

January 2016

FDA's Integration to the Automated Commercial Environment/ International Trade Data System

Office of Enforcement and Import Operations

Office of Regulatory Affairs

Food and Drug Administration

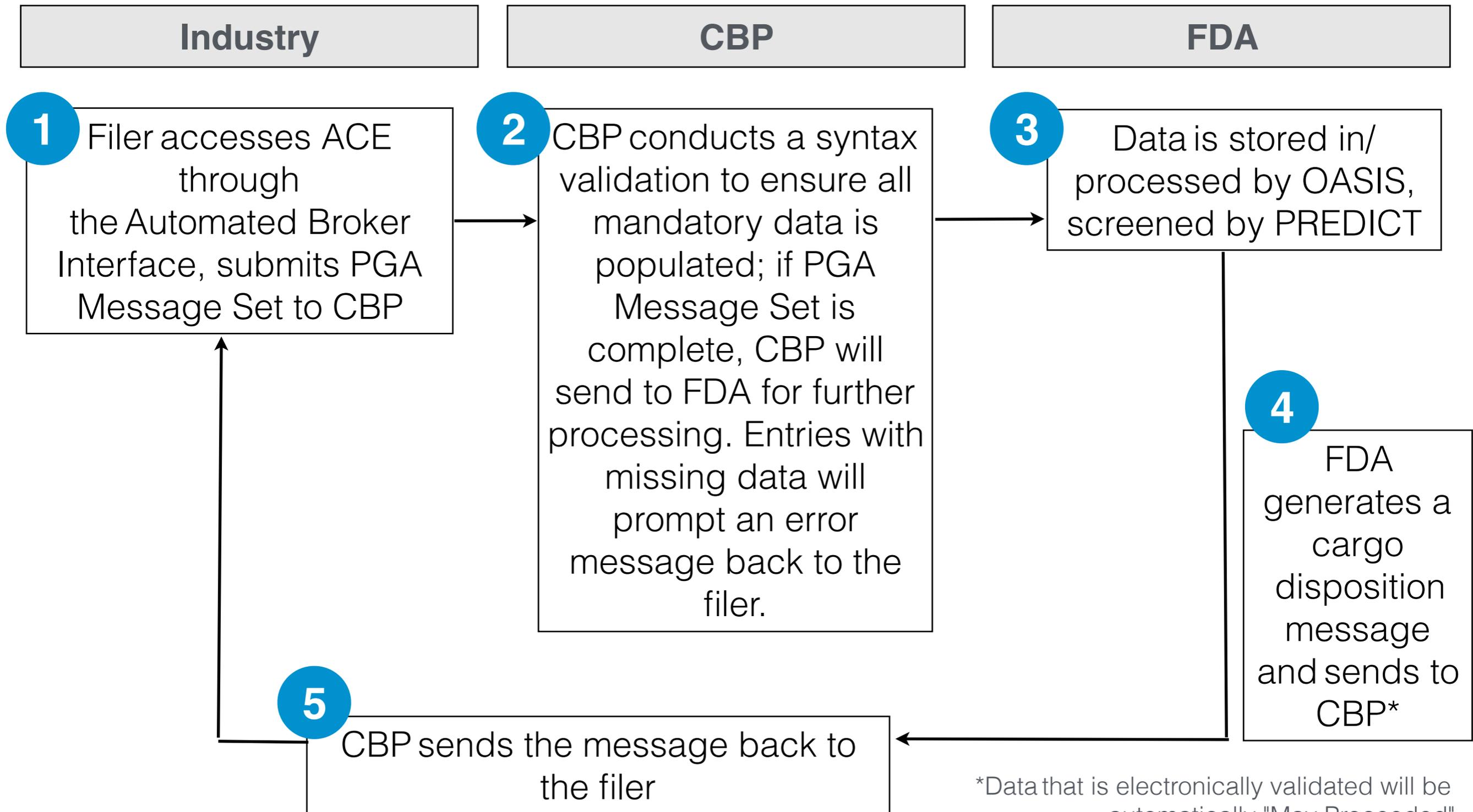
Objective

- To provide an overview of FDA's transition from ACS to ACE
- To provide an update on FDA's pilot status
- To provide Points of Contact

What does ACE/ITDS mean to me?

- A single, harmonized data set collected electronically by CBP
- Early validation and rejection of entries that do not pass business rules result in better data quality for targeting and shorter initial admissibility decision times for FDA
- Coordinated, consolidated status messaging across agencies
- *Note: FDA will continue to use ITACS until the Document Image System has line-level functionality*

End-to-End ACE Process



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

FDA Pilot Status

- Began August 19, 2015
- Processing ACE entries and onboarding new participants daily; approximately **8000** successful transmissions to date
- Open to all commodities, all ports (pilot includes disclaimed entries)
- Federal Register Notice:

<https://www.federalregister.gov/articles/2015/08/27/2015-21266/modification-of-national-customs-automation-program-ncap-test-concerning-the-submission-of-certain>

How to Prepare

- Software Readiness: Programming must meet requirements within FDA's Supplemental Guide; Check with your vendor on your software's readiness
- Populate correct and complete data sets for certification testing and production
- Work in collaboration with FDA to prepare for your first filing

Helpful Information

- FDA Supplemental Guide: <http://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16> (Data elements required for admissibility)
- Draft Guidance for Industry-Prior Notice of Imported Foods Questions and Answers: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm078911.htm>
- Product Code Builder: <http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm>
- FDA Duns Portal: www.fdadunslookup.com (Query or request DUNS numbers for free)

Points of Contact

To participate in the pilot or for questions about certification testing or FDA's requirements, contact:

ACE_Support@fda.hhs.gov