



# CONNECTIVITY TO ACE/ITDS by U.S. FOOD AND DRUG ADMINISTRATION



2015

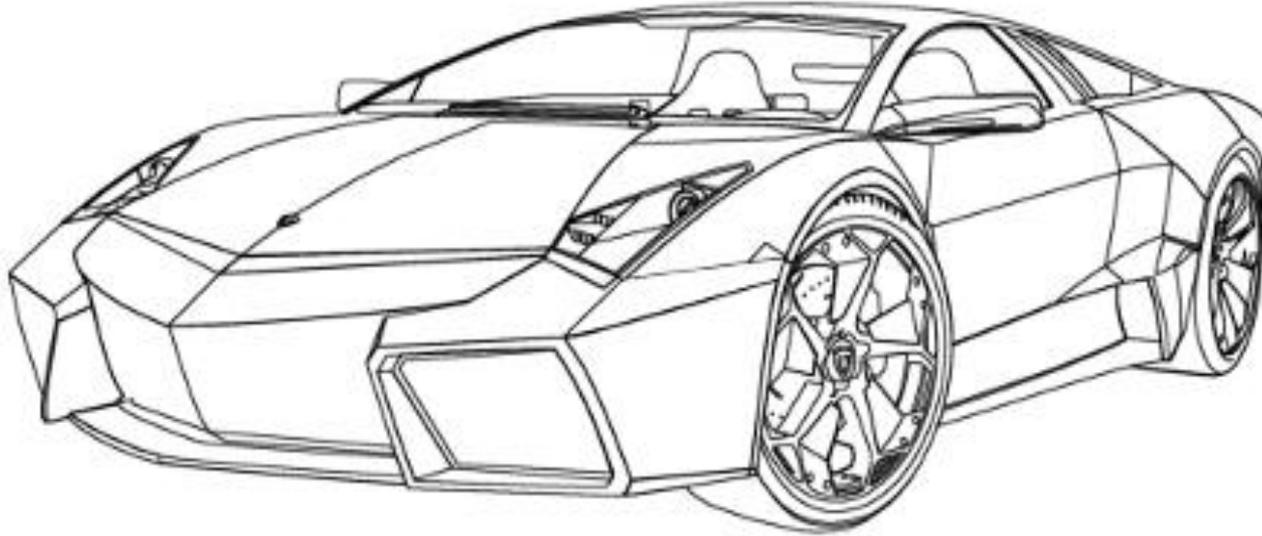
*Customs and Border Protection  
Modernization  
New World, New Tools*



- **Overview and status of the Food and Drug Administration's (FDA) connection to the new cargo release functionality in ACE/ITDS and**
- **Brief high- level explanation of the FDA's new web services interface --- IWS (Interoperability Web Service) interface to ACE/ITDS (*Automated Commercial Environment/International Trade Data System*)**



# FDA's "ACE Analogy"



- **High-Octane Fuel = Correct and Complete FDA Data Import Requirements (PGA Message Set)**
- **Fuel Pump = IWS- Interoperability Web Services**
- **Air Filter = FDA PREDICT SCREENING**
- **Turbo Engine = New IWS/OASIS/MARCS ER**
- **Accelerator or Brake = Entry Review Disposition**





## IWS DEVELOPMENT

- New FDA IWS interface will be stood-up on July 1, 2015 - for all FDA commodities
- IWS will accommodate the (FDA) PGA Message Set
- Supplemental Guide, Version 2.2
- FDA cargo disposition messages to be issued by ACE to Trade

## TESTING

- Bi-directional CERT testing FDA and CBP ---all FDA commodities
- Trade (and Software Developer) CERT testing via ABI with FDA and ACE – Drugs
- Real Time Data Exchange: End-to-End Testing
- Electronic Communications – feedback, troubleshooting and cargo disposition messages



# Selected Ports/Products



- FDA currently relies upon Electronic Submission of Entry Data and it will continue in ACE/ITDS
- Initial Testing/Pilot Ports: Philadelphia, Baltimore, and Otay Mesa (Alternative Port – Buffalo)
- Initial Testing/Pilot [FDA] commodities: Drugs [Human/Animal], Medical Devices and Biologics. Followed by foods, including PN, tobacco, cosmetics, rad health products and all others).
- In fiscal year 2014, FDA managed over 32 million cargo lines ( expected to increase in FY 2015).



# FDA PRODUCT CODES



## \* GREATEST NUMBER OF LINES

- \* CDRH - 3,862
- CTP - 40
- \* CFSAN - 7,013
- CVM - 554
- \* CDER - 3,562
- CBER - 157



# FDA Link to Supporting ACE/ITDS Documents



- Supplemental Guide (Version 2.2 )

- Available online: <http://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16>



# FDA TIMELINE



IWS Connectivity,  
Outreach Initiation

Testing

FDA connects to  
ACE/ITDS (Pilot)

Presidential  
Deadline

September 2014

April 2015

July 2015

December 2016

