

SABIT GROUP PROGRAM

How to Import your Medical Devices in Compliance with the U.S. Food and Drug Administration and U.S. Customs and Border Protection



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Agenda

- Exports from Pakistan
- FDA Mission & Laws/Regulations
- Medical Device Basics
 - What is a Medical Device
 - How to Classify Medical Devices
 - Due Diligence Requirements
 - 510k / PMA
 - GMP/QSR
- FDA Import Process
- Detention Without Physical Examination
- Import Alerts – Pakistan



Quiz Time!

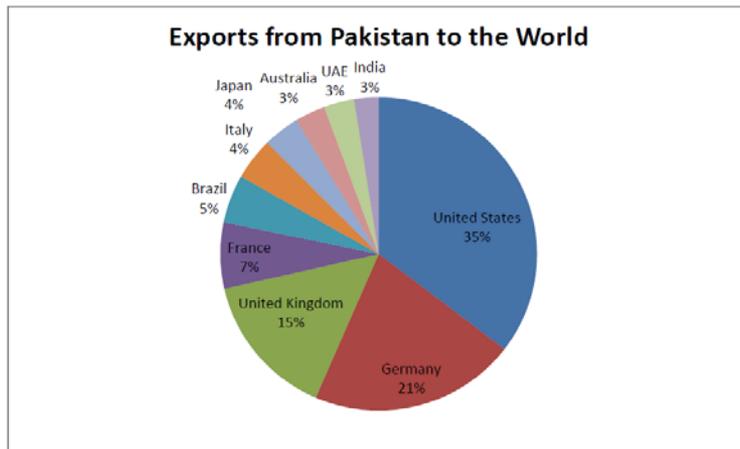


- Which organization assists and promotes the Pakistani medical supply manufacturing industry?
 - A. The Medical Supplies Association of Pakistan (MSAP)
 - B. The Surgical Instruments Manufacturers Association of Pakistan (SIMAP)
 - C. The Surgical Supplies Industry Association of Pakistan (SSIAP)
 - D. The Pakistan Association of Surgical Instruments (PASI)

Opportunity!!

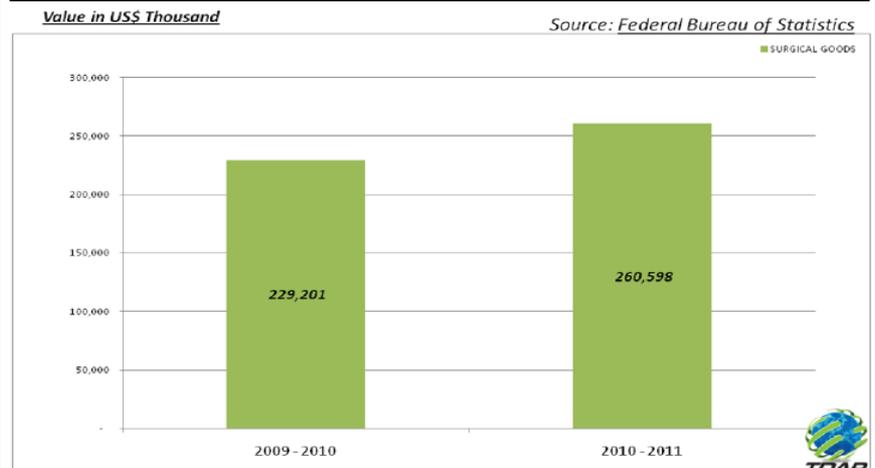
Currently, Pakistan is capturing only 0.75 percent of the total world market of surgical instruments.

Figure 1: Export from Pakistan to the World in Surgical Sector.



Source: SIMAP and Trademap (trade data of 2010)

**EXPORTS OF SURGICAL SECTOR FROM PAKISTAN
2009-2010 VS 2010-2011**



Access to FREE Trade Data!

<http://www.ic.gc.ca/eic/site/tdo-dcd.nsf/eng/Home>

The screenshot shows the Industry Canada website's Trade Data Online (TDO) page. At the top, there is a navigation bar with the Canadian flag, the text "Government of Canada / Gouvernement du Canada", and links for "Canada.ca", "Services", "Departments", and "Français". Below this is the "Industry Canada" logo with a red maple leaf and the word "Canada" in a stylized font. A search bar labeled "Search Industry Canada" is positioned to the right. A menu bar contains "All topics", "Just for businesses", "Just for consumers", and "Forms, reports, guides ...". The main content area features the heading "Trade Data Online (TDO)" and a sub-heading "Generate reports by product or industry". Two buttons, "Search by product" and "Search by industry", are provided. To the right is an illustration of a globe with a truck, a forklift, and an airplane. Below the illustration, a text box states: "Trade Data provides the ability to generate customize reports on Canada and U.S. trade in goods with over 200 countries." At the bottom, there is a navigation bar with three tabs: "Overview" (which is selected), "Latest Data", and "Related Sites and Information".

Increase in Imports of Surgical Instruments

Title	U.S. Imports
Products	HS 9018 - instruments and appliances used in Medical, Surgical or VeterinAry
Origin	TOP 10 Countries
Destination	United States
Period	Latest 5 years
Units	Value in Thousands of U.S. Dollars

Change Criteria

Report

	2009	2010	2011	2012	2013
Mexico	3,481,658	4,053,519	4,401,602	4,426,237	4,560,165
Germany	2,064,123	2,161,640	2,524,182	2,413,009	2,472,217
Japan	1,227,205	1,433,849	1,454,341	1,508,392	1,621,615
Ireland	1,065,750	1,088,020	1,250,298	1,284,252	1,379,600
China	683,204	954,431	1,060,539	1,215,748	1,307,679
Costa Rica	629,160	679,462	709,241	879,403	910,691
Switzerland (including Liechtenstein)	469,661	533,024	688,545	743,621	823,607
Dominican Republic	509,058	567,699	576,924	647,470	705,984
Israel	338,667	341,075	353,078	393,130	418,663
Canada	289,324	326,150	384,170	364,393	379,556
Sub-total	10,757,809	12,138,870	13,402,921	13,875,655	14,579,777
Others	2,445,990	2,691,263	2,995,846	3,073,896	3,258,076
Total All Countries	13,203,799	14,830,132	16,398,767	16,949,551	17,837,853

Data Source: Statistics Canada & US Census Bureau

Industry Canada

Canada

All topics - Just for businesses - Just for consumers - Forms, reports, guides ...

Home > Import, Export and Investment > Trade Data Online

Trade Data Online

Help | Return to Trade Data Online

Report

Report Date: 2014-10-02

Criteria

Title	U.S. Imports
Products	HS 9018 - instruments and appliances used in Medical, Surgical or VeterinAry Sciences
Origin	All Countries (Total)
Destination	United States
Period	Latest 5 years
Units	Value in Millions of U.S. Dollars

Change Criteria

Report

	2009	2010	2011	2012	2013
All Countries (Total)	13,204	14,830	16,399	16,950	17,838

Data Source: Statistics Canada & US Census Bureau

Source – Trade Data Online - <http://www.ic.gc.ca/eic/site/tdo-dcd.nsf/eng/Home>

Pakistan - #26 – Room for GROWTH

Trade by Commodity - Imports												
Current date:												
10/02/2014 2:29												
Country - Pakistan												
Time	District	July 2014	June 2014	June 2014 - July 2014	July 2014 YTD	July 2013 YTD	July 2013 YTD - July 2013	2013	2012	2011	2010	2010 - 2013
Commodity	Measures	All Districts										
9018 Medical, Surgical, Dental Or Vet Inst, No Elec, Pt	Value (Dollars)	\$ 6,942,558.00	\$ 6,366,349.00	9.05	\$ 44,907,072.00	\$ 43,380,854.00	3.52	\$ 73,344,116.00	\$ 71,999,990.00	\$ 63,385,207.00	\$ 52,359,252.00	40.08
	Quantity											
	Unit Price											

- See handout – Pakistan is #26!

Challenges

1. Brand Development is a challenge for surgical industry
 2. Product Development
 3. Standards and certification
 4. The industry needs to resolve internal conflicts
- The industry has the potential of exporting over US \$1.25 billion per year!!!

FDA's Mission



- FDA is charged with protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation emitting products; and regulating tobacco products.

FDA Laws/Regulations

- LAW - United States Code
 - 21 U.S.C.
- REGULATIONS - Code of Federal Regulations
 - 21 C.F.R
- 21 U.S.C. 381 – Imports and Exports
 - Imports, list of registered foreign establishments
 - Disposition of refused articles
 - Reimportation
 - Exports
 - Temporary holds at ports of entry
 - Warning notice
 - Prior Notice



Federal Food, Drug and Cosmetic Act

- Imported medical devices must fully comply with the Federal Food, Drug and Cosmetic Act before the device is released by U.S. Customs. 21 U.S.C. 301
- For further information, see FDA's Office of Regulatory Affairs Import Start Page accessible at:
(www.fda.gov/ora/import/default.htm)



FDA's Center for Devices and Radiological Health

- FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating companies which manufacture, repackage, relabel, and/or import medical devices sold in the United States.



What is a Medical Device?



- The term "device" means an instrument, apparatus, implement, machine, implant, or other similar or related article, including any component, part, or accessory, which is:
 - (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
 - (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - (3) intended to affect the structure or any function of the body of a person or animal, and which does not achieve its primary intended purposes through chemical action within or on the body of a person or animal.

Quiz Time!

- Which of the following products is NOT a medical device?
 - A. Surgical Scissors
 - B. Sunscreen
 - C. Defibrillator
 - D. Thermometer
 - E. Dental Mouth Mirror



CHECKLIST TO IMPORT MEDICAL DEVICES

- Establishment Registration previously on Form FDA-2891 (now online)
 - For Manufacturer AND Initial Importer
- Device Listing previously on Form FDA-2892 (now online)
- Quality System Regulation (QSR) (also referred to as good manufacturing practices or GMPs)
- Premarket Notification (510(k)), unless exempt, or Premarket Approval (PMA)
- Labeling Requirements
- Medical Device Reporting
- U.S. Designated Agent (for imported devices) (<http://www.fda.gov/cdrh/usagent>)



Medical Devices Classes

- The [Food and Drug Administration \(FDA\)](#) established classifications for approximately 1,700 different generic types of devices.
- Device classification depends on the *intended use* of the device and also upon *indications for use*.



Device Classification

- 1700 generic groups of devices
- Classified within 16 medical specialties
- 21 C.F.R. 862-892
 - 862 = Chemistry/Toxicology
 - 864 = Hematology/Pathology
 - 866 = Immunology/Microbiology
 - 868 = Anesthesiology
 - 870 = Cardiovascular
 - 872 = Dental
 - 874 = Ear, Nose and Throat
 - 876 = Gastro/Urology
 - 878 = General Plastic Surgery
 - 880 = General Hospital
 - 882 = Neurological
 - 884 = Obstetrical/Gynecological
 - 886 = Ophthalmic
 - 888 = Orthopedic
 - 890 = Physical Medicine
 - 892 = Radiology



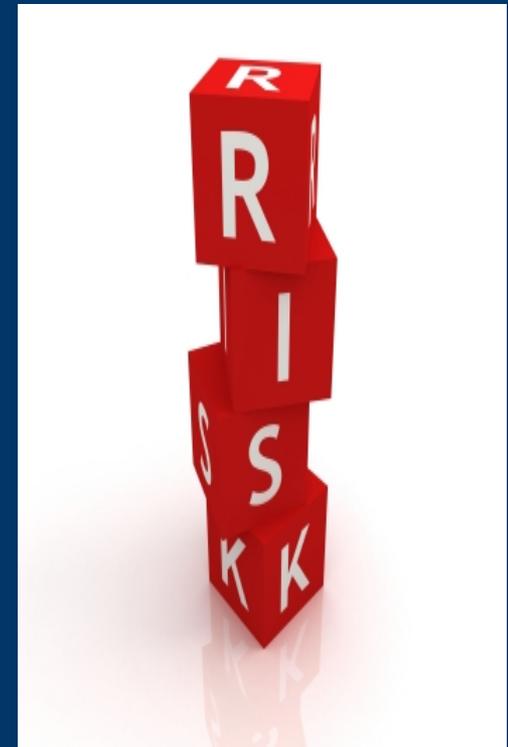
Quiz Time!

- How many classes of medical devices are there?
 - A. 5
 - B. 3
 - C. 12
 - D. 2



Medical Devices Classes

- **Risk Based** - Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device.
- The class to which your device is assigned determines, among other things, the type of premarket submission or application required for FDA clearance to sell the device.



Medical Devices Classes

- CLASS I – most (93%) are exempt from Premarket Notification
 - Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.
- CLASS II – most (91%) require a Premarket Notification
 - Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.
 - Most Class I devices and some Class II devices are exempt from 510(k) submission. A list of exempt devices is located at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>
- CLASS III – those that support or sustain human life, most require a Premarket Approval (PMA)
 - Examples of Class III devices which require a premarket approval include replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

Quiz Time!

- What Device Class is a surgical scissor?
 - A. I
 - B. II
 - C. III
 - D. None of the above



Class I

Product Classification

[FDA Home](#) [Medical Devices](#) [Databases](#)

[New Search](#)

[Back To Search Results](#)

Device	Scissors, General, Surgical
Regulation Description	Manual surgical instrument for general use.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	LRW
Premarket Review	Office of Device Evaluation (ODE) Division of Surgical Devices (DSD) General Surgery Devices Branch Two - Surgical (GSDB2)
Submission Type	510(K) Exempt
Regulation Number	878.4800
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Class I

CFR - Code of Federal Regulations Title 21

[FDA Home](#) [Medical Devices](#) [Databases](#)

New Search

[Help](#) | [More About 21CFR](#)

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2014]
[CITE: 21CFR878.4800]



[See Related Information](#)

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 878 -- GENERAL AND PLASTIC SURGERY DEVICES
Subpart E--Surgical Devices

Sec. 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applicator, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

Surgical Scissors

- What you would provide to your customs broker:
 - Manufacturers Establishment Registration
 - Importers Establishment Registration
 - Device Listing
 - Class 1
 - Product Code LRW
 - 510k Exempt



Dental Mouth Mirrors – Class 1

- Class 1
- Product Code – EAX
- 510k Exempt
- FDA Regulation – [872.4565](#)
- [GMP Exempt No!](#)

New Search	Back To Search Results
Device	Mirror, Mouth
Regulation Description	Dental hand instrument.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	EAX
Submission Type	510(K) Exempt
Regulation Number	872.4565
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of [reserved devices](#)) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](#). Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in [21 CFR Parts 862-892](#), a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment. Please see the [registration and listing website](#) for additional information.

Class I Device

▪ Class I Devices

- Lowest risk devices
- General controls are sufficient to provide reasonable assurance of safety and effectiveness
- Requires Establishment Registration
 - Manufacturer
 - Initial Importer
 - Device Listing
- Most are exempt from Premarket Notification (510(k))
 - A list of exempt devices is located at:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>



DUE DILIGENCE – CLASS I

- Does the foreign manufacturer, and initial importer or distributor have a current Establishment Registration?
- Check FDA Website:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>



Establishment Registration & Device Listing

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

Other Databases

[510\(k\)s](#)
[Registration & Listing](#)
[Adverse Events \(MAUDE\)](#)
[Recalls](#)
[Pre-Market Approvals \(PMAs\)](#)
[Inspections](#)
[Device Classification](#)
[Standards](#)
[Total Product Life Cycle](#)
[CFR Title 21](#)
[Radiation-Emitting Products](#)
[X-Ray Assembler](#)
[Medsun Reports](#)
[CLIA](#)

Search Database



Help



Download Files

Establishment Name	<input type="text"/>	Registration Number	<input type="text"/>
Owner/Operator Name	<input type="text"/>	Owner/Operator Number	<input type="text"/>
Proprietary Name	<input type="text"/>	Classification Device Name	<input type="text"/>
Product Code	<input type="text"/>	Establishment Type	<input type="text"/>
Establishment State (U.S.)	<input type="text"/>	Establishment Country	<input type="text"/>

[Quick Search](#)

[Clear Form](#)

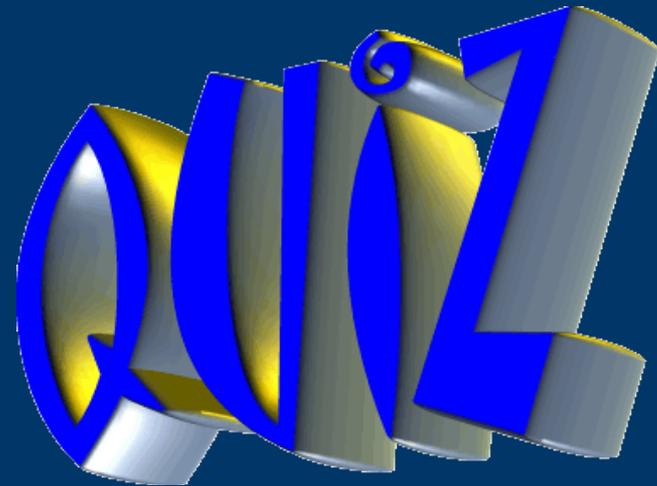
Need to update your information?

To modify, add, or delete information, [log onto your FURLS account](#).

Note: Changes will appear when the database is updated (usually every Monday).

Quiz Time!

- It is a customs brokers responsibility to register establishments with the FDA?
 - True or False?



Purpose of Establishment Registration

- Provide FDA with:
 - location of the device manufacturing facilities and importers
 - Information about the types of devices being manufactured and imported
- DOES NOT constitute approval by FDA of the establishment or the device

Who Must Register

- Who must register?
 - Manufacturers
 - Initial Importers
 - Foreign Establishments
 - Contract Manufacturers
 - Contract Sterilizers
 - Specification Developers
 - Repackers and Relabelers
 - Reprocessors of single use devices
 - Remanufacturers
 - Component Manufacturers
 - Accessory Manufacturers



QUIZ Time!

- If two facilities are 3 miles apart and produce the same device, do both need to be registered?
 - YES
 - NO



DUE DILIGENCE – U.S. Agent

- Foreign manufacturers must also designate a U.S. Agent that resides or maintains a business address in the U.S.
 - Cannot use a P.O. Box
 - Cannot use an answering service
 - Must be available during business hours
- U.S. Agents assist FDA in:
 - Communicating with the foreign establishment
 - Responding to questions concerning the devices
 - Scheduling inspections



Medical Device Listing

- Most medical device establishments required to register with FDA must also identify to FDA the devices they have in commercial distribution including devices produced exclusively for export.
- This process is known as medical device listing and is a means of keeping FDA advised of the generic category(s) of devices an establishment is manufacturing or marketing.

Who Must List a Medical Device?

- Manufacturers
- Foreign Establishments (including exporters)
- Specification developers
- Repackers and Relabelers
- Reprocessors of single use devices
- Remanufacturers
- Component Manufacturers
- Accessory Manufacturers
- Contract Manufacturers
- Contract Sterilizers
- Initial Importers



U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration A-Z Index

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary |

Establishment:
Affinity Medical Technologies
1732 Reynolds Ave
Irvine, CA 92614
Registration Number: 2031044
Status: Active
Date Of Registration Status: 2010

Owner/Operator:
Affinity Medical Technologies
1732 Reynolds Ave
Irvine, CA 92614
Owner/Operator Number: 10023185

Class II Devices

- Class II devices
 - Intermediate risk devices
 - Most require a Premarket Notification - 510(k)



DUE DILIGENCE – 510K - CLASS II

- **Who must submit a 510 (k)?**
 - Domestic manufacturers introducing a device to the U.S. market;
 - Specification developers introducing a device to the U.S. market;
 - Repackers or relabelers who make labeling changes or whose operations significantly affect the device.
 - Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market



510 (k) – Substantial Equivalence

- A device is substantially equivalent if, in comparison to a predicate it:
 - has the same intended use; **and**
 - has the same technological characteristics; OR

 - has the same intended use; **and**
 - has different technological characteristics **and** the information submitted to FDA;
 - does not raise new questions of safety and effectiveness; **and**
 - demonstrates that the device is at least as safe and effective as the legally marketed device.

Premarket Notification – 510 (k)

- Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device.
- Once the device is determined to be SE, it can then be marketed in the U.S.
- The SE determination is usually made within 90 days and is made based on the information submitted by the submitter.

510 (k) – Substantial Equivalence

- If FDA determines that a device is **not** substantially equivalent, the applicant may:
 - resubmit another 510(k) with new data,
 - request a Class I or II designation through the [de novo](#) process
 - (An applicant of a 510(k) who receives a Not Substantially Equivalent (NSE) determination placing the device into a Class III category can request a de novo classification of the product into Class I or II)
 - 60 day review period
 - file a [reclassification petition](#), or
 - 180 day review period
 - submit a premarket approval application ([PMA](#)).

Class III Devices

- Class III devices
 - Devices that support or sustain human life
 - Most require a Premarket Approval (PMA)
 - Under the greatest scrutiny by the U.S. FDA



DUE DILIGENCE – CLASS III Premarket Approval (PMA)

- High risk devices that pose a significant risk of illness or injury
- The PMA process is more involved and includes the submission of clinical data to support claims made for the device.



Premarket Approval (PMA)

- The PMA is an actual approval of the device by FDA.
- FDA has 180 days to review the PMA and make a determination (usually takes longer)
- A description of the process and instructions for filing a PMA application can be found at:
<http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketnotification510k/default.htm>.

Quiz Time!

- Class I devices generally require a 510k submission?
 - TRUE or FALSE



Quiz Time!

- Class II devices generally require a 510k submission?
 - TRUE or FALSE



Quiz Time!

- Class III devices generally require a PMA submission?
 - TRUE or FALSE



Quiz Time!

- Initial Importers Registration with the FDA is FREE?
 - True or False



RISE OF FDA USER FEES FOR 2015

CLASS		2014 FEES	2015 FEES
I	Manufacturer & Initial Importer Registration	\$3,313	\$3,750
II	510(k)	\$5,170 (Small Business \$2,585)	\$5,018 (Small Business \$2,509)
III	Pre-Market Approval (PMA)	\$258,520 (Small Business \$64,630)	\$250,895 (Small Business \$62,724)

What Information Should YOU Provide Your Broker To Expedite Clearance?

- Product Code
- Device Class
- FDA Regulation Number
- Manufacturer or Exporter Establishment Registration Number
- Initial Importer Establishment Registration Number
- If Applicable:
 - 510k
 - PMA

Documentation – Affirmation of Compliance Codes

- If A or C codes are submitted when presenting the entry it allows FDA to quickly check the information without having to request additional documentation.
- If this information is not provided then FDA will probably put the shipment on hold and then request it.
 - DEV – Device Establishment Registration (foreign manufacturer) For example: DEV 3001234567
 - DFE – Device Foreign Exporter Registration (exporter who exports or offers to export for a foreign entity in a foreign country, including devices originally manufactured in the US).
 - DII – Device Initial Importer Registration (the importer that takes first title to the device in the U.S)
 - LST – Listing Number for a specific product – example LST A654321 *Note: This is proprietary information and can not be found by searching FDA's website.*
 - PMN – PreMarket Notification (501K) examples:
 - PMN K011234
 - PMN DEN010123 (Effective 6/2014 the new codes start with DEN)
 - PMA – PreMarket Approval Number, example: P000058

Quality System Regulation (QSR)

- Also referred to as Good Manufacturing Practices (GMP)
- The quality system regulation includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices.
- Manufacturers must develop Quality Systems (QS) commensurate with the risk presented by their devices
- No set formula – have to create one specific to you!



PART 820

QUALITY SYSTEM REGULATION

- **Subpart A--General Provisions**
 - § 820.1 - Scope.
 - § 820.3 - Definitions.
 - § 820.5 - Quality system.
- **Subpart B--Quality System Requirements**
 - § 820.20 - Management responsibility.
 - § 820.22 - Quality audit.
 - § 820.25 - Personnel.
- **Subpart C--Design Controls**
 - § 820.30 - Design controls.
- **Subpart D--Document Controls**
 - § 820.40 - Document controls.
- **Subpart E--Purchasing Controls**
 - § 820.50 - Purchasing controls.
- **Subpart F--Identification and Traceability**
 - § 820.60 - Identification.
 - § 820.65 - Traceability.
- **Subpart G--Production and Process Controls**
 - § 820.70 - Production and process controls.
 - § 820.72 - Inspection, measuring, and test equipment.
 - § 820.75 - Process validation.
- **Subpart H--Acceptance Activities**
 - § 820.80 - Receiving, in-process, and finished device acceptance.
 - § 820.86 - Acceptance status.
- **Subpart I--Nonconforming Product**
 - § 820.90 - Nonconforming product.
- **Subpart J--Corrective and Preventive Action**
 - § 820.100 - Corrective and preventive action.
- **Subpart K--Labeling and Packaging Control**
 - § 820.120 - Device labeling.
 - § 820.130 - Device packaging.
- **Subpart L--Handling, Storage, Distribution, and Installation**
 - § 820.140 - Handling.
 - § 820.150 - Storage.
 - § 820.160 - Distribution.
 - § 820.170 - Installation.
- **Subpart M--Records**
 - § 820.180 - General requirements.
 - § 820.181 - Device master record.
 - § 820.184 - Device history record.
 - § 820.186 - Quality system record.
 - § 820.198 - Complaint files.
- **Subpart N--Servicing**
 - § 820.200 - Servicing.
- **Subpart O--Statistical Techniques**
 - § 820.250 - Statistical techniques.

Quiz Time!

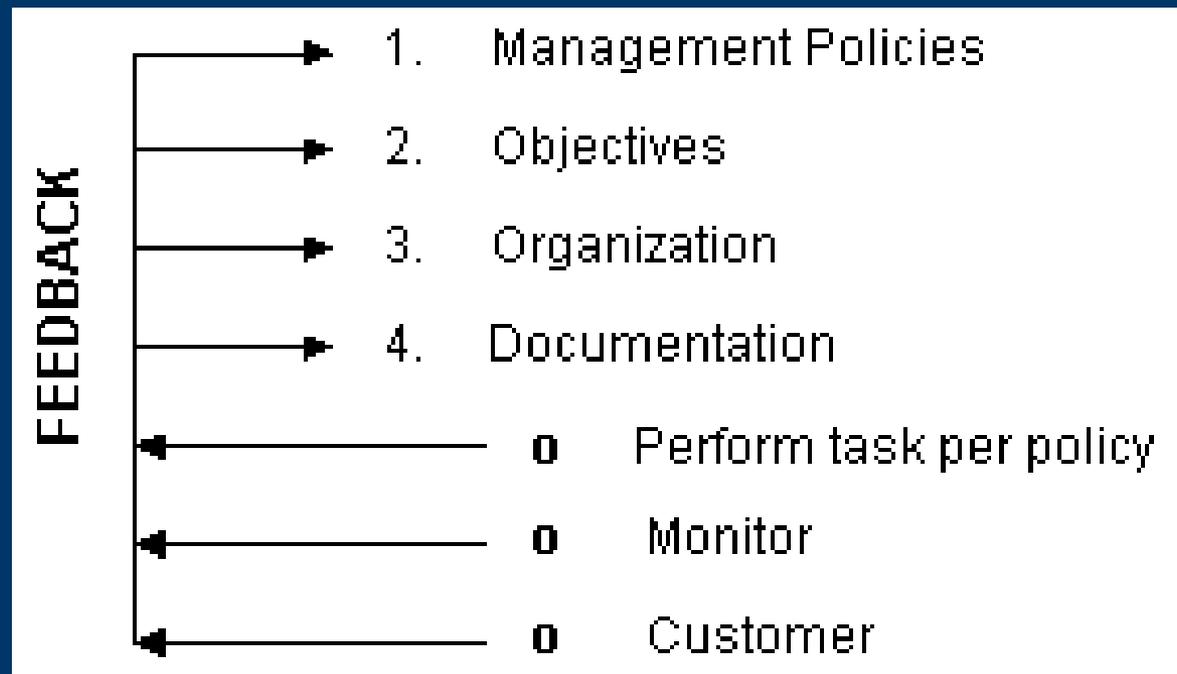
- All records relating to QSR have to be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer?
 - True or False?



Quality System Regulation (QSR)

- 7 subsystems:
 1. Corrective & Preventative Actions
 2. Design Controls
 3. Management
 4. Production & Process Controls
 5. Material Controls
 6. Records, Documents, & Change Controls
 7. Equipment & Facility Controls

Elements of a Quality System



FDA Import Process

Import Trade Auxiliary

Communication System (ITACS)

- ITACS is a web-based application that FDA has deployed in an effort to increase efficiency and modernize their procedures. It allows users to upload documentation to FDA electronically, and also provides the entry status on a shipment.
- Currently no login or account is required to see this information, you just need the complete entry number.

ITACS

Welcome to Import Trade Auxiliary Communications System

ITACS allows the Import Trade Community to:

1) Check status of Entries 2) Input Line Availability 3) Submit Requested Documents

 To get started, at a minimum please enter an Entry Number. If you would like to narrow your entry search, please provide a Line Number. The security letters are required for entry, when provided by the system.

* are required fields

Entry Number: * (Example: xxx-xxxxxx-x)
CBP Line Number:
FDA Line Number:

s t a t e d

 Hear a set of letters

 Get a new set of letters

Please enter the letters provided: *

 SUBMIT  RESET

Helpful Links

[Access FDA Product Code Query](#)
[FDA Import Office Locations and Contact Information](#)
[Import Refusals](#)

[Import Program Page](#)
[Import Alerts](#)

ITACS - sample



Import Trade Auxiliary Communications System

Status and Actions

Results

Entry Number: BVX-0306462-3

Entry Level Status: Entry Closed by FDA

Select	Entry/CBP-FDA[Suffix]	Product	Product Code	Quantity
<input type="checkbox"/>	BVX-0306462-3/1-1	SYSTEM, IMAGE PROCESSING	90L--LZ	Total: 1.0 Pieces (1.0 Pieces)

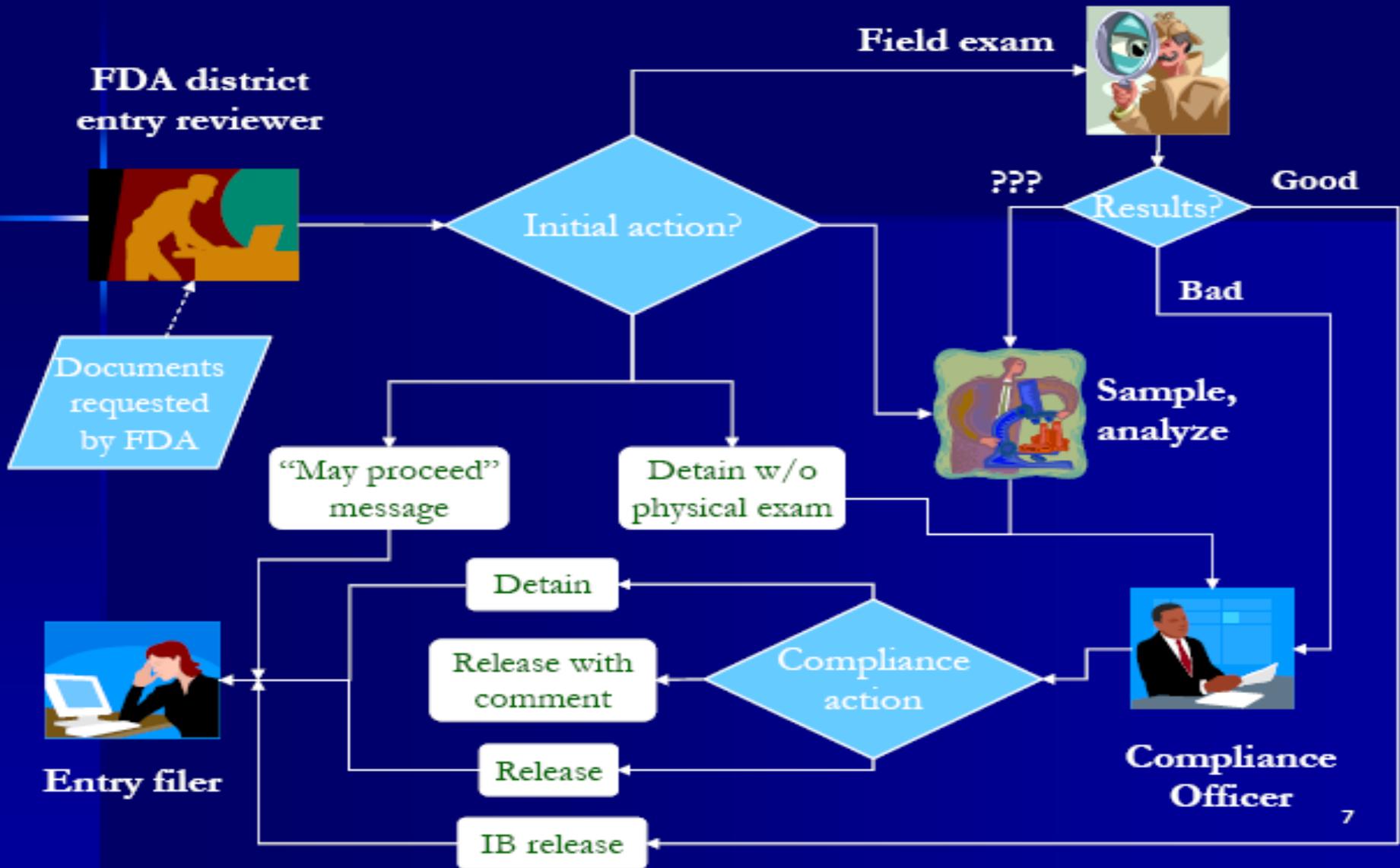
Quantity	Country Name	Status	Status Date	ITACS Status
Total: 1.0 Pieces (1.0 Pieces)	United States	May Proceed Without FDA Examination	06/19/2014	Document Submitted

FDA Review Process Flowchart

The next slide is an overview of the FDA review process

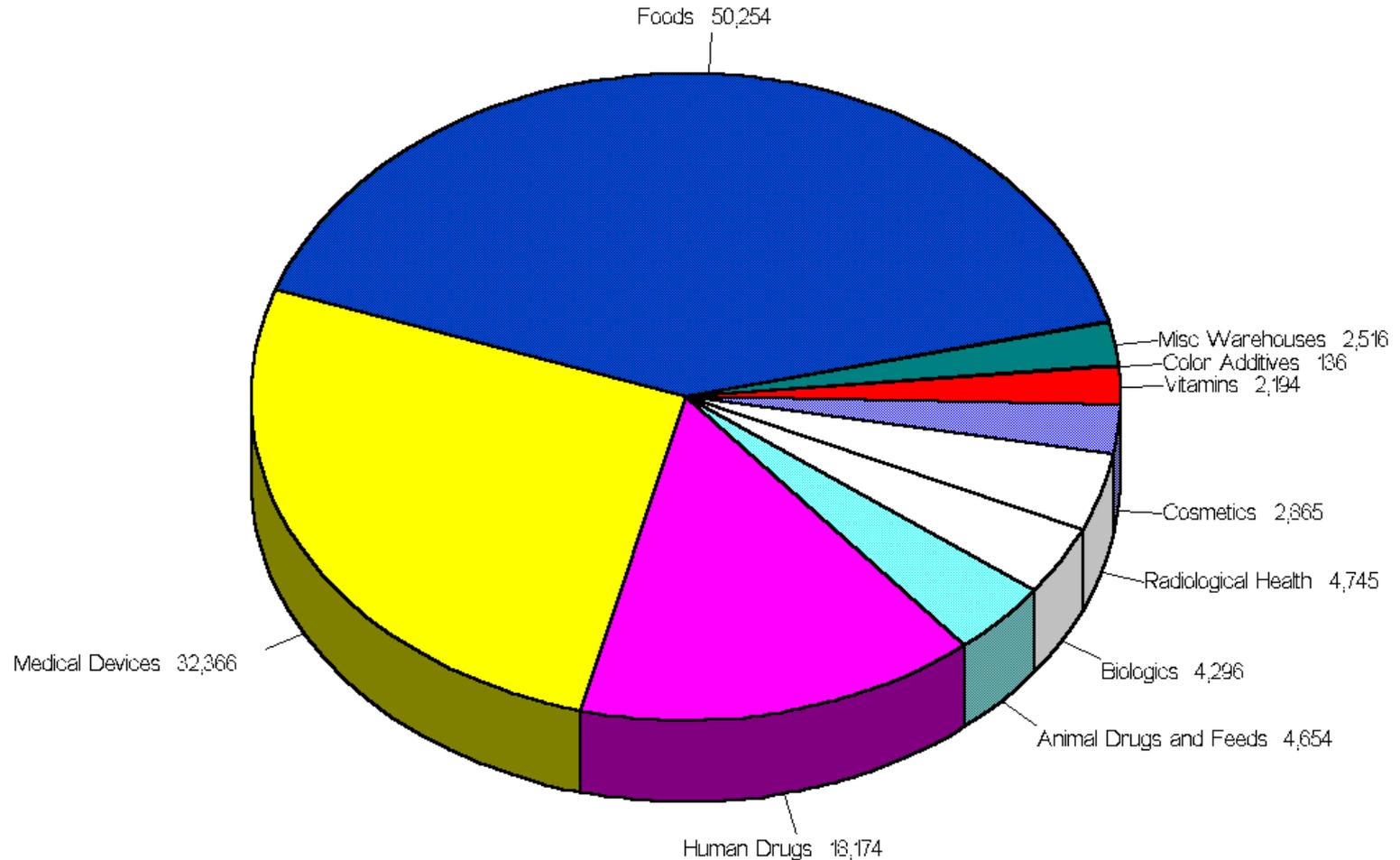


FDA Review Process



FDA Inspection Responsibilities

Total Establishments* 113,170



*FDA defines establishments as a business or other facility under one ownership and at one geographic location or address that processes, manufactures, labels, repacks, stores, distributes, tests, or otherwise manipulates products under the jurisdiction of FDA. In addition, certain individuals or groups of individuals whose activities fall under the jurisdiction of FDA are also establishments. The sum of all categories is greater than the total because some establishments do business in more than one category.

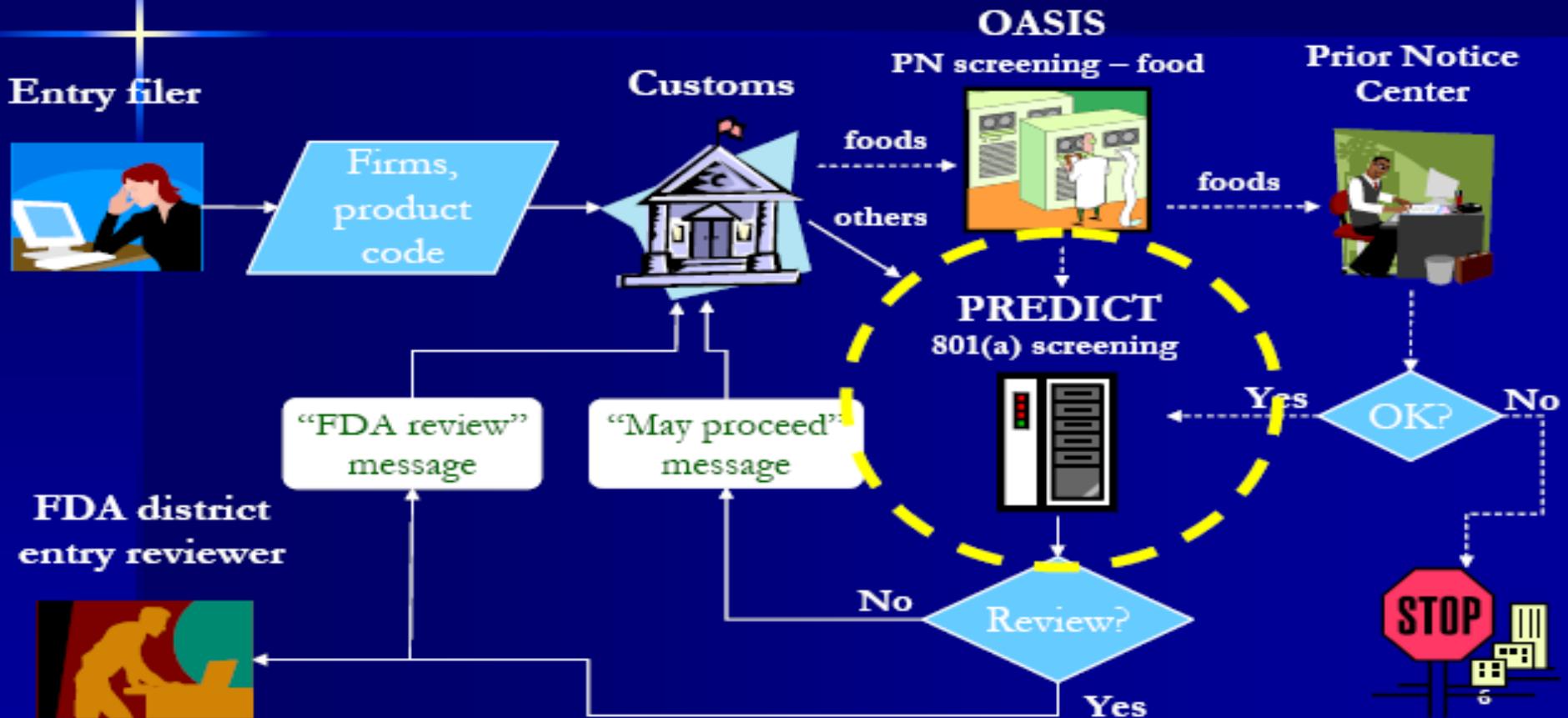
PREDICT

- PREDICT - Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
- Purpose:
 - Improve import screening and targeting to
 - Prevent the entry of adulterated, misbranded, or otherwise violative goods
 - Expedite the entry of non-violative goods

PREDICT



Electronic Transactions Import Entry Lines



Quiz Time!



- True or False?
 - FDA may detain shipments if an incorrect AOC is provided?

DUE DILIGENCE

Compliance History of Manufacturer

- What is the compliance history of the manufacturer, importer, and device?
 - **Warning Letters** (www.fda.gov/foi/warning.htm)
 - **Recalls (Enforcement Report)** (www.fda.gov/opacom/Enforce.html)

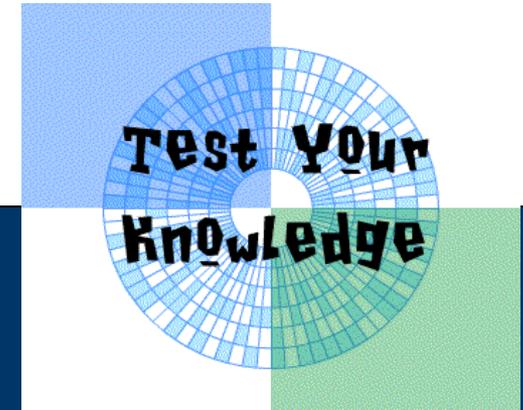
DUE DILIGENCE

- **Is the manufacturer or device subject to an Import Alert??**

- Import Alerts –

- used to initiate automatic detentions of regulated products
 - www.fda.gov/ora/fiars/ora_import_alerts.html

Quiz Time!



- Once you are placed on an Import Alert it is impossible to be removed?
 - True or False?

Import Alert



U.S. Food and Drug Administration

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[Tobacco Products](#)

Import Alert 76-01

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(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 76-01

Published Date: 09/22/2014

Type: DWPE

Import Alert Name:

Detention Without Physical Examination Of Medical Instruments from Pakistan

Reason for Alert:

NOTE: The revision of this Import Alert dated 10/03/2011 updates the Guidance section and Reason for Alert section to reflect current Agency thinking regarding removal from detention without physical examination. Changes are noted and bracketed with three asterisks (***)

*** In 1991, FDA issued Import Alert 76-01 for stainless steel surgical instruments manufactured in Pakistan. The import alert provided guidance that the instruments appeared to be violative under section 501(c) of the Act, as the quality of the instruments appeared to fall below that which they were purported or represented to possess.

The import alert was put in place after documented analysis revealed great variability in chromium content, causing concern that medical instruments manufactured from Pakistan were not compliant with the quality system regulations. FDA implemented a third party Quality System Audit Program to verify the compliance of manufacturers of medical instruments intended to be distributed within the United States. This third party auditor verification was coupled with sample analysis regimen to exempt firms from Detention Without Physical Examination.

Import Alert

- Import Alerts are listed by Country and Industry
 - Import Alert # 76-01
 - Published Date: 02/23/2012
 - Type: DWPE (Detention Without Physical Examination)
 - Import Alert Name:
 - "Detention Without Physical Examination of Surgical Instruments" from Pakistan

Reason for Import Alert

- *** In 1991, FDA issued Import Alert 76-01 for stainless steel surgical instruments manufactured in Pakistan. **The import alert provided guidance that the instruments appeared to be violative under section 501(c) of the Act, as the quality of the instruments appeared to fall below that which they were purported or represented to possess.**

The import alert was put in place after documented analysis revealed great variability in chromium content, causing concern that medical instruments manufactured from Pakistan were not compliant with the quality system regulations. FDA implemented a third party Quality System Audit Program to verify the compliance of manufacturers of medical instruments intended to be distributed within the United States. This third party auditor verification was coupled with sample analysis regimen to exempt firms from Detention Without Physical Examination.

FDA has recently reviewed this program, and now believes verification of firms compliance with the Quality System Regulation should be sufficient evidence to exempt a firm from Detention Without Physical Examination without any additional sampling regimen.

Firms will be placed on the Green List of this Import Alert after having a Quality System audit by a third party auditor which demonstrates there are no significant quality system deficiencies. The audit results and supporting documents should be submitted to CDRH/OC for review and approval. ***

Detention Without Physical Examination (DWPE)

- Detention without physical examination, is appropriate when there exists a
 - **history of the importation of violative products,**
 - **or products that may appear violative,**
 - **or when other information indicates that future entries may appear violative.**
- Detention without physical examination properly places the responsibility for ensuring compliance with the law on the importer



Removal from Import Alert List

- FDA's [Regulatory Procedures Manual](#)
 - [Ch. 9 - Import Operations And Actions](#)
- **9-6 - Detention without Physical Examination (DWPE)**
 - <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179271.htm>

Import Alert

- Import Alerts are listed by Country and Industry
 - Import Alert # 76-01
 - Published Date: 7/11/2011
 - Type: DWPE (Detention Without Physical Examination)
 - Import Alert Name:
 - "Detention Without Physical Examination of Surgical Instruments" from Pakistan

Removal from Import Alert List – Petition

- Make sure you include:
 - Corrective action!!
 - IA information
 - Entry Information
 - 5 non-violative shipments
 - CBP Entry Forms
 - Invoice
 - Packing list, BOL



Removal from Import Alert List

- Send Petitions to:
 - ImportAlerts2@fda.hhs.gov OR
 - Division of Import Operations and Policy (DIOP)
 - Food and Drug Administration
 - 12420 Parklawn Drive
 - ELEM-3109
 - Rockville, MD 20857

Quiz Time!!

- FDA regulates collateral material like posters, websites, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets in addition to the actual product?
 - True or False?

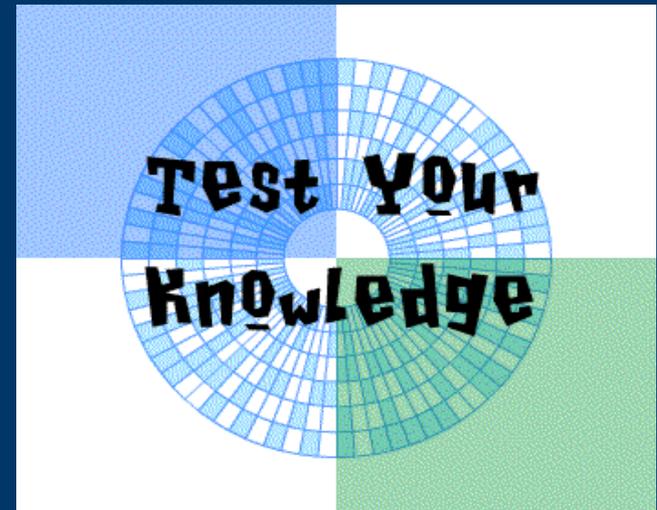


TOP Reasons for Detention of Medical Devices

- The manufacturer is not registered with the FDA
- The initial importer is not registered with the FDA
- The device is not listed with the FDA
- The product does not contain a 510k or PMA
- Product labeling is not compliant (FDA does not pre-approve medical device labeling, it is up to importers to assure it is compliant before importing)
- **Common labeling violations include:**
 - Label is not in English
 - Label is false or misleading

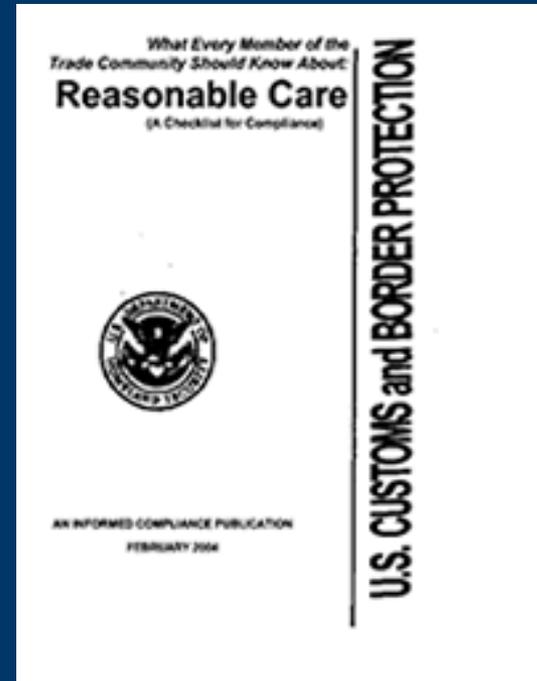
Quiz Time!

- How long does U.S. Customs require Importers and Exporters of Record to keep records of the entry and export of their merchandise?
 - A. 1 Year
 - B. 3 Years
 - C. 5 Years
 - D. 7 Years



Customs (CBP) Considerations

- “Reasonable Care”
- Have you obtained a **Customs ruling** regarding the description of the merchandise of its tariff classification?
- Have you consulted a **Customs “expert”** (lawyer, customs broker, or customs consultant) for advice?



Customs (CBP) Considerations



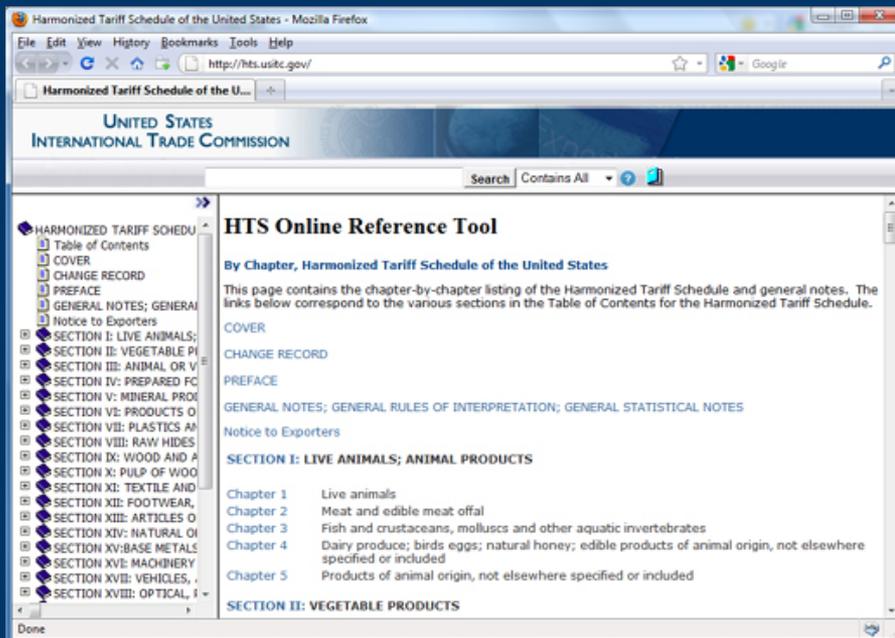
U.S. Customs and Border Protection
Securing America's Borders

CROSS CUSTOMS RULINGS
ONLINE SEARCH SYSTEM

- Request Binding Rulings for:
 - Classification
 - Valuation
 - Country of Origin
- Search Binding Rulings:
 - <http://rulings.cbp.gov/>
- Submit Rulings:
 - <https://apps.cbp.gov/erulings/index.asp>
- Total Rulings: **OVER 171,152!**

Harmonized Tariff Schedule (HTSUS)

- When Importing:
 - Confirm you're using the correct HTSUS necessary for proper assessment of duties.
 - The classification of merchandise under the HTSUS is governed by the principles set forth in the HTSUS.
 - In addition, Section Notes and Chapter Notes should always be reviewed.



The screenshot shows the 'HTS Online Reference Tool' website. The page title is 'UNITED STATES INTERNATIONAL TRADE COMMISSION'. The main heading is 'HTS Online Reference Tool'. Below this, it says 'By Chapter, Harmonized Tariff Schedule of the United States'. A paragraph explains that the page contains a chapter-by-chapter listing of the Harmonized Tariff Schedule and general notes. A search bar is visible at the top right. The left sidebar contains a tree view of the HTSUS sections, including 'SECTION I: LIVE ANIMALS;', 'SECTION II: VEGETABLE PRODUCTS;', 'SECTION III: ANIMAL OR VEGETABLE ORALS;', 'SECTION IV: PREPARED FOODS;', 'SECTION V: MINERAL PRODUCTS;', 'SECTION VI: PRODUCTS OF WOOD;', 'SECTION VII: PLASTICS AND SEMI-CONDUCTORS;', 'SECTION VIII: RAW HIDES, SKINS, ANIMALS;', 'SECTION IX: WOOD AND WOOD PRODUCTS;', 'SECTION X: PULP OF WOOD;', 'SECTION XI: TEXTILE AND APPAREL;', 'SECTION XII: FOOTWEAR, TRUNKS, VANES, BAGS, SADDLERY, AND HARNESS;', 'SECTION XIII: ARTICLES OF WOOD, WOOD PULP, PAPER, STRAW, WOOD WASTE, AND WASTE OF WOOD;', 'SECTION XIV: NATURAL OR CULTIVATED DIAMONDS, GEMSTONES, AND PRECIOUS METALS;', 'SECTION XV: BASE METALS AND ARTICLES THEREOF;', 'SECTION XVI: MACHINERY AND ELECTRICAL, ELECTRONIC, OPTICAL, PHOTOGRAPHIC, CINEMATOGRAPHIC, SOUND RECORDING, TELEVISION, TELECOMMUNICATIONS, AND INSTRUMENTS;', 'SECTION XVII: VEHICLES, TRAILERS, SEMI-TRAILERS, AND TRAILER BODIES;', 'SECTION XVIII: OPTICAL, PHOTOGRAPHIC, CINEMATOGRAPHIC, SOUND RECORDING, TELEVISION, TELECOMMUNICATIONS, AND INSTRUMENTS, AND PARTS AND ACCESSORIES THEREOF.'



The screenshot shows the 'CROSS' (Customs Rulings Online Search System) website. The page title is 'About the Customs Rulings Online Search System (CROSS)'. The main heading is 'About the Customs Rulings Online Search System (CROSS)'. Below this, it says 'CROSS is a searchable database of CBP rulings that can be retrieved based on simple or complex search characteristics using keywords and Boolean operators. CROSS has the added functionality of CROSS retrieving rulings from the initial search result set with their modified, residual or relevant counterparts. Rulings collections are organized into Headquarters and New York and span the years 1989 to present. Collections can be searched individually or collectively. For more information about features or how to use CROSS, please visit the [HELP](#) section. What's New: CROSS was last updated 01/14/2011 09:04 AM with 276 rulings, bringing the total number of searchable rulings to 100000. The most recent ruling is dated 01/14/2011 09:04 AM. Related Trade Information: Downloadable rulings: Downloadable rulings spanning 1989 to present. Trade website links: Includes links to the Harmonized Tariff Schedule, Customs Bulletin, Internal Compliance, Code of Federal Regulations, and more... Customs Valuation Encyclopedias (1989-2000): Download the Customs Valuation Encyclopedias (1989-2000) from the CBP web site. Informational Note: Please be aware that not all rulings issued by HQ and NY since 1989 are yet included in the database. They are still being collected and we hope to have 100% inclusion as soon as possible. To obtain software required to view rulings, please visit the plugins page on this page. Get Plugins. Please submit any technical concerns related to CROSS to [CBP website technical assistance](#).

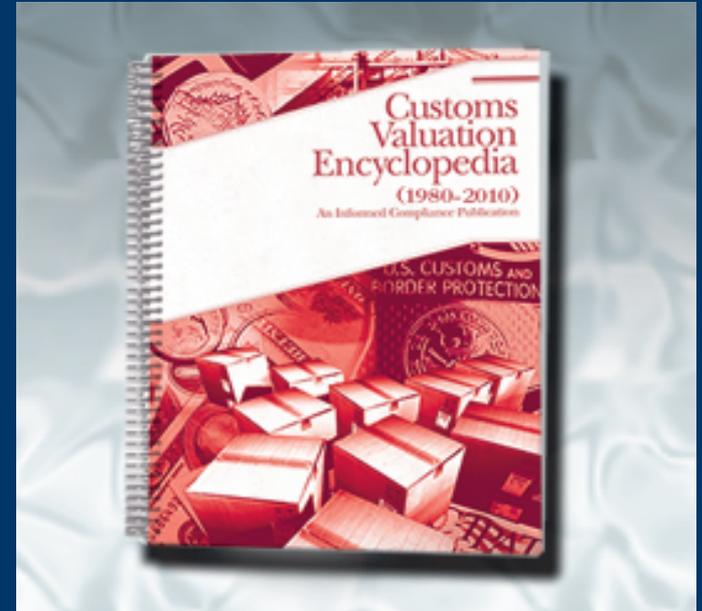
HTS's Commonly Used

- Six broad categories under which Pakistan is exporting surgical sector to the world market.
- The categories include;
 - 9018 – Instruments for medical, surgical and dental;
 - 9021 – Orthopedic appliances;
 - 9022 – Equipment using X-rays, alpha, beta, gamma rays and
 - 9402 – Med, surg, dental furniture (e.g. dentists' & barbers' chairs)
 - 8213 – Scissors, tailors' shears and similar shears, and blades thereof
 - 8214 – Article of cutlery, nes, cleavers, pedicure sets

Valuation

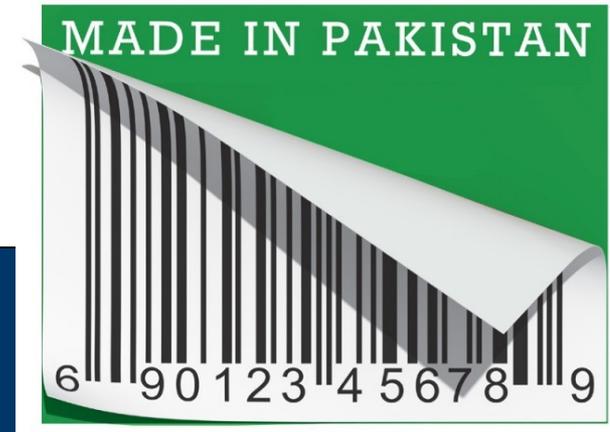


- The amount or cost on which CBP applies duty and fees.
- Primary method of appraisal is transaction value - "the price actually paid or payable for the merchandise when sold for exportation to the United States..."
- Confirm you're using the correct value for your product
- Do you use related parties?



Country of Origin

- Confirm you're using the correct Country of Origin.
 - Do you source products from many countries?
- Country of manufacture, production, or growth of any article of foreign origin entering the U.S.
- Further work or material added to an article in another country must effect a **substantial transformation** in order to render such other country the "country of origin" within the meaning of this part.
- Additional duties or penalties may also be imposed for deceptive marking.



Fraud Penalties - 19 U.S.C. 1592

<u>Type of Penalty</u>	Fraud	Gross Negligence	Negligence
<u>1592(c) – Maximum Penalties</u>	Domestic Value of the Merchandise	4 times loss of revenue (duties, taxes and fees) to CBP	2 times loss of revenue (duties, taxes and fees) to CBP

Useful Links

- **DEVICE ADVICE!!!**
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>
- **FDA Regulations – Device Classification**
 - http://www.access.gpo.gov/nara/cfr/waisidx_10/21cfrv8_10.html
- **Establishment Registration/Listing**
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>
- **Import Alerts**
 - <http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm>
- **Trade Data Online**
 - <http://www.ic.gc.ca/eic/site/tdo-dcd.nsf/eng/Home>

Useful Links - CBP

- Customs & International Trade Law Blog - <http://www.customsandinternationaltradelaw.com>
- Basic Importing and Exporting - http://www.cbp.gov/xp/cgov/trade/basic_trade/
- CBP's Legal Decisions/Publications - <http://www.cbp.gov/xp/cgov/trade/legal/>
- Importing into the U.S.: A Guide for Commercial Importers (Includes a reasonable care checklist)
 - <http://www.cbp.gov/linkhandler/cgov/newsroom/publications/trade/iius.ctt/iius.pdf>
- CBP's Legal Decisions/Publications - <http://www.cbp.gov/xp/cgov/trade/legal/>
- Customs Rulings Online – <http://rulings.cbp.gov/>
- Harmonized Tariff Schedule - Online Reference Tool - <http://hts.usitc.gov/>
- Protecting your intellectual property rights! - http://www.cbp.gov/xp/cgov/trade/priority_trade/ipr/

Blog

- <http://www.customsandinternationaltradelaw.com/>

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Home > Best Practices > FDA Discusses TOP Reasons for Detention of Goods

FDA Discusses TOP Reasons for Detention of Goods

By Jennifer Diaz on March 20th, 2013
Posted in Best Practices, Cosmetics, FDA Issues, Food, FSMA, Import, Import Alert, Medical Devices



At today's Import Operations Training, sponsored by the U.S. Food and Drug Administration (FDA) and the Florida Customs Brokers and Forwarders Association (FCBF), top officials from FDA traveled to Miami to educate importers and brokers. Topics ranged from a general overview of FDA compliance, TOP rationales for FDA detentions, Food Safety and Modernization Act (FSMA) updates, an overview of the newly re-

organized (now DIO) Division of Import Operations (formerly DIOP – policy has now been removed), an overview of CBP & FDA's Joint Team 488 – which handles liquidated damages claims for underlying FDA violations and much more. **Highlights of the TOP rationale for detentions follows, as I feel this is of most value to you to know and is arranged by commodity.**

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Legal and Business Strategists

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Now That We Have Our Paws Dirty... Any Questions?



SABIT GROUP PROGRAM

How to Import your Medical Devices in Compliance with the U.S. Food and Drug Administration and U.S. Customs and Border Protection



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