



FDA Imports Overview – APO Import Forum

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Program Development and Implementation Branch



U.S. Department of Health and Human Services

Food and Drug Administration



OVERVIEW



- I. FDA Overview/Organization
 - ↪ What is FDA-regulated?
 - ↪ General Import Data

- II. General Overview of FDA Import Law
 - ↪ “appears” and
 - ↪ “or otherwise”

- III. FDA Import Overview
 - ↪ Import Process
 - ↪ Food and Feed
 - ✓ Two Tier Process
 - ✓ Requirements
 - ↪ Field Activities

 - ↪ Import Alert System
 - ✓ Addition to
 - ✓ Removal from



Products Regulated by FDA

- ↪ Human foods (exceptions: most meat and poultry)
- ↪ Dietary Supplements
- ↪ Animal feeds
- ↪ Cosmetics
- ↪ Drugs (both human and animal)
- ↪ Biologics (including human cells and tissues)
- ↪ Medical devices
- ↪ Electronic products that emit radiation
- ↪ Tobacco



FDA Organization



Office of the
Commissioner



Center for
Food
Safety &
Applied
Nutrition



Center for
Drug
Evaluation &
Research



Center for
Biologics
Evaluation &
Research



Center for
Devices &
Radiological
Health



Center for
Veterinary
Medicine



Center for
Tobacco
Products



National
Center for
Toxicological
Research



Office of
Regulatory
Affairs



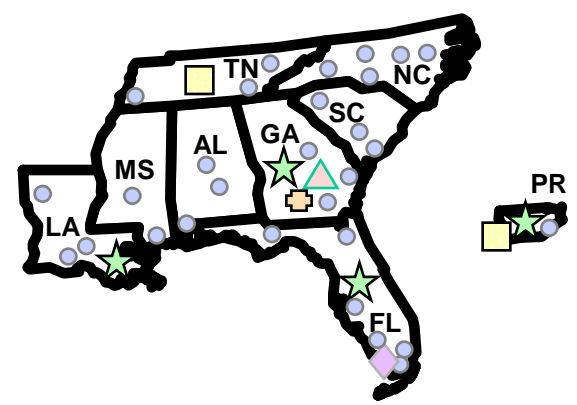
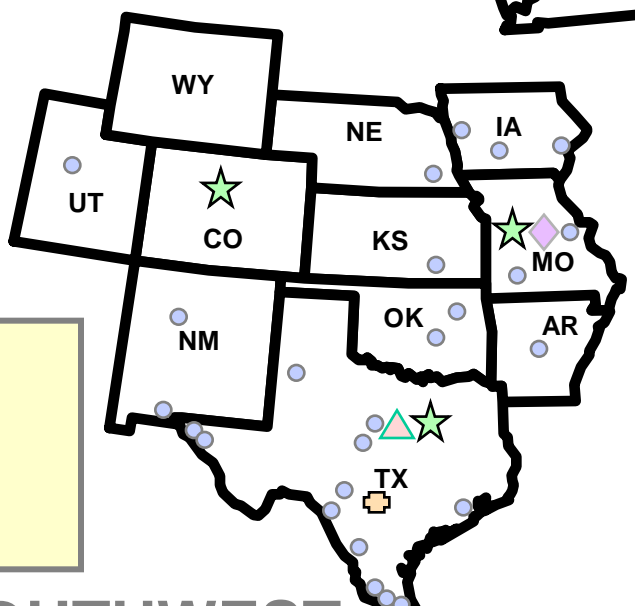
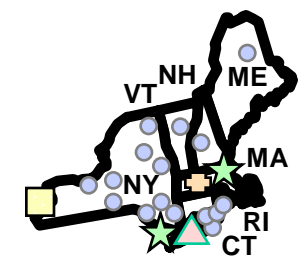
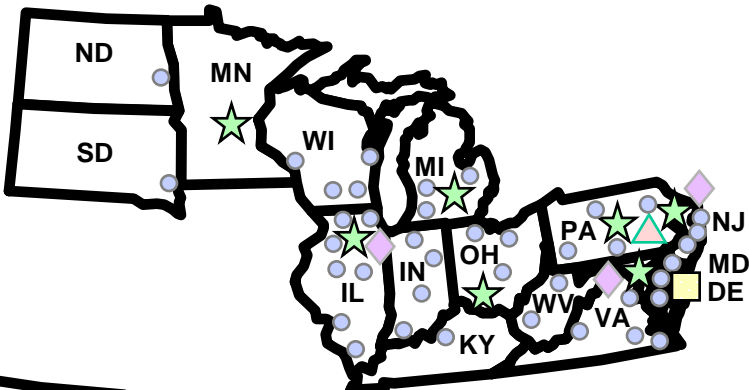
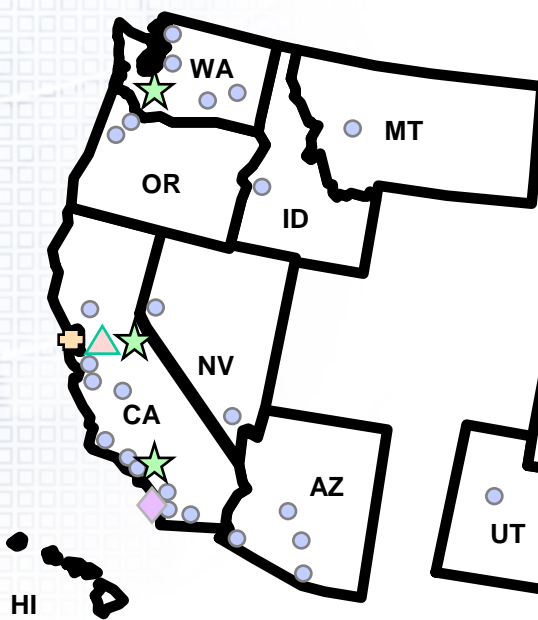
Office of Regulatory Affairs



PACIFIC

CENTRAL

NORTHEAST



SOUTHEAST

- REGIONAL OFFICES - 5
- DISTRICT OFFICES - 19
- RESIDENT INSPECTION POSTS - 137
- OCI FIELD OFFICES - 6
- OCI RESIDENT OFFICES - 4
- OCI DOMICILES - 4

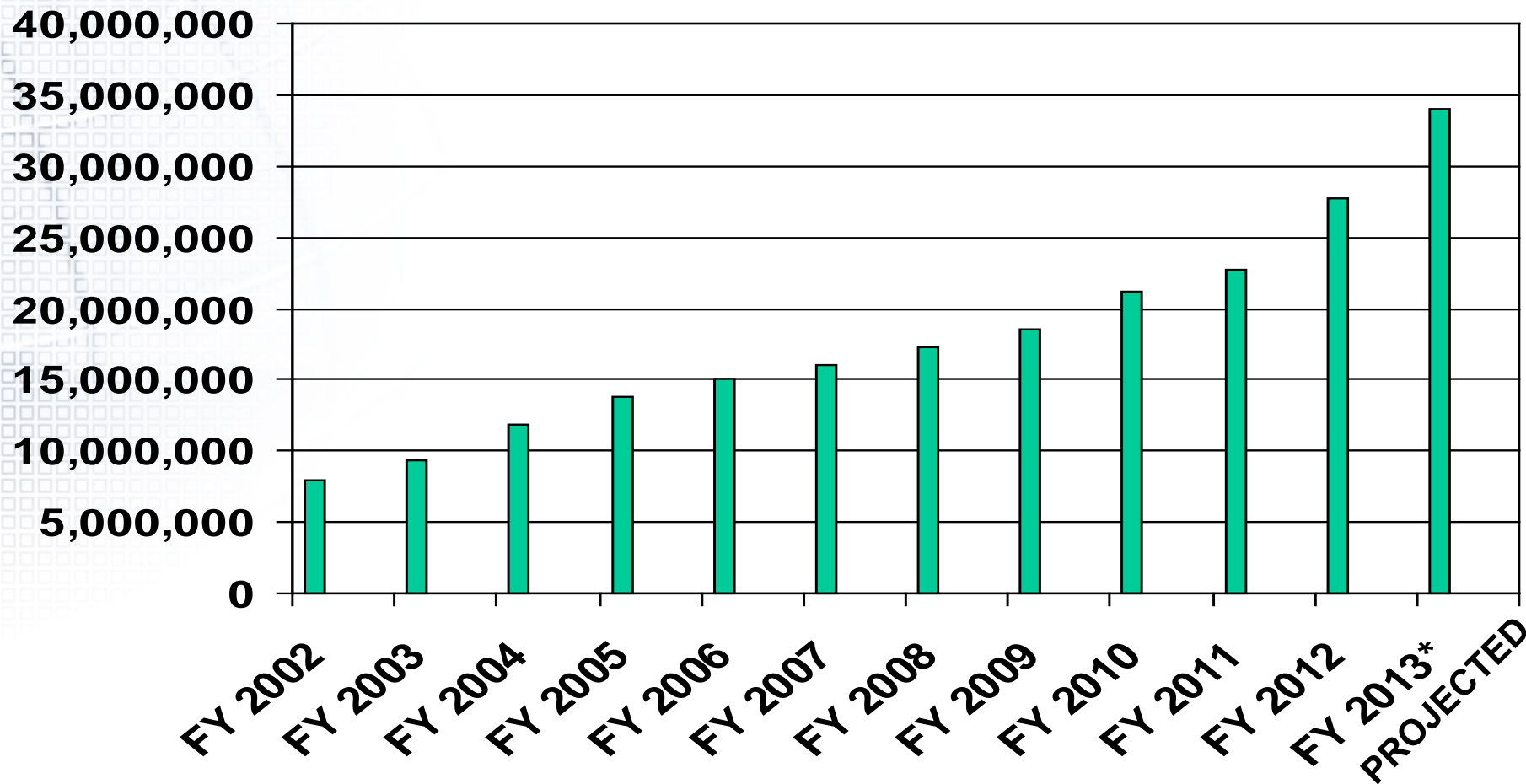
SOUTHWEST



FY 2002 – 2013*

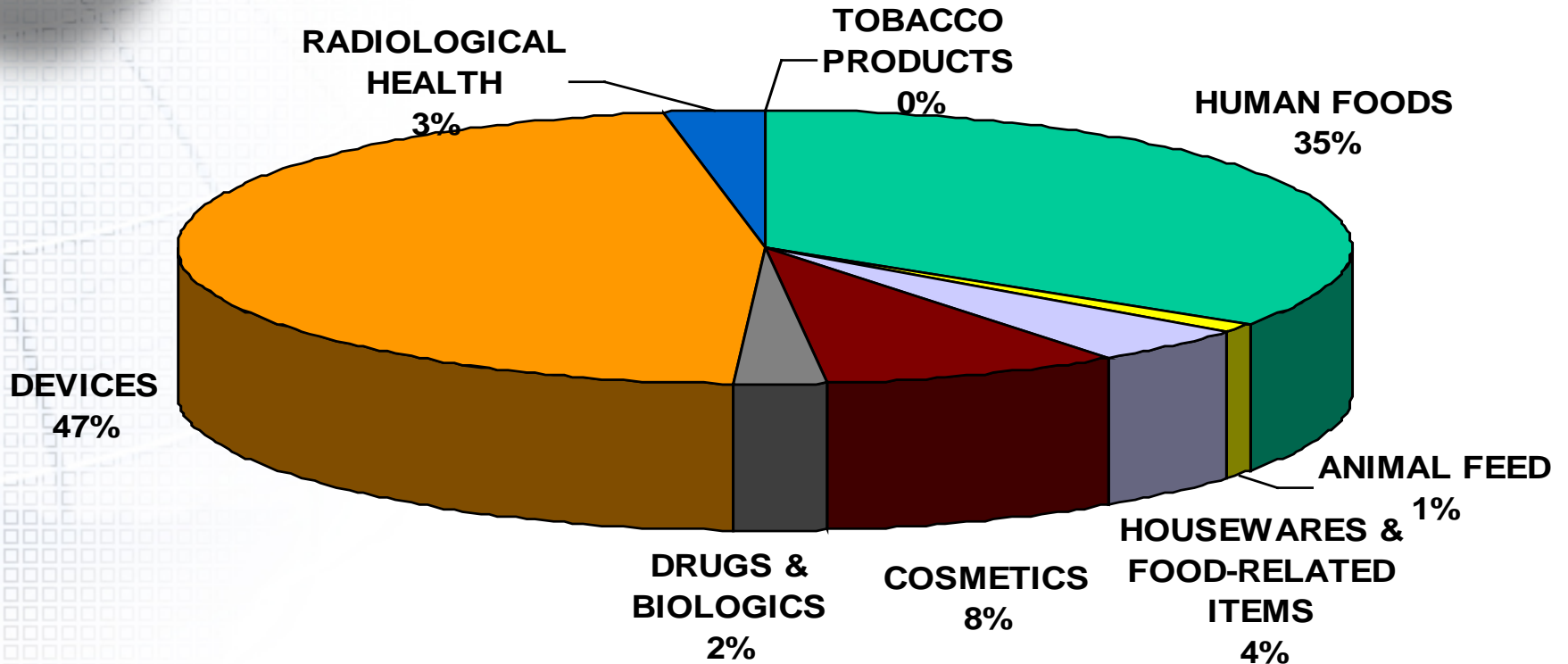


TOTAL IMPORT LINES





FY 2012 LINES BY INDUSTRY



■ HUMAN FOODS

■ ANIMAL FEED

■ HOUSEWARES & FOOD-RELATED ITEMS

■ COSMETICS

■ DRUGS & BIOLOGICS

■ DEVICES

■ RADIOLICAL HEALTH

■ TOBACCO PRODUCTS



- **Section 801 of the FFD&CA**

“If it appears from the examination of such samples *or otherwise* that...”

- (1) such article has been manufactured, processed, or packed under insanitary conditions... or
- (2) such article is forbidden or restricted in sale in the country in which it was produced ... or
- (3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)

“then such article shall be refused admission...”



- “appears” – provides FDA’s standard of proof
 - ↳ We can refuse entry to goods that:
 - ✓ Appear to be adulterated or misbranded;
 - ✓ Appear to be unapproved new drugs;
 - ✓ Appear to have been manufactured not in accordance with GMPs.



- “or otherwise” – allows FDA to make admissibility decisions using:
 - ↳ Historical data;
 - ↳ Examinations (vs. sample collections);
 - ↳ Information from other sources;
 - ↳ Other evidence.



Food Drug & Cosmetic Act (FDCA)

Chapter VIII – Imports and Exports



- “...*shall* be refused admission...” – directs FDA’s action
 - ↳ The intent of the law is to deny importation of violative articles;
 - ↳ Articles are expected and required to be in compliance *at the time of entry*;
 - ↳ Compare to other sections of FDA law (seizure).



U.S. Customs & Border Protection



- Customs and Border Protection (CBP) has the initial authority for all imported products:
 - ↳ 19 United States Code;
 - ↳ Title 19 Code of Federal Regulations;
 - ↳ Harmonized Tariff Schedule of the United States (HTSUS).



Customs Territory of the U.S.



- 50 States;
- District of Columbia; and,
- Puerto Rico.

↳ Note: Insular Possessions (IPs - Guam, Virgin Islands, American Samoa, etc.) are not included

The Import Process



- Entry is made to Customs
- If FDA regulated, Customs forwards to FDA



The Import Process: Food and Feed Only Tier 1 – Prior Notice



- Food and Feed Imports Requiring Prior Notice
 - ↳ Food imported for use, storage, or distribution in the U.S.;
 - ↳ Food transshipped through the U.S. to another country;
 - ↳ Food imported for future export;
 - ↳ Food for use in a Foreign Trade Zone.



How Entry is Made



- Whether the 2-step process or “Live Entry”, once all documents are in order, and if CBP has no reason to detain or exclude the articles, CBP issues a “conditional release.”
- The conditional release is a release from CBP custody, yet still subject to the terms and conditions of the importer’s bond with CBP.



From CBP to FDA



- Entry is made with CBP
 - ↳ CBP refers entries of FDA-regulated articles to FDA
 - ✓ If electronic, from CBP's Automated Commercial System (ACS)/Automated Commercial Environment (ACE) to FDA's OASIS system (Operational and Administrative System for Import Support)/Mission Accomplishments and Regulatory Compliance Services (MARCS); or,
 - ✓ If non-electronic, documents are hand-carried from one office to another.



From CBP to FDA



- Electronic entries include CBP data (Importer & Consignee, Tariff code, etc) plus FDA specific data:
 - ↳ FDA Country of Origin;
 - ↳ FDA Product Code;
 - ↳ FDA Manufacturer;
 - ↳ FDA Shipper;
 - ↳ Product Description;
 - ↳ Affirmations of Compliance;
 - ↳ Quantity and Value.



From CBP to FDA



- Human reviewers check “FDA Review” entries, if necessary
 - ↳ Conformity with statutory & regulatory requirements
 - ✓ Biologics for a license;
 - ✓ Drugs & Devices for approvals, listing & registration;
 - ✓ LACF/AF products for process filing;
 - ✓ Etc.
 - ↳ History of commodity and/or manufacturer
 - ✓ Import Alerts;
 - ✓ Import Bulletins;
 - ✓ Local intelligence;
 - ↳ Compliance programs, assignments, etc.



Drugs



- In addition to automated database look-ups against the entry information transmitted to FDA, human reviewers will verify (if necessary) the:
 - ↳ Drug product approval;
 - ✓ Drug products, with the exception of investigational new drugs, must be approved prior to importation;
 - ✓ Both product and foreign source/manufacturing site specific; and,
 - ✓ Includes dosage form and strength.
 - ↳ Drug product listing; and,
 - ✓ Both product and manufacturing site specific (NOT the corporate office); and,
 - ✓ Includes dosage form and strength.
 - ↳ Drug facility registration(s).
 - ✓ Site specific; and,
 - ✓ Effects the drug listing for the product.



Medical Devices



- In addition to automated database look-ups against the entry information transmitted to FDA, human reviewers will verify (if necessary) the:
 - ↳ Medical device approval;
 - ✓ Most Class II Medical devices + a select few Class I, with the exception of investigational devices and biological devices where a biologics license application (BLA) is in effect, must have a cleared premarket notification (PMN)/510(k);
 - ✓ Most Class III Medical devices + a select few Class II, excluding investigational devices and biological devices with a BLA, must have an approved premarket application (PMA)/515(a) prior to importation; and,
 - ✓ Product specific only.
 - ↳ Medical device listing;
 - ✓ Both product and manufacturing site specific (NOT the corporate office);
 - ↳ Medical device facility registration(s).
 - ✓ Site specific; and,
 - ✓ Effects the medical device listing for the product.



Biologics



- In addition to automated database look-ups against the entry information transmitted to FDA, human reviewers will verify (if necessary) the:
 - ↳ Biological product licensing;
 - ✓ Biological products must be licensed (approved) before being offered for import;
 - ✓ Similar to a drug or device approval; and,
 - ✓ Both product and manufacturing site specific;
 - ↳ Biological product listing and facility registration;
 - ✓ Registration and listing is required for human cells, tissues and cellular/tissue-based products (HCT/Ps);
 - ✓ Registration only is required for blood establishments; and,
 - ✓ Otherwise, not required unless the biologic is also a drug or device.



The Import Process, cont.

Tier 2 - Admissibility Decision



- FDA will decide to:
 - ↳ Release the goods
 - ↳ Detain the goods without exam
 - ✓ Based on submission of required information
 - ✓ Based on import alerts
 - ↳ Obtain more information:
 - ✓ Through documents associated with the entry
 - ✓ Through examination and/or sample collection



From CBP to FDA - FDA Document Review



- Review of documents will result in:
 - ↳ Release;
 - ↳ Detention; or,
 - ↳ Examination or sampling assignment.
- The process for each then begins



The Import Process, cont. Release



- ↪ Product may be distributed;
- ↪ FDA still has jurisdiction;
- ↪ Does not preclude FDA action if a violation/problem/issue is found later in domestic commerce;
- ↪ Ends the conditional release period; CBP has 30 days from the date of FDA release to order redelivery.



The Import Process, cont.

Examination/Sample Collections



- ↪ FDA field personnel are trained in examination and sampling techniques
- ↪ Examinations may uncover “appearance” of violations
- ↪ Samples normally analyzed by FDA laboratories



From CBP to FDA - Examination/Sample Collections



- Articles not made available to FDA for examination
 - ↳ There is no FDA violation;
 - ↳ FDA can request CBP issue an order for redelivery;
 - ↳ Importer has 30 days to make goods available at the port of entry;
 - ↳ If not, liquidated damages may be assessed.



From CBP to FDA - Examination/Sample Collections



- Notice of FDA examination/sampling extends the conditional release period;
- Non-violative examinations and sample analyses result in release;
- Violative examinations and sample analyses result in detention.
 - ↳ Detention and Hearing Process begins

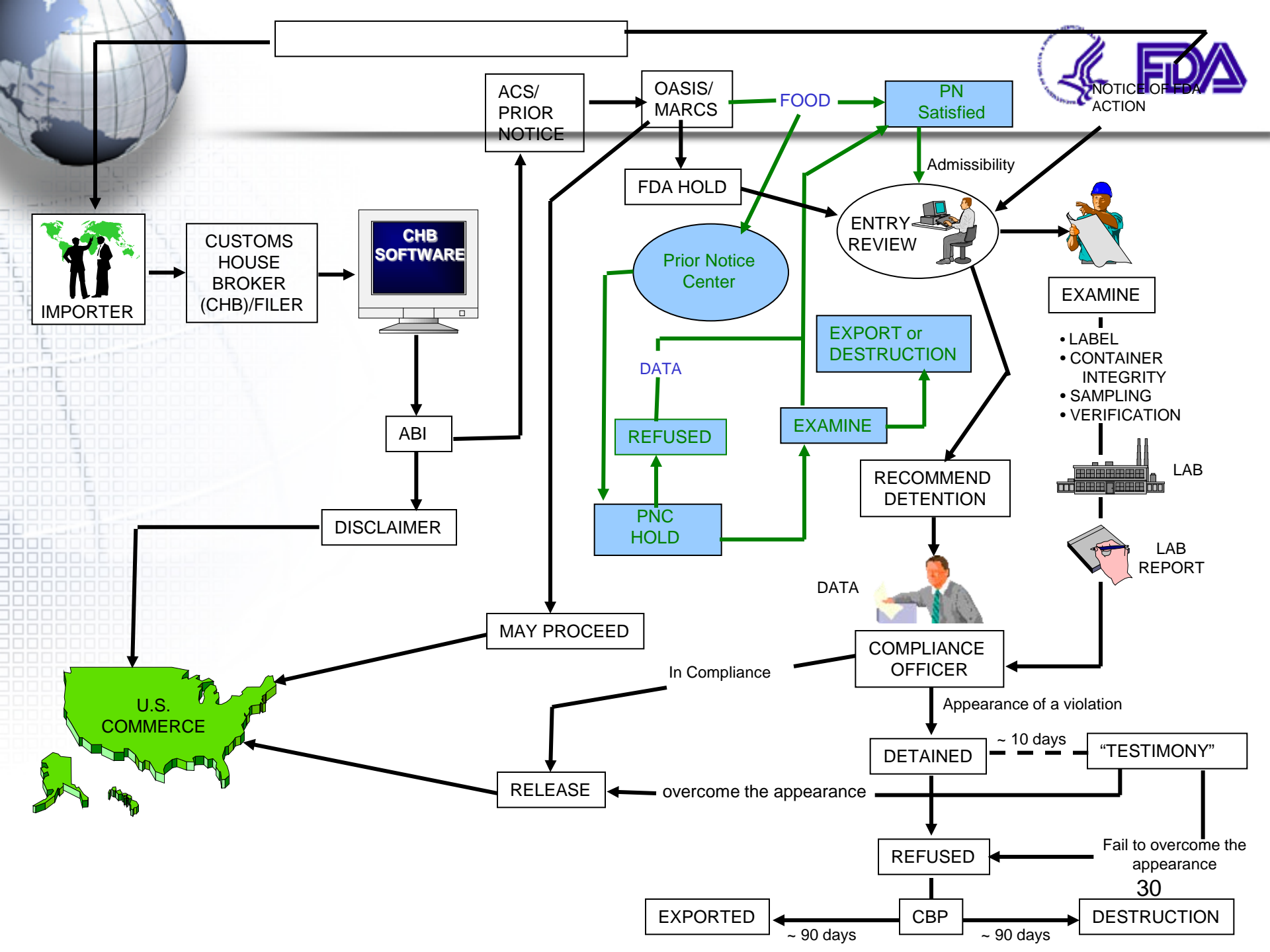


The Import Process, cont.

Detention



- ↪ FDA can detain based upon “appearance” of a violation
- ↪ Importer has the right to give evidence to refute this appearance or bring the product into compliance
 - ✓ This is known as the “Detention and Hearing Process”
- ↪ Based on the evidence, the detention will either stand (refusal) or be overturned (release)
- ↪ Importer can also petition to recondition the goods to bring them into compliance
 - ✓ Reconditioning must be approved by FDA





The Import Process, cont.

Import for Export



- ↪ The FDA Export Reform and Enhancement Act of 1996 (Export Reform Act) amended section 801(d)(3) of the Act to allow the importation of certain articles that are unapproved or otherwise do not comply with the Act, provided that those imported articles are further processed or incorporated into products that will be exported from the United States.
- ↪ By law, only components of drugs and devices, along with food additives, color additives and dietary supplements are permissible for import for export.
 - ✓ Thus all other products FDA regulates may not be imported for export under this provision, including foods, tobacco, etc.



The Import Process, cont.

Import for Export



- ↪ Section 801(d)(3) allows for the importation of otherwise non-compliant products and articles for manufacturing, further processing or incorporation and export.
 - ✓ **Storage** for future export is **NOT** permissible under the import for export provisions of the Act.
- ↪ For food/feed products, prior notice is still required at the port of arrival, unless one of the exemptions is met.
- ↪ For the purposes of FDA, there is no limitation on the time before the article must be further processed or incorporated into a product and exported or destroyed.
 - ✓ The timeframes are typically linked by the conditions of the bond with CBP.



Import Alerts



Import Alert System



- Chapter VIII of the Food Drug and Cosmetic Act, supported by sufficient evidence, forms the basis for Detention Without Physical Examination (DWPE)
- A List of All Current Import Alerts may be found on FDA's internet website:

↳ http://www.accessdata.fda.gov/cms_ia/ialist.html



Import Alert System



- ↪ It prevents potentially violative products from being distributed into the United States
- ↪ It frees up Agency resources to examine other shipments
- ↪ Provides uniform coverage across the country
- ↪ Places the responsibility back on the importer
 - ✓ It is the responsibility of the importer to ensure that the products offered for entry into the U.S. are in compliance with our laws and regulations.



Import Alert System



Import Alerts do not create new requirements



The requirements already exist as the FFD&CA defines what adulterated and misbranded mean,

- ✓ Import Alerts are a repository which lists those firms and/or products wherein the FDA has evidence which appears to meet those definitions



Criteria for DWPE can be found in FDA's Regulatory Procedures Manual @

(<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>) and other publicly available guidance



Import Alert System



- **Products are not subject to DWPE because they are on Import Alert; they are on Import Alert because they are subject to DWPE.**



Import Alert System



- Adding a firm, product and/or importer to DWPE:
 - ↳ Based on evidence from our field offices -
 - ✓ Most often cause for DWPE
 - ✓ Violative sample analyses or examinations
 - ↳ Based on evidence from foreign inspections -
 - ✓ Violative inspections
 - ✓ Most often lead to Good Manufacturing Practices charges
 - ↳ Other sources of information, e.g. foreign governments, states, other federal agencies -
 - ✓ Rarer than others but does occur
 - ✓ Evidentiary standard remains the same



Import Alert System



- Different types of DWPE Import Alerts:
 - ↳ Product/Firm Specific
 - ✓ Lists products from specific manufacturers, possibly shippers, which appear to be violative;
 - ✓ Often contain a “RED LIST”;
 - ✓ Examples: 45-02, 16-81, 99-08.
 - ↳ Product General
 - ✓ For products that are inherently problematic;
 - ✓ May contain a “GREEN LIST” or none at all;
 - ✓ Examples: 21-07, 61-07.



Import Alert System



- Different types of DWPE Import Alerts cont.:
 - ↳ Country- or area-wide
 - ✓ Geographic areas meeting certain criteria;
 - ✓ May contain a “GREEN LIST” or none at all;
 - ✓ Examples: 02-01, 16-131, 99-30.



Detained Without Exam



- ↳ Regardless of the nature of the detention:
 - ✓ Importer has the right to give evidence to refute the appearance of a violation
 - ✓ Based on the evidence, the detention will either stand (refusal of admission) or be overturned (released)

- ↳ Not all charges are the same, or need the same evidence to refute the appearance of a violation:
 - ✓ Not every detention can be cleared up with a private lab test
 - ✓ However, not every detention needs a private lab test
 - ✓ Very difficult to overcome processing issues



Detained Without Exam



- ↳ Importer can also petition to recondition the goods to bring them into compliance
 - ✓ Relabeling a misbranded product;
 - ✓ Cleansing an adulterated product; and/or
 - ✓ Manipulating a product so the article is not subject to FDA jurisdiction.

- ↳ Reconditioning must be approved by FDA



Removal from DWPE



- ↳ In order to remove a product/firm from DWPE:
- ✓ Remedial actions must be adequate;
 - ✓ Verified through evaluation of actual entries;
 - ✓ Assurance the cause of the violation has been corrected;
 - ✓ Assurance of consistent compliance.



Removal from DWPE



- **Process:**

- ↳ Firms, importers and/or their representative may petition to be removed from DWPE:

- ✓ Industry submits the petition
- ✓ FDA reviews the petition

- ↳ Petitions should be submitted to:

- ✓ ImportAlerts2@fda.hhs.gov (for electronic submission)

or:

- ✓ FDA - Division of Import Operations and Policy (for hardcopy submission)
12420 Parklawn Drive, ELEM-3109
Rockville, MD 20857



Removal from DWPE



- **Process cont.:**

- ↳ Acknowledgement sent in-kind
 - ✓ Includes case number
 - ✓ Includes contact person and phone/email
- ↳ Reviews are done first in-first out
- ↳ The petition review order is not re-arranged without good reason
- ↳ Reviews can take 2-3 months to process
 - ✓ Turnaround time is decreasing



Removal from DWPE



- **Process cont.:**

- ↳ Decision Letter sent to the petitioner
 - ✓ Denial letters include explanation;
 - ✓ All denials are specifically reviewed by DIO management;
 - ✓ Approval letters include our notice to field offices;
 - ✓ Approvals are effective immediately.
- ↳ Decision Letter closes the case



Removal from DWPE



- **Generally, what to submit in a removal petition:**
 - ↪ Investigation into the cause of the initial violation (if applicable)
 - ↪ Remedial actions and/or steps to prevent future violations
 - ↪ All Import Alert specific information
 - ✓ Review the import alert
 - ✓ Firms with GMP and similar violations may need an inspection to be removed from an Import Alert
 - ↪ Entry documentation for five (5) non-violative entries:
 - ✓ U.S. Customs Form 3461, U.S. Customs Form 7501, or equivalent Customs form such as an e-manifest;
 - ✓ Invoice;
 - ✓ Packing List;
 - ✓ Bill of Lading or Airway Bill;
 - ✓ **Private laboratory results are not necessary.**



Removal from DWPE



- **What FDA reviews:**

- ↳ Remedial actions

- ✓ FDA needs assurance the cause of the violation has been corrected
 - ✓ Inadequate remedial actions is cause for denial
 - ✓ Failure to submit corrective actions is cause for denial

- ↳ FDA's Internal Databases

- ✓ We review all related shipments, not just the five (5) submitted in support of the petition
 - ✓ Product failures/refusals is cause for denial

- ↳ Anything else indicated in the Import Alert

- ✓ Failure to submit is cause for denial

We will always specifically ask for anything missing



Removal from DWPE



- **Common reasons for denial:**

- ↪ Failure to submit remedial actions
- ↪ Failure to submit entry documentation
 - ✓ Provides manufacturer information for verification against shipping history
- ↪ Failure to submit other information
- ↪ Product failures
- ↪ Staging shipments
 - ✓ Breaking up large shipments into smaller entries to count as more than one (1) for the purposes of the removal petition
 - ✓ Shipping small quantities of product as opposed to the 'normal' commercial quantity for the firm/product-type



Import Alert Case Study



http://www.accessdata.fda.gov/cms_ia/importalert_401.html

The End Questions?

