Border Issues and Statistics: Regulatory Activities

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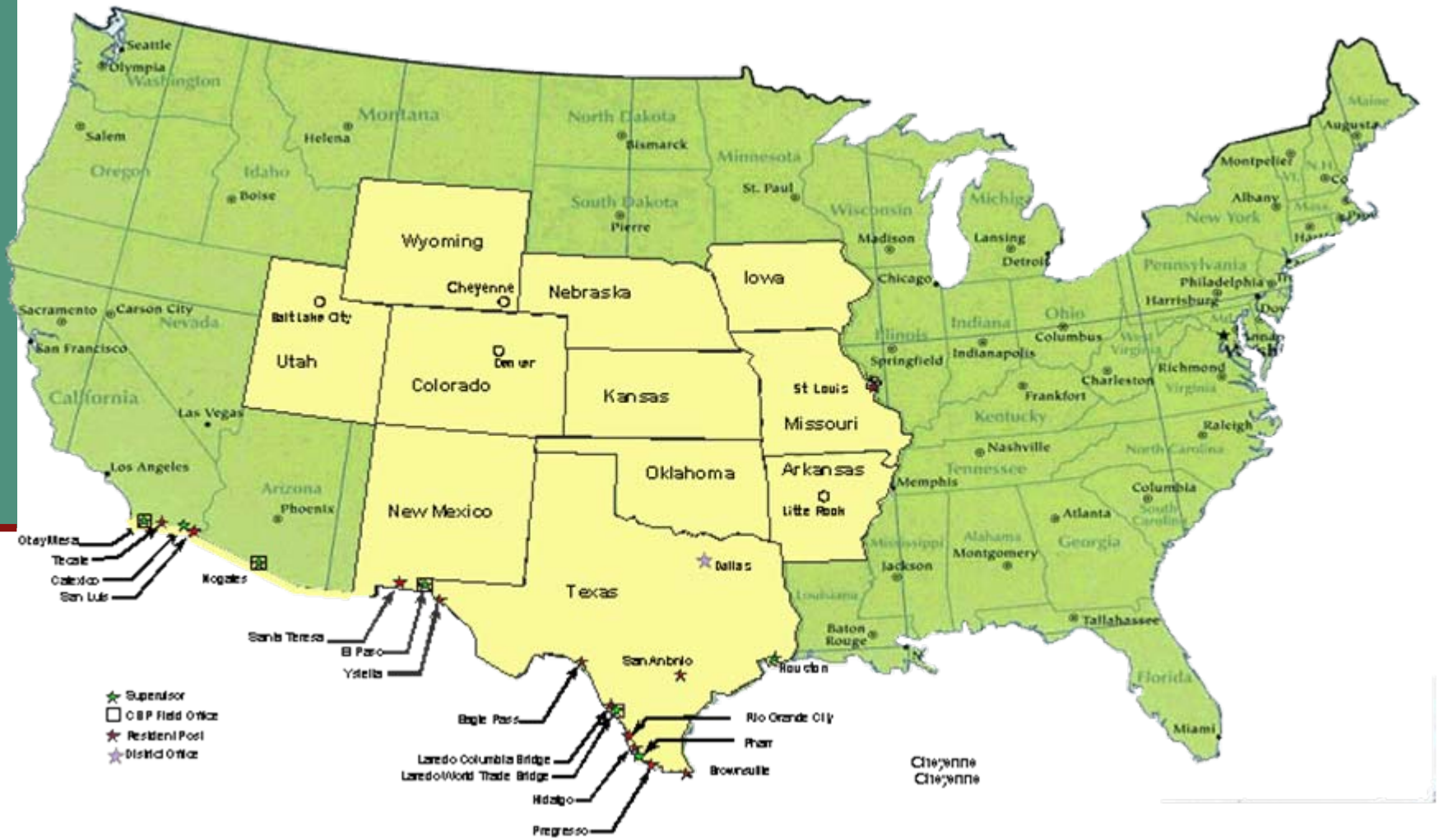
U.S. Food & Drug Administration Mission Statement

- The Food & Drug Administration is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics and products that emit radiation.

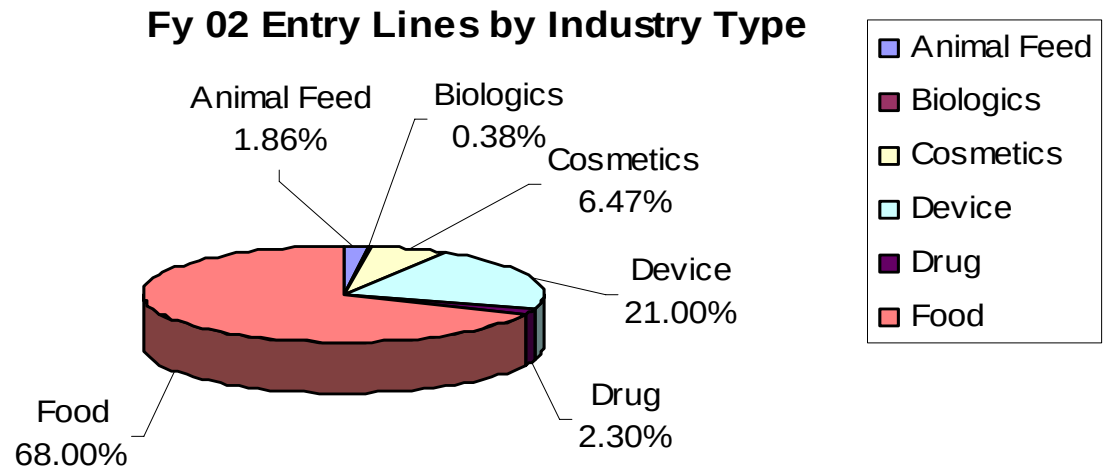
Southwest Import District

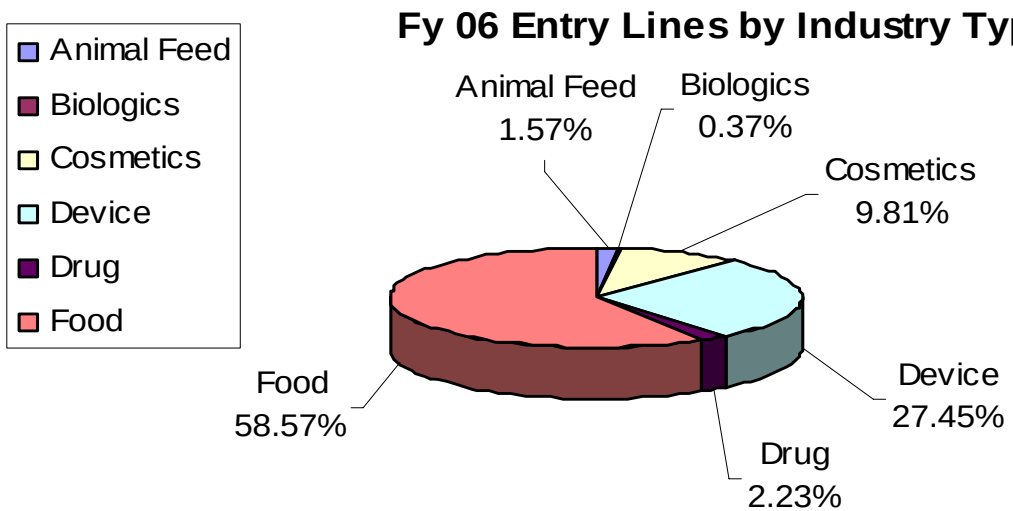


U.S. Food, Drug, and Cosmetic Act: Section 801

- Section 801 (a) of the FD & C Act, authorizes FDA examination of foods, drugs, cosmetics and devices offered for entry into the United States.

Comparisons of Product Types





Federal Food, Drug and Cosmetic Act:

- Requirements to Import Drugs
- Requirements to Import Medical Devices
- Import Issues
- Regulatory Activities

Federal Food, Drug, and Cosmetic Act: Drugs

- Section 510:
- Requires manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and human biological products to register their establishment(s) and submit a listing of every product in commercial distribution with the FDA.

Prescription Drug Marketing Act

- The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law by the President April 12, 1988. The PDMA was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs.

- http://www.fda.gov/cder/regulatory/PDMA/default.htm

Prescription Drug Marketing Act

- Sec. 203.10 Restrictions on reimportation. No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.

Code of Federal Regulations] [Title 21, Volume 4]

Federal Food, Drug and Cosmetic Act: Drugs

- The Bioterrorism Act of 2002 amended the listing section of the Act to require foreign drug establishments whose drugs are imported into the U.S. to submit certain information with their annual registration. This information is in addition to the regular registration requirements.

http://www.fda.gov/cder/drls/registration_listing.htm

Federal Food, Drug and Cosmetic Act: Drugs

- The Bioterrorism Act of 2002 (cont):
- Each importer/consignee of each drug in the U.S. known to the manufacturer at the time of registration
- Each person who imports or offers to import the manufacturer's drugs
- The name and contact information of U.S. Agent

Drug vs. Dietary Supplement

- **Definition of a Drug**:
- “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and (B) articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)]. “

Import Issues: Drug vs. Dietary Supplement

- **Definition of a Dietary Supplement**:
- “Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular, and metabolites.

Import Issues: Drug vs. Dietary Supplement

- Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement.”

Federal Food, Drug and Cosmetic Act: Device

- 21 CFR Part 807 :
- Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA.
- All medical devices that are manufactured and imported into the U.S. are required to be listed with the FDA on Medical Device Listing form FDA-2892.

http://www.fda.gov/cdrh/devadvice/overview.html

Federal Food, Drug and Cosmetic Act: Device:

- 21 CFR Part 807
- If your device requires the submission of a Premarket Notification 510(k) you can not commercially distribute the device until you receive a letter of substantial equivalence from FDA authorizing you to do so. A 510(k) must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent

Federal Food, Drug and Cosmetic Act: Device (cont)

- Firms that are required to list their devices are those that:
- manufacture, repackage and relabel, develop specifications, reprocess single-use devices, remanufacture
- manufacture accessories and components sold directly to the end user
- A separate device listing form must be submitted for each type of device

Import Issues

- Harmonized Tariff Codes
- FD Flags
- Disclaim errors
- Improper Product Codes
- Lack of Affirmation of Compliance
- Lack of Registration and Listing

Import Issues

- **Harmonized Tariff Codes**: U.S. Customs method of identifying products imported into the U.S. which determines duties, quotas, and **other government agency requirements.**
- **9018.39.0020** catheter, drain

Import Issues: FD Flags

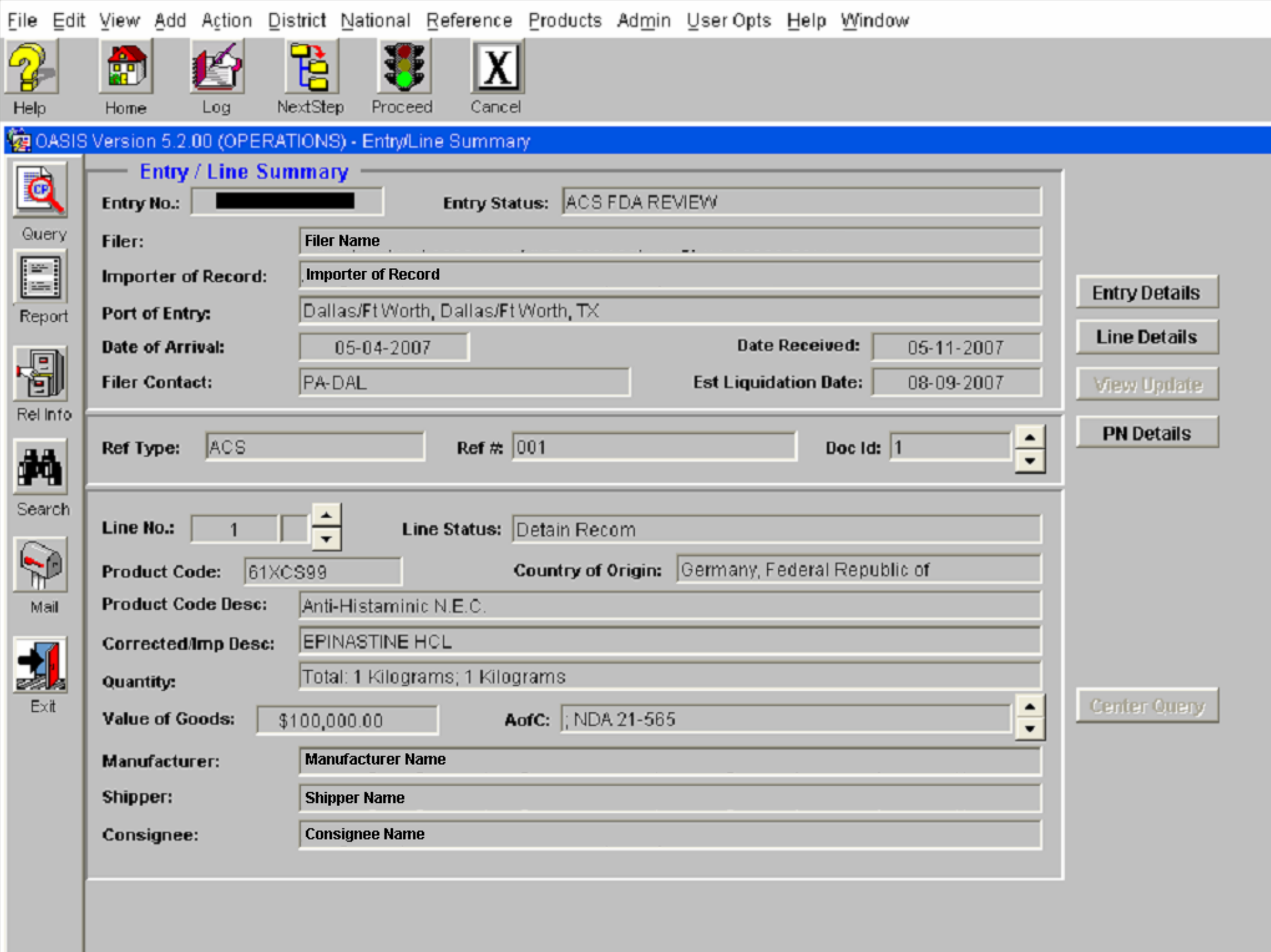
- FD0: FDA has determined the article, even though subject to FDA's laws & regulations, is acceptable for CBP release without further presentation of Prior Notice or other entry information to FDA
- FD1: Indicates that the article **may be** subject to FDA jurisdiction. For products not subject to FDA, filer can "disclaim"
- FD2: Indicates the article is under FDA jurisdiction and review of entry information by FDA under section 801(a) will take place.
- FD3:Indicates that the article **may be** subject to **prior notice** under section 801(m) of the Act and 21 CFR part 1, subpart I, article has food and non-food use
- FD4:Indicates that the article is "food" for which **prior notice is** required under section 801(m) of the act and 21 CFR1,subprt I

Import Issues: Disclaimed Errors

- An error by filer: Harmonized Tariff did not flag other government agency requirement
- Filer did not “disclaim” correctly under FD flag
- Importer information to Filer not clear on intended use of product
- Clerical error
- Circumventing FDA requirements

Import Issues

- **Improper Product Code**:
- Product Code should identify product
- Incorrect Product Coding can delay process of entry
- May give the appearance of circumventing the FDA requirements


File Edit View Add Action District National Reference Products Admin User Opts Help Window
Help
Home
Log
NextStep
Proceed
Cancel
OASIS Version 5.2.00 (OPERATIONS) - Entry/Line Summary
Query
Report
Rel Info
Search
Mail
Exit
Entry / Line Summary
Entry No.: [redacted]
Entry Status: ACS FDA REVIEW
Filer: Filer Name
Importer of Record: Importer of Record
Port of Entry: Dallas/Ft Worth, Dallas/Ft Worth, TX
Date of Arrival: 05-04-2007
Date Received: 05-11-2007
Filer Contact: PA-DAL
Est Liquidation Date: 08-09-2007
Ref Type: ACS
Ref #: 001
Doc Id: 1
Line No.: 1
Line Status: Detain Recom
Product Code: 61XCS99
Country of Origin: Germany, Federal Republic of
Product Code Desc: Anti-Histaminic N.E.C.
Corrected/Imp Desc: EPINASTINE HCL
Quantity: Total: 1 Kilograms; 1 Kilograms
Value of Goods: $100,000.00
AofC: ; NDA 21-565
Manufacturer: Manufacturer Name
Shipper: Shipper Name
Consignee: Consignee Name
Entry Details
Line Details
View Update
PN Details
Center Query

Import Issues

- **Affirmation of Compliance**:
- This field should include: importer registration number, foreign establishment registration number and name of U.S. Agent, medical device listing number, PreMarket Notification 510(k)
- If this field is left blank, delay in process of entry

Import for Export

- FD&C Act Section 801(d) – BT Act changed this section
- Additional requirements for Import for Export
  - Component of food, drug, dietary supplement, color additive, food additive, device, etc…
  - Intended for further manufacturing and re-export (warehouse/storage does not qualify for exemption)

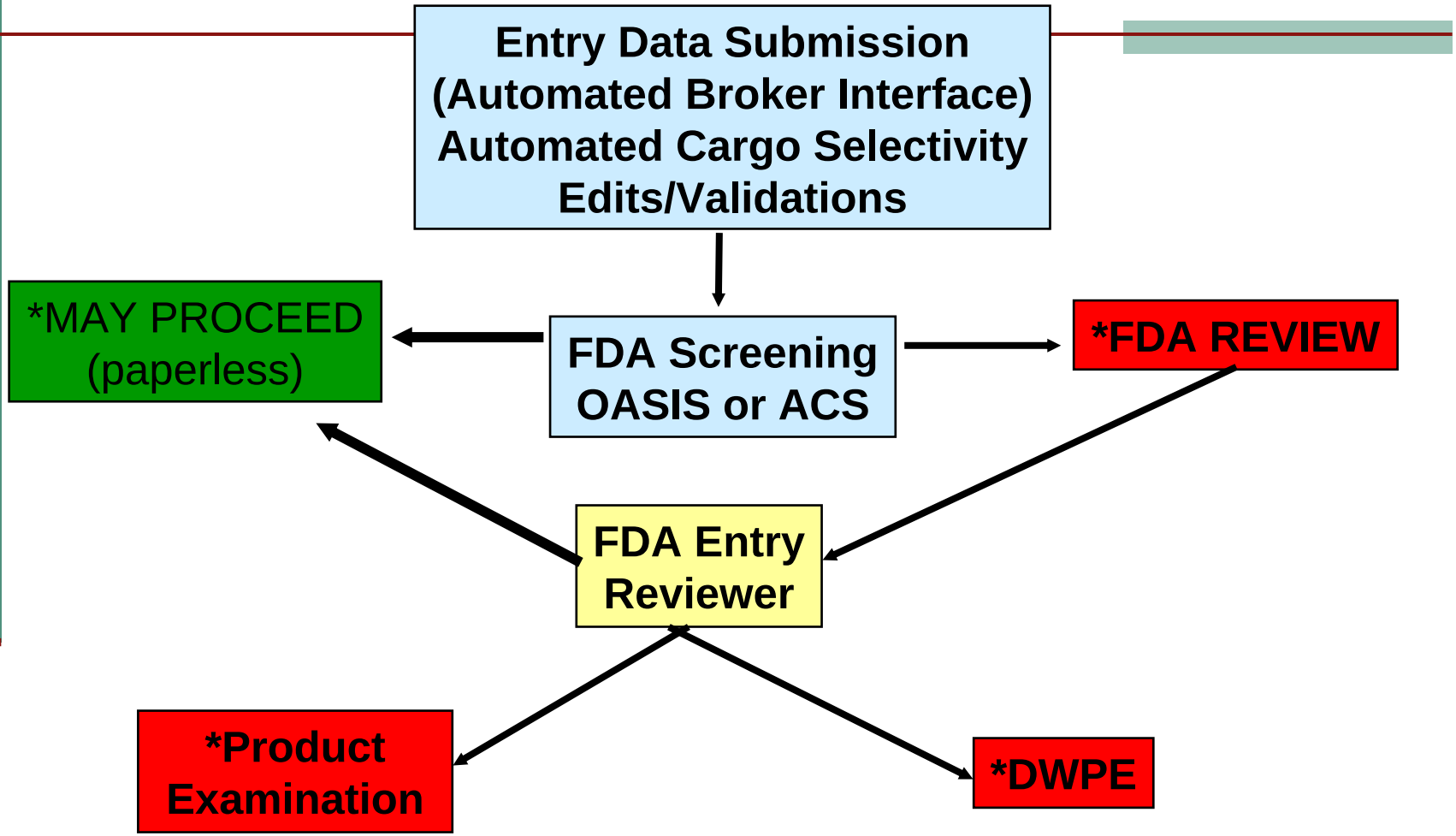
Import for Export – “May Proceed”

- Firm must maintain records regarding manufacturing, export, etc.
- Follow up verification conducted during routine inspectional operations at responsible US establishment
- No time limit

Import for Export: April 2007

Industry	Total
Cosmetics	314
Vit/Min/Prot/Unconv Diet(Human/Animal)	4
Antibiotics (Human/Animal)	16
Bio & Licensed In-Vivo & In-Vitro Diag	4
Human and Animal Drugs	2
Human and Animal Drugs	28
Human and Animal Drugs	6
Human and Animal Drugs	42
Medicated Animal Feeds	6
Cardiovascular	2362
Chemistry	20
Ear,Nose And Throat	54
Gastroenterological & Urological	250
General & Plastic Surgery	4
General Hospital/Personal Use	152
Hematology	24
Microbiology	46
Obstetrical & Gynecological	30
Ophthalmic	14
Grand Total	3378

OASIS Entry Process

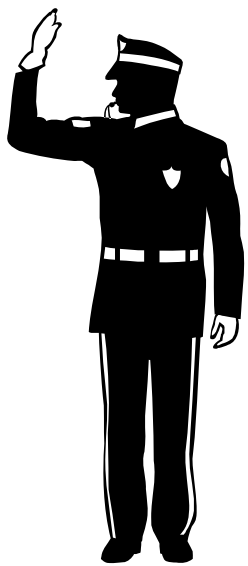


FDA Options When Undergoing “FDA Review”

- May Proceed
- May Proceed – Import for Export
- Conduct field examination
- Detain based on document review- Detention Requested (DTR) or Detention Without Physical Examination (DWPE)
- Collect sample

“May Proceed”

- If “May Proceed” electronically provided to filer
  FDA may override the electronic “May Proceed” FOR CAUSE.
- This notification is provided to the filer via hard copy.



Importation Procedure

- Entry Reviewed by FDA reviewer
- Registration and Listing not provided, documents are requested
- Registration & Listing not provided
- CSO/CSI Query of Registration & Listing data base, if not found, will recommend Detention

Importation Procedure

- Notice of Detention: Filer/Importer has 14 business days to submit evidence, documents, that can over come the appearance of the violation
- After 14 days, if there is no evidence submitted, a Refusal Notice will be issued

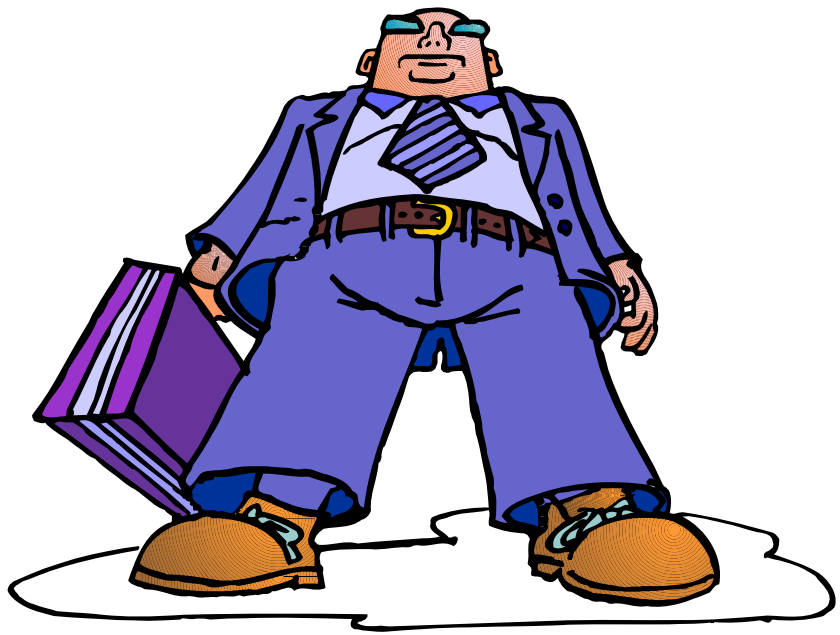
Refusal Process

- Customs Border Protection will issue a Redelivery Request (4647) to Filer
- 90 days from date of Refusal Notice issued by FDA, to return product to port of entry
- Filer/Importer given opportunity to export to country of origin or destroy

Charges chart

Enforcement Actions

- FDA Detention/Refusal
- Place foreign manufacturer/ shipper/ product on DWPE
- FDA Initiated Recall
- Seizure (304)
- Injunction
- Prosecution



CBP Actions
Initiated at FDA request

- Bond Actions (i.e. liquidated damages)
  - Triple damages (3 x invoice value)
  - Domestic value
- CBP Seizure (contrary to law)
- Civil Money Penalty
- Cargo restrictions – withdrawal of cargo release privileges
- Penalty (i.e. suspension or revocation of filer's license; fines)

Criminal Activity

- Smuggling of violative FDA regulated articles
- False declaration
- Substitution
- False 3499/7512 (export/destruction)
- Re-importation of previously refused goods

Citation/Prosecution may be Considered in the Following Instances

- Repetitive illegal distribution after receipt of a sampling notification or detention; or
- Submission of false or misleading entry documents
- Repeated entry of previously refused article
- Evidence of other fraud

HELPFUL FDA WEB SITES

- **General**
- **FDA:** www.fda.gov

- **Imports:** www.fda.gov/ora/import/default.htm

- **FDA Product Codes** (Product Code Builder):
- www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm

- **Drugs**
- **Import and Export of Human Drugs and Biologics:**
- www.fda.gov/cder/about/smallbiz/ImportExportInfo.htm

- **National Drug Code Directory:**
- www.fda.gov/cder/ndc/database/default.htm

- **Devices**
- **CDRH Web Page, Device Advice, Importing Into the U.S.:**
- /www.fda.gov/cdrh/devadvice/39i.html