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# Importing/Exporting FDA Regulated Products

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# Increased Government Attention

- Import Safety Issues Drive Government Concern
  - Melamine
  - Heparin
  - Tainted toothpaste
  - Lead in children's toys
  - Tainted infant formula
- Global Health Concerns
  - Swine Flu



# Legislation

- H.R. 759 – “FDA Globalization Act of 2009”
  - Safe and Secure Food Program
  - Drug Imports
    - Additional entry requirements for drug imports, including potential third-party verification
- S. 882 – “Drug and Device Accountability Act of 2009”
  - Origin labeling requirements for drugs and devices
  - Internet exception
  - Revising admission standards, and good distribution and importer practices



# Legislation

- H.R. 999 – “Keeping America’s Food Safe Act of 2009”
  - Certification of Food Importers
  - Certification that meets, or exceeds, standards for U.S. produced foods
- S. 510 – “FDA Food Safety Modernization Act”
  - Use risk-based assessment methods to target inspection of domestic facilities, foreign facilities, and ports of entry; annual report
  - [Mandatory] Foreign supplier verification program
  - Voluntary qualified importer program
  - Authority to require import certifications for food
  - Inspection of foreign food facilities



# Legislation

- “Food Safety Enhancement Act” H.R. 2749 (passed House July 30, 2009)
  - Requires registration of importers and brokers
  - Increased regulation of food facilities
  - Safety standards for raw fruits, nuts, and fungus
  - Increase inspections
  - Increased penalties for food violations
  - Currently in Senate Committee for Health, Education, Labor, and Pensions



# FDA Import Initiatives

- Good Importer Practices
- Secure Supply Chain Pilot
- PREDICT
- ITACS



# Good Importer Practices

- Guidance Document Issued (in January 2009) for comments (by April 12, 2009)
- General Recommendations
  - Know the foreign firms that produce the products and any other firms with which they do business and through which such products pass (e.g., consolidators, trading companies, distributors);
  - Understand the products that they import and the vulnerabilities associated with these products;
  - Understand the hazards that may arise during the product life cycle, including all stages of production;
  - Ensure proper control and monitoring of these hazards; and
  - Institute practices to identify and minimize risks.



# Good Importer Practices

- Little detailed guidance specific to import processes
  - Know what you are importing
  - Know your supply chain
  - Hire knowledgeable brokers
  - Audit your entries
  - Be familiar with regulatory requirements
- Nothing specific to FTZs



# Secure Supply Chain (SSC) Pilot Program

- Notice of Pilot Program: 74 Fed. Reg. 2605 (Jan. 15, 2009)
- Authority
  - § 302 of the Bioterrorism Act
- History – Increasing FDA recognition of the need for risk-based analysis



## SSC Goals

- Allow agency to focus resources on imported drugs that pose greater risks of adulteration, misbranding, terrorism, counterfeiting, diversion, or being unapproved
- Increase likelihood of expedited entry for drugs meeting program criteria
- And also: “FDA can verify and/or audit all data”



## SSC Scope (Pilot)

- 100 qualified applicants
- 5 products per applicant
- Product Coverage
  - Finished drug products
  - APIs



# SSC Criteria for Participation

1. Applicant must be the NDA/ANDA holder, or the foreign manufacturer
2. Must be in compliance with registration, listing and cGMP requirements for past 3 years
3. Ultimate consignee must be identified in the NDA/ANDA
4. API must be used in the manufacture of an approved drug product
5. The covered imports must
  - a. Be from the foreign manufacturer identified in the application
  - b. Arrive through the identified port of entry and port of arrival
  - c. Use the identified broker/filer
  - d. Be intended for the identified ultimate consignee



## SSC Criteria for Participation

6. Foreign manufacturer must be in compliance with applicable requirements of the act
7. Must be validated C-TPAT Tier II participant, or certified pending validation
8. Primary/secondary contact must be able to answer questions
9. Must have a plan for promptly correcting issues raised by FDA regarding SSC or specific importations
10. Must have a recall plan
11. Broker/filer must be qualified for paperless entry in OASIS



# Benefits

- Reduced inspections
- “Increased likelihood” of expedited entry



# Issues

- Pilot – 2 years
- No guarantee of expedited clearance
- May actually get increased scrutiny
- Cannot change supply chain without amending application
- Limited to:
  - Drugs
  - Finished drug or API form
  - U.S. approved
  - Ultimate consignee – In compliance with FDA requirements for last three years



# FTZ Impact

- May be combined with FTZ operations
  - But not specifically designed to fit
- Not as beneficial as FTZ FDA Weekly Entry Procedure
  - Automatic “May Proceed”



# FDA Developments

- PREDICT implementation
- ITACS implementation
- Developments in Regulation of FTZs

