



Trade Support Network Plenary Session

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PGA Panel Discussion

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FDA

U.S. Department of Health and Human Services

Food and Drug Administration



What does FDA do?



FDA is responsible for:

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health



The Office of Regulatory Affairs (ORA)



➤ **VISION**

- All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

➤ **MISSION**

- ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products



OASIS

Operational and Administrative System for Import Support



- ✓ Legacy system operating 24/7 FDA-wide since 1998
- ✓ The only system in the Federal government which exchanges import admissibility data with U.S. Customs & Border Protection in real time
- ✓ Provides --
 - Electronic screening of entry lines
 - Workflow management for entry reviewers, investigators, and compliance officers
 - Generation of notices regarding admissibility decisions



MARCS Imports



- **Three major components integrated with OASIS**
 - PREDICT
 - Import Trade Auxiliary Communications Service (ITACS)
 - Improved cross-district entry review capability

- **Redesigned, modern screens for entry reviewers**



ITDS Integration into ACE



- ✓ The transition to ACE will complete FDA's upgrade to modernize its automated import system and its interface with Customs and Border Protection's Automated Commercial System (ACS) for screening and processing of FDA -regulated cargo and mandatory Prior Notice submissions.
- ✓ The PGA Message Set will enable brokers to make a direct entry into MARCS through ACE as they always have done, however, it will remove the need for affirmation of compliance codes (AofC) and
- ✓ It will improve communication and the sharing of information electronically between agencies.



The Work Continues



1. Finalize the MOU with CBP and other Agencies
2. Provide additional data elements as a result of new legislation
3. Digital Imaging Systems of each agency need to be modified to the same format
4. Obstacles of sharing of information needs to be identified and solved.