AFDO
The Import Process

Houston, TX

June 19, 2017

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Challenges Presented by Globalization

- **World Wide Web** has made purchasing products more global rather than purely domestic sources.
- More **foreign facilities** supplying global market
- More **outsourcing** of manufacturing
- Greater **complexity in supply chains**
- Imports coming from countries with less developed regulatory systems
- More opportunities for **Economic Fraud** and **counterfeiting** schemes
Globalization: Old Shenzhen (1970)
Globalization: Shenzhen Today!
Program Aligned Organizational Model
FDA Import Operation Mission

Prevention and Investigation of Adulterated, Unapproved and Misbranded FDA Products from coming into the United States.

- Import Product Review
  - Entry Review (PREDICT)
  - Field Examinations
  - Product Sample Collection
  - Investigations
- Inspections
  - Establishment Inspections
  - Facility Inspections
  - Importer Inspections
- Investigations
  - Consumer Complaints
  - Emergency Response
  - Smuggling Investigations
- Recall
- Seizure of Products at the Border
State of the FDA Import Operations—nationally and locally

• Consolidated Import Operations from 16 Districts to 5 Import Districts (North, South, West and 2 in the East) = 5 Import Program Directors reporting to OEIO

• Will provide uniform and consistent application of Import Procedures through centralized management.

• Will provide more standardized training and operating procedures.

• Will help improve communication and correspondence with FDA Port Offices and expedite review and release of compliant shipments.
Division of West Coast Imports

MAIN IMPORT OPERATIONS OFFICE – Long Beach, CA

States of:
- California
- Oregon
- Washington
- Nevada
- Hawaii

Airports

Seaports

CENTRALIZED EXAMINATION STATIONS (CES)

International Mail Facility (IMF)
GENERAL IMPORT PROCESS

Mandatory Fields

Pharmaceutical
Medical Device
Biologics
Tobacco

IMPORTS

PREDICT/District Screening and Review

Human and Animal Food

DIVISION OF FOOD DEFENSE TARGETING (DFDT)
(formerly the PRIOR NOTICE CENTER)
What is ACE/ITDS?

Today, traders must submit the same information to multiple agencies, multiple times through processes that are largely paper-based and manual. THE SINGLE WINDOW WILL STREAMLINE THIS PROCESS.
REALIZING THE SINGLE WINDOW

The Automated Commercial Environment (ACE) is the system through which the United States government has implemented the “single window,” the primary system for processing trade-related import and export data required by government agencies. This transition away from paper-based procedures results in faster, more streamlined processes for both government and industry.

U.S. Single Window for trade unifies border coordination, fosters government and industry collaboration, and yields prosperous and secure trade worldwide.

FASTER DATA

Built on a modernized platform, ACE expedites transaction processing.

33 PERCENT REDUCTION in wait times at land border truck processing ports.

68 TIMES FASTER processing of single and continuous bonds.

http://www.cbp.gov/ace

PAPER REDUCTION

ACE has streamlined manual intensive processes by automating paper forms. This makes it easier to comply with U.S. laws and regulations, while enhancing transparency and increasing predictability in the movement of goods.

300 FORMS AUTOMATED across U.S. Customs and Border Protection and 49 partner government agencies.

REDUCED COSTS

ACE reduces costs by digitizing manual processes, and reducing wait times.

9 MILLION DOLLARS SAVED annually through participation in the Periodic Monthly Statement program.

1.5 MILLION DOLLARS SAVED annually by digitally submitting export licenses.
Ask Questions, verify, research documents
Requested, Redeliver

Entry filer

FDA district entry entry reviewer

Initial action?

“May proceed” message

Detain w/o physical exam

Detain/Refuse

Set Up Assignments or Investigations, CBP Seizure

Release

IB release

Results?

Sample, analyze

Compliance action

Compliance Officer (Hearings Officer)

Good

Bad

???
Tips for Importing FDA-Regulated Products in ACE

Diagram depicts mandatory data elements by commodity type. For certain products, additional data elements may apply. Refer to FDA’s Supplemental Guide for further instruction. For more information email: ACE.Support@fda.hhs.gov.

**Drugs:**
- Intended Use Code*
- Affirmations of Compliance*

**Biologics:**
- Intended Use Code
- Brand or Proper Name (except for cells and tissues)
- Affirmations of Compliance*

**Food Products requiring Prior Notice:**
- Country of Shipment; Place of Growth (if applicable)
- Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee (in lieu of DP), Grower or Consolidator if Applicable
- Container Number
- Quantity, Packaging
- Affirmations of Compliance*
- Anticipated Port of Arrival

**Medical Devices & Radiation-Emitting Products:**
- Intended Use Code
- Name and Address of Device
- Initial Importer (medical devices only)
- Affirmations of Compliance*

**Animal Drugs & Devices:**
- Intended Use Code (Animal Drugs only)
- Affirmations of Compliance*

**Tobacco:**
- Brand Name
  - (for consumer-use products only)

**Required Data Elements for all FDA Products:**
- Commodity & Subtype
- Product Code
- Country of Production or Source
- Product Description
- Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party
- Contact Information
- Estimated Arrival Date & Time

*Indicates data elements are mandatory in some instances but not required for all scenarios. Cosmetics and Food Contact Items do not require any additional data elements other than what is listed in the center of the diagram.

Note: The following data elements are optional, but may expedite processing if transmitted: DUNS or FEI, Quantity and Value, and Filer Contact Information (FK).
Drug Imports

All foreign firms that manufacture, prepare, propagate, compound, or process a drug offered for import into the U.S. for commercial distribution are required to:

1. Register name and place of business
2. List all drug products offered for import into the U.S.
3. Designate a U.S. agent

Misconception: Registration and Listing does not indicate FDA’s approval of a firm or its products [21 CFR 207.39].
A Secure Supply Chain

- We need to know **who is manufacturing** drug products, **where they are located**, and that these facilities are **accountable** for what goes into their products as well as the products they produce.

- The benefits of a secure supply chain are an incentive for drug manufacturers to **develop secure routes to import drugs which facilitate entry clearance**. In turn enabling the FDA to focus on drugs imported via less secure supply routes.

- Public health protection is a **global endeavor**. All nations deserve the opportunity to participate and prosper in this global economy. We all have a role in creating a **global safety net**.
PGA Relationships

DEA
(Drug Enforcement Administration)

HSI
(Homeland Security Investigations)

US POSTAL INSPECTORS

US Dept. of Agriculture
(USDA – SITC, FSIS, Aphis, Agri)

FWS
(Fish and Wildlife Service)

CPSC
(Consumer Product Safety Commission)

NOAA
(National Oceanic and Atmospheric Administration)

SHARE THE SAME COMMON GOAL: PROTECT PUBLIC HEALTH
Imported, Stuffed Teddy Bears!
Stuffed with Counterfeit Viagra!
Counterfeit Challenges

The public health significance of counterfeit or unapproved drugs is that they may contain harmful impurities, may be superpotent, subpotent, may contain nothing, is ineffective and/or have altered bioavailability.

Counterfeit medicines may cause

• Death
• Disease
• Disability
• Discomfort
• Dissatisfaction

COUNTERFEIT DRUGS KILL!

COUNTERFEIT LINK

Tainted Supplements Link
FDA IMPORT OPERATIONS
STRATEGIC APPROACHES

• Pre-arrival intelligence leveraging information from multiple sources.
• Portable Devices
• Using Track and Trace Technology – holograms, lot codes, chemical tags, RFID - Working with Industry
• Trace back investigation from retail outlets to method of entry
• Task Force Operations
FDA Technology at the Ports

• Portable Devices
  – XRF (X-ray Fluorescence = DS, toxic elements, vitamins, minerals, herbals and botanicals)
  – IMS Assignment (Ion Mobility Spectrophotometer = Two main API’s: subutramine and fluoxetine)
  – CD3 – counterfeit markings

• Track and Trace Technology
  – Lot Codes
  – Holograms
  – Chemical Tags
  – RFID

• IT Technology
  – PREDICT
  – Web based applications
  – Search engines
  – Tablets (EFieldX – Import Investigators)
Other Tools

• Secure the product *Technology-based approach*
  – Implement track/trace technologies
    • RFID
    • Barcodes
    • other?

• Use authentication/anti-counterfeiting technologies
  – *Overt* - *e.g.*, holograms, color shifting ink, watermarks
  – *Covert* – *e.g.*, inks and dyes that fluoresce or absorb UV light, invisible bar codes, some watermarks
  – *Forensic* – *e.g.*, chemical markers, taggants, other unique chemical features of a substance

• *Technology-based solutions* *e.g.*, cell phones, hand held units
Good Importer Practices

Guiding Principle IV
Taking Corrective and Preventive Action When the Imported Product or Firm Is Not Compliant with U.S. Requirements

• *FDA recommends importers undertake the following actions:

• * Establish procedures for developing corrective action plans if a product is not compliant with U.S. requirements or is a safety concern.

• * Identify and investigate the root cause for non-compliance with U.S. requirements.

• * Take steps to remediate and prevent harm from present and future shipments, and to ensure non-compliant and safety problems do not recur.

• * Work with the non-compliant firm to meet U.S. requirements, or stop conducting business with that firm.
FDA Imports Enforcement Tools

- Detentions/Refusals
- Import Alerts
- Refuse shipments from mfr that denied foreign inspections of their facility
- Product Seizures (FDA and CBP)
- Injunction
- Debarment
- Criminal Charges
- Warning Letter/Untitled Letter
- Increased Bond request to CBP
- Cargo Control = All shipments from the Importer will be examined at an examination site.
New Import Alerts Website

• **Import Alerts** = Import alerts inform FDA field staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination (**DWPE**) of products that appear to be in violation of FDA laws and regulations. These violations could be related to the **product, manufacturer, shipper and/or other information**. Before importing into the United States, importers should know if their products are subject to DWPE. DWPE allows the agency to detain a product without physically examining it at the time of entry.

**LINK**

• [http://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm](http://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm)
New FDA Import Operations Website

• New Imports Program website: http://www.fda.gov/ForIndustry/ImportProgram/default.htm

FDA Exportation

• FDA issues Export Certificates = Section 801 (e)(4) of the Act provides that FDA shall, upon request, issue certificates for human drugs and biologics, animal drugs and devices that ...meet applicable requirements of the Act and maybe marketed legally in the US.

• The Act does not require FDA to issue certificates for food, including animal feed, food and feed additives, dietary supplements or cosmetics. If foreign governments require it, the FDA Centers shall issue upon request and as resources permit.
FDA Exportation

- For further information on Export Certification processing for specific product areas refer to the following websites:
  - For **Biological Products** visit [Importing & Exporting (Biologics)](http://www.cfsan.fda.gov/~lrd/impoly.html) to obtain a Certificate of Exportability, Certificate to Foreign Government, Certificate of a Pharmaceutical Product, or a Non-Clinical Research Use Only Certificate.
  - For **Medical Devices** visit [Exporting Medical Devices](http://www.cfsan.fda.gov/~lrd/medsdev.html) to obtain a Certificate of Exportability, Certificate to Foreign Government, or a Non-Clinical Research Use Only Certificate.
  - For **Drug Products** visit [Certificate of a Pharmaceutical Product Application Instructions](http://www.cfsan.fda.gov/~lrd/certifi3.html) to obtain a Certificate of a Pharmaceutical Product.
  - For **Veterinary Products** visit [Exporting - Animal Feed and Drugs](http://www.cfsan.fda.gov/~lrd/animal.html) to obtain a Certificate of Exportability, Certificate to Foreign Government, Certificate of Free Sale, or a Certificate of a Pharmaceutical Product.
  - For **Cosmetics** visit [Cosmetic Exports](http://www.cfsan.fda.gov/~lrd/cosmetic.html) to obtain a General Certificate or Product Specific Certificate.
  - For **Foods** (including **Dietary Supplements**) visit "[Enter a Food Export Certificate Application Step-by-Step Instructions](http://www.cfsan.fda.gov/~lrd/foodexport.html)" to obtain a Certificate of Free Sale or Certificate of Export.
  - European Union (EU) Export Certificates For Fishery and Aquaculture Products visit "[Export Certificates for Fishery/Aquaculture Products and Live/Raw Molluscan Shellfish](http://www.cfsan.fda.gov/~lrd/Import.html)."
- For further information on FDA Issued/Supported Export Certificates for Food visit [http://www.cfsan.fda.gov/~lrd/certifi3.html](http://www.cfsan.fda.gov/~lrd/certifi3.html).
What do I do if I want to Import FDA Regulated Products into the United States?

• Hire a certified Customs Broker. They know many of the Government Requirements and have done the homework for you.

• Do your own homework and know your commodity at www.FDA.gov.

• Know Affirmation of Compliance Codes related to your product.

• Know what Port of Entry your products will be shipped into.

• Know which Compliance Officer is assigned to your case.
Importation Strategies

- Keep and obtain any FDA analytical results, memos and documentations handy.
- Cooperate with FDA Investigators
- Build good compliance history
- Look at the Import Alerts and study how to be removed from an Import Alert. It is not an automatic process.
- Get Training! On FSVP, PC and Produce for foods! On GMP’s for others...
- It is okay to politely asked the FDA Investigator or Compliance Officer, when you should circle back with them.
- Be cordial, polite and professional to the FDA Investigators. They have been trained to do the same.
- If Product quality is an issue due diligence at the manufacturing site and investigate.
- Retain documentation.
Common Mistakes

- Provide wrong manufacturer information, address, MID and FEI numbers (will delay processing).
- Importer is new and does not know process or procedures to follow. – Hire an experience Customs Brokers
- Attempts to calls all FDA extensions known.
- Emails more than one FDA Officers
- Demands FDA to release shipments, immediately
- Falsifying documents – Title 18
- Ignoring FDA Notice of Actions
- Ignoring CBP summons and penalty notices
- Sells adulterated products into commerce
- Does not cooperate with recall coordinator
- Submits after the Detention notice due date
- Ask FDA to rescind a Refusal
FORMS OF COMMUNICATION WITH DIVISION OF WEST COAST IMPORTS

- Phone Numbers for Division of West Coast Imports in Long Beach, Ca)
  - General status line (562) 256-7700
  - Compliance status line (562) 256-7707
  - Fax line (562) 256-7701
- General email address: WCID@fda.hhs.gov
- Los Angeles District Consumer Complaint Hotline: (949) 608-3530
- FDA National Emergency Operations Number: 1-866-300-4374 or (301) 796-8240
- FDA General Inquiry: 1-888-INFO-FDA
- For Adverse Event of illness call 1-800-FDA-1088 or online
- For Drug Inquiries: CDERSmallBusiness@fda.hhs.gov or (866)-405-5367
- For Medical Device Inquiries: industry.device@fda.hhs.gov or (800) 638-2041
- To report e-mails promoting medical products that you think might be illegal, forward the email to: webcomplaints@ora.fda.gov.
- Food and Cosmetic Information Center by phone and/or e-mail Monday through Friday, from 10 a.m. to 4 p.m. at 1-888-SAFEFOOD (1-888-723-3366). Or, submit questions by filling out the online form.

Note: Fastest response is email.
Thank you!
Email address: 
Dan.Solis@fda.hhs.gov, and 
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