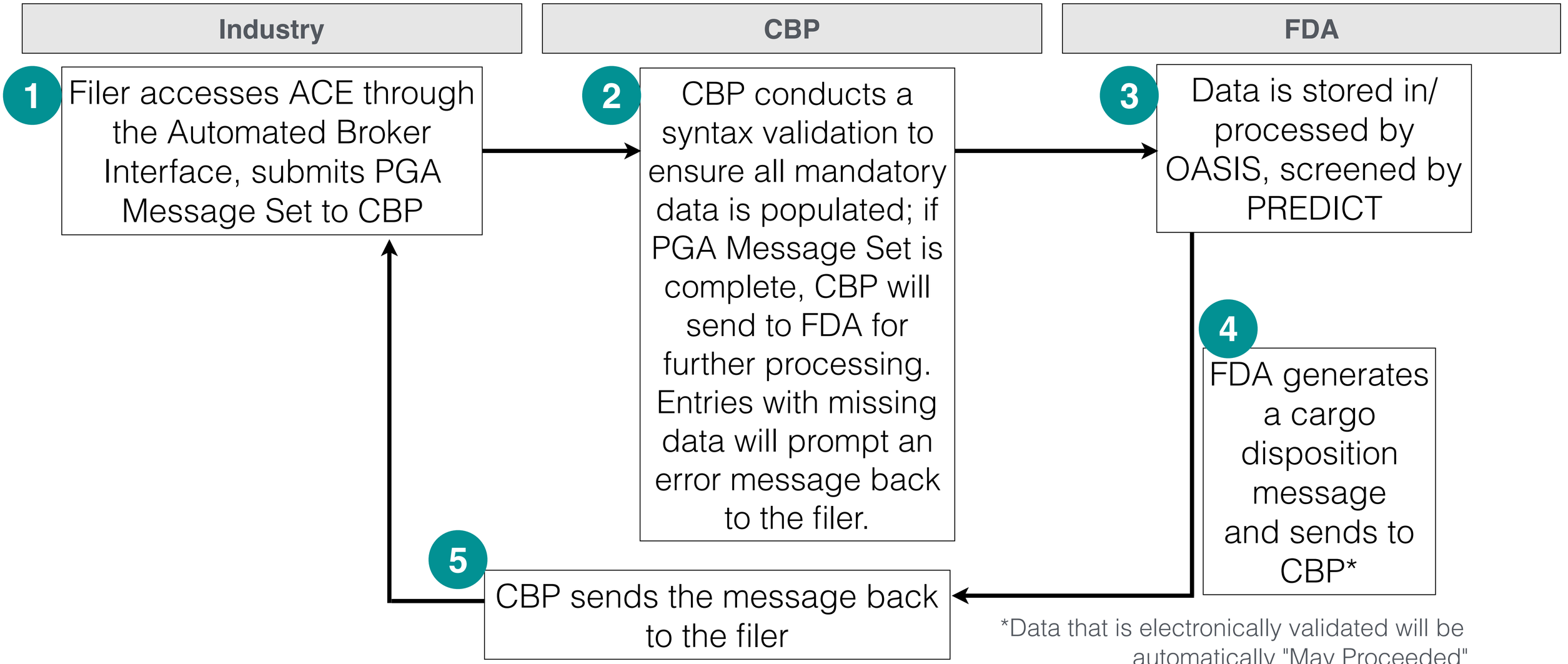
Current Status

- **CSMS 16-000093: Updated ACE Transition Guidance**

"*FDA filings will continue to be allowed in ACS to provide more time for industry to transition to ACE. Further information will be provided on the mandatory filing in ACE for FDA data*"

- **CBP and FDA are highly encouraging ACE filings and will prioritize resources to support ACE entries**

Overview: How ACE Works



*Data that is electronically validated will be automatically "May Proceeded"

Tips for Avoiding Rejections

- Ensure the Country of Production/Growth matches the country listed for the Manufacturer/Grower/ Consolidator
- Declare appropriate Affirmations of Compliance
- Declare required entities for transaction type
  - Seven Entities are required for Prior Notice
- Point of Contact is required for each FDA line (Filers First Name, Last Name, Phone and Email)

Tips for Importing Medical Devices

Expedite FDA's Processing by Providing:

- Correct Product Code & Intended Use
- Brand Name
- Name, Address **and FEI** for:
  - MF, Shipper, Importer, Delivered To Party, and Device Initial Importer (DII is no longer an AofC)
- Affirmations of Compliance: (required based on Intended Use)
  - DEV (Device Registration)
  - DFE (Device Foreign Exporter Registration)
  - LST (Device Listing Number)
  - PM# (Premarket Number - formerly PMA/PMN)

Verify information in CDRH Registration & Listing Database and obtain FEI#:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Tips for Importing Drugs

Expedite FDA's Processing by Providing:

- Active Ingredient Name and Dosage
- Brand Name
- Name, Address (**and DUNS# if known**) for:
  - MF, Shipper, Importer, Delivered To Party, and API Producer
- Affirmations of Compliance: (required based on Intended Use)
  - REG (Drug Registration)
  - DLS (Drug Listing)
  - DA (Drug Application Number)
  - IND (Investigational New drug)

Tips for Importing Food Products with Prior Notice

- Correct Product Code
- Country of Production/Growth (and Country of Shipment for Prior Notice)
- Name, Address (**and DUNS# if known**) for:
  - MF/Grower/Consolidator, Shipper, Importer, Ultimate Consignee, PN Submitter, PN Transmitter, Owner
- Affirmations of Compliance: (required based on product and MOT)
  - PFR or FME (Food Facility Registration or Exemption with Reason Code)
  - VFT (Voyage, Flight, Trip Number)
  - VES (Vessel Name)
- Container Number

ITACS

- Entry documents should continue to upload documents to ITACS
- CSMS 16-000057 FDA's Import Auxiliary Communication System (ITACS) is not Receiving Arrival Notifications for ACE Entries
    - FDA will display "FDA Entry Status to Available" for all truck and air shipments
    - FDA is working with CBP to resolve this issue
    - Issue does not impact uploading of documents

Reference Material

- FDA Supplemental Guide: http://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16 (Full list of data elements required for admissibility)

- FDA Duns Portal: www.fdadunslookup.com (Query or request DUNS numbers for free)

Getting Started & Support

- Contact your software developer & work with him/her to start filing ACE Entries
    - Request a demo of your new screens

- To start filing in ACE for FDA or for questions on requirements of help with an ACE entry, email ACE_Support@fda.hhs.gov

FDA continues to support you throughout your transition to ACE. We remain mindful of the overall goal of this project: to facilitate trade and reduce supply chain barriers to commerce while continuing to protect national security and public health.

Contact Information

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