

FIME 2009

**How to Effectively Resolve Typical
U.S. FDA & U.S. CBP issues for Medical Devices**

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Agenda

- Medical Device Basics
- Typical FDA Detention and Refusal Process
- Typical U.S. Customs Liquidated Damages Process

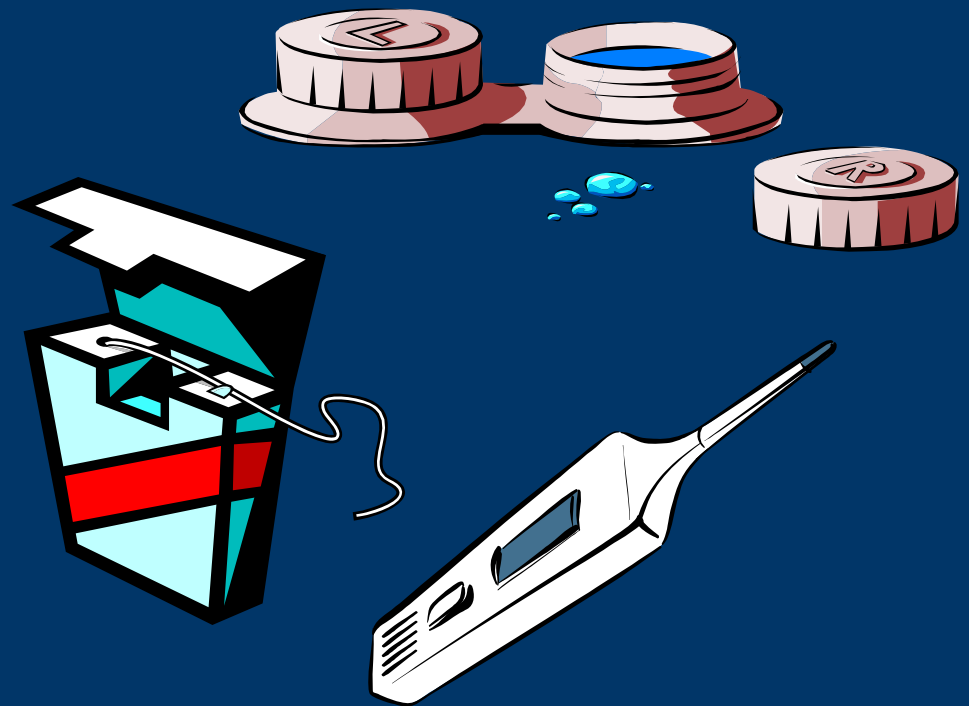
What is a Medical Device?

- 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.

What is a Medical Device?

- Examples of Medical Devices:

- Pacemakers
- Contact Lenses
- Hearing Aids
- Dental Floss
- Thermometer



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.
- 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.

CHECKLIST TO IMPORT MEDICAL DEVICES

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

Medical Devices Classes

- 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 are exempt from Premarket Notification
- CLASS II – most require a Premarket Notification
 - 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/cfp/cd/315.cfm>
- CLASS III – those that support or sustain human life, most require a Premarket Approval (PMA)

DUE DILIGENCE

- Does the foreign manufacturer, and initial importer or distributor have a current Establishment Registration?
- Check FDA Website: Check FDA Website:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>



FDA Logo links to FDA home page



[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
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Establishment Name

Establishment Registration Number

Owner/Operator Number

Sort by

Establishment Name (A-Z)

For full-text search, select *Go To Simple Search* button

10

Records per Report Page

DUE DILIGENCE – U.S. Agent

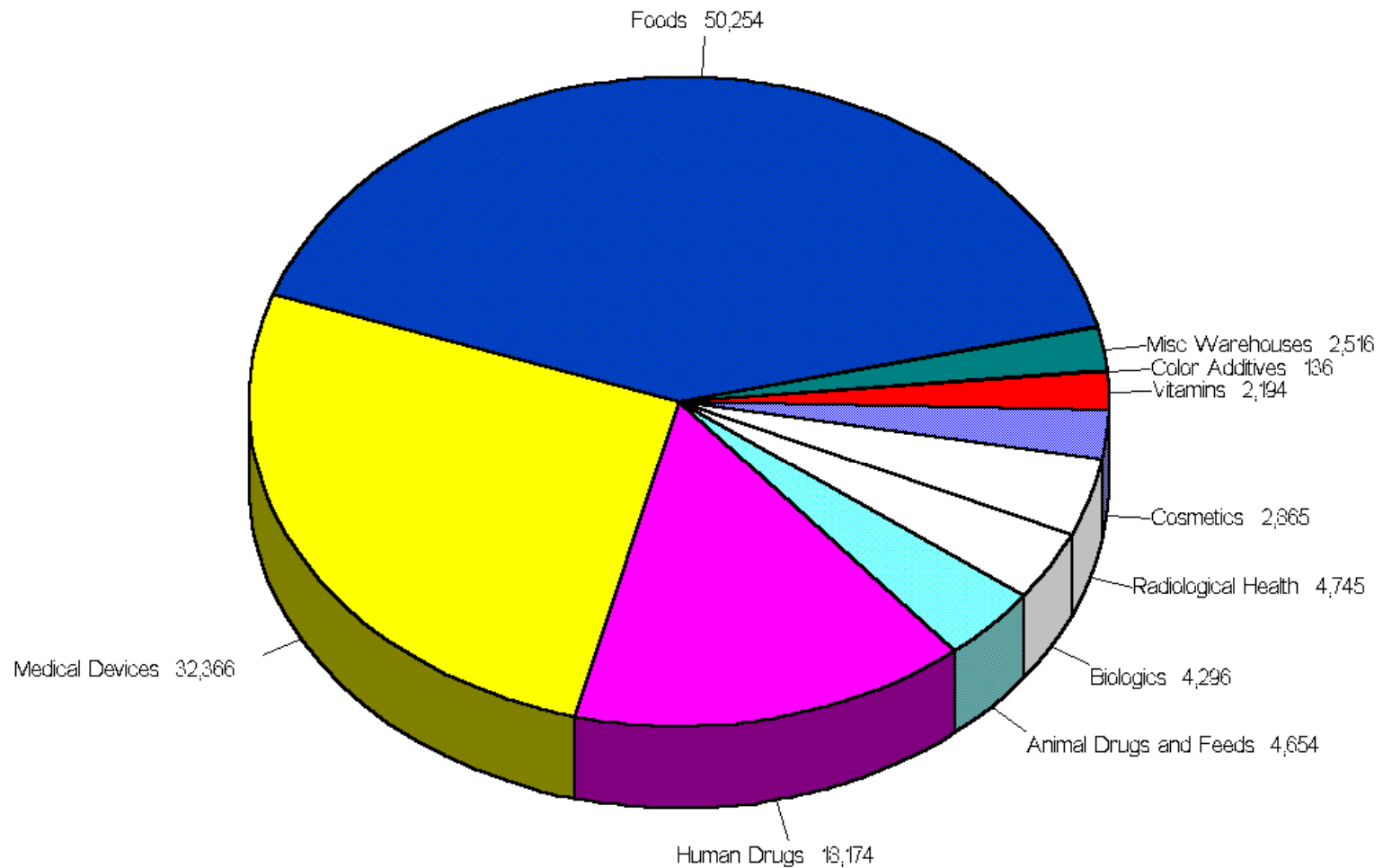
- Foreign manufacturers must also designate a U.S. Agent.
- Information on U.S. Agents can be found at:
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053196.htm>

U.S. Agents

- FDA will use a foreign facility's U.S. agent for routine communications with the foreign facility.
 - The responsibilities of the U.S. agent include:
 - assisting FDA in communications with the foreign establishment,
 - responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States,
 - assisting FDA in scheduling inspections of the foreign establishment and
 - if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

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, manufacturers, 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.

Notice of FDA Action #1

- Products that appear (from examination or otherwise) to be violative may be detained and ultimately refused entry into the U.S.
- The standard for detention and refusal is extremely low - detention is permissible without actual observation of a product or its labeling.
- The ability to challenge the FDA is limited almost exclusively to legal, as opposed to factual, issues.

Detention Process

Notice of FDA Action

- The Food, Drug, and Cosmetic Act authorizes the FDA to detain a regulated product that appears to be out of compliance.
- The FDA District Office will then issue a "Notice of FDA Action" specifying the nature of the violation to the owner or importer.

Informal Hearing

- The owner or importer is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product.

2nd Notice of FDA Action

- If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue another "Notice of FDA Action" Refusing admission of the product.

Refusal

- The product then has to be exported or destroyed (in accordance with CBP Bulletin) within 90 days otherwise subject to Liquidated Damages.



Liquidated Damage Claim

- Redelivery Notice (date)
- Redelivery Required (date)
- “Describe merchandise not redelivered into Customs custody after refused admission by the FDA”
- Three times the value of the refused merchandise or maximum amount of the Customs bond

Liquidated Damage Claim

- The provisions of 21 C.F.R. 1.97 require that the port director of Customs and the district director of FDA be in agreement as to the amount to be accepted in cancellation of the claim for liquidated damages.
- All Petitions for relief received by Customs in FDA cases must be referred to FDA for recommendation.
- With few exceptions, Customs must follow the recommendation of FDA.

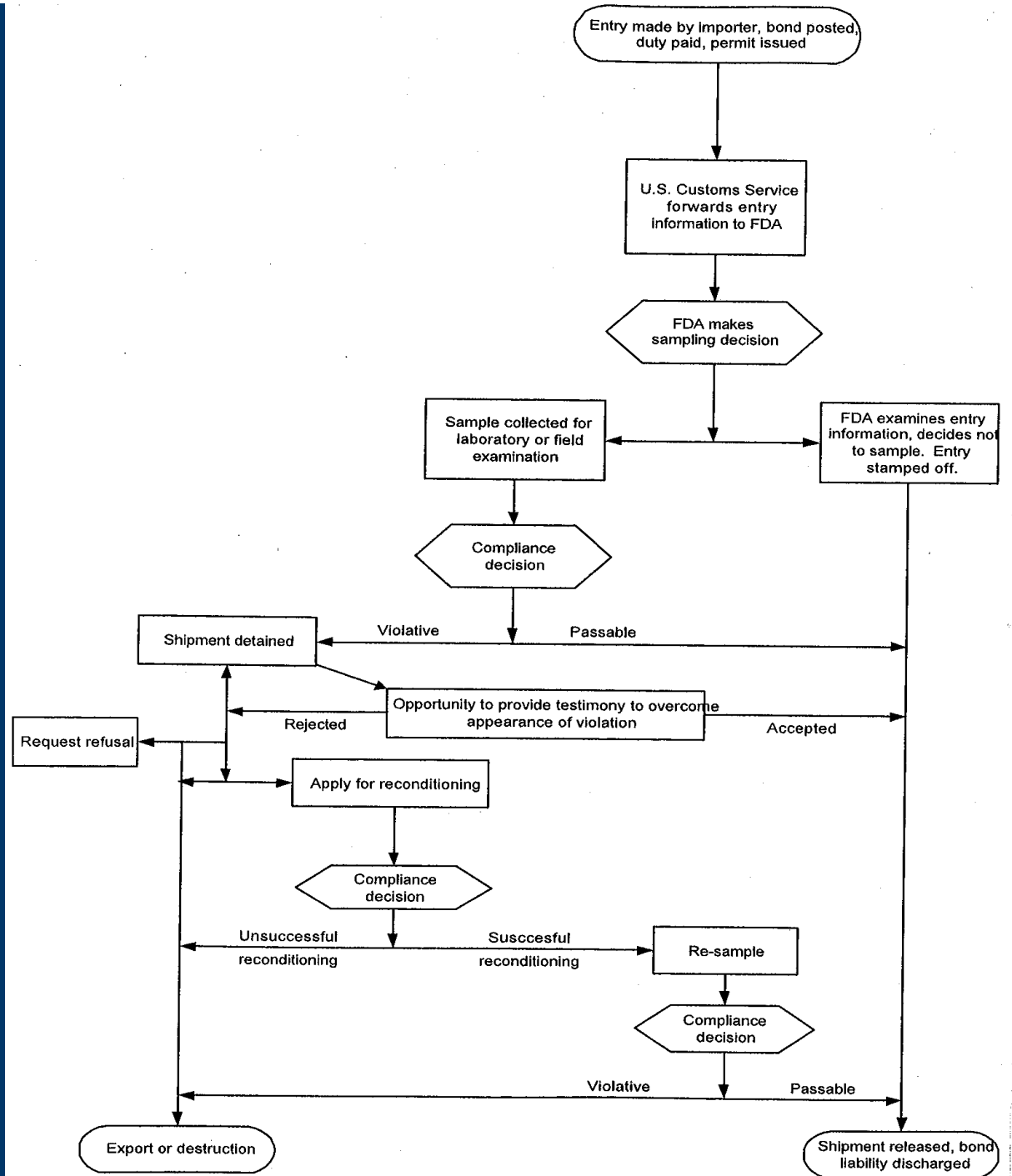
FP&F Petition Process

- Claim from CBP
- 60 days to respond
- Mitigating Factors

Import Procedures Flowchart

The next slide is an overview of the import process





How a Typical Case Commences with U.S. Customs and Border Protection:

- U.S. Customs places the merchandise on hold for “intensive examination”.
- U.S. Customs formally detains the merchandise.
- U.S. Customs (Fines, Penalties & Forfeitures Office) issues the Seizure Notice.

Statutory authority for seizure & forfeiture:

Title 19 U.S.C. § 1595a

Merchandise introduced contrary to U.S. law.

What should be done upon receipt of a Detention Notice or Seizure Notice?

- During the detention process, establishing proof of compliance with U.S. law avoids seizure of the merchandise, administrative delays, and related costs.
- Critical stage to get legal counsel involved.
- Administrative petition process for seizures can take months to resolve before medical devices returned.

If merchandise is seized, Fines, Penalties & Forfeitures Office issues Seizure Notice:

- Case assigned to Paralegal Specialist at FP&F.
- FP&F Officer is empowered to remit or mitigate on such terms and conditions as, under the law and factual circumstances, he or she deems appropriate.
- Petition must be filed within 30 days, establishing merchandise entered or exported consistent with U.S. law (factual & legal arguments).
- Oral argument often requested and granted by FP&F.
- Supplemental Petition may be filed within 60 days of adverse decision based upon presentation of new facts or law.

FP&F refers certain Petitions to Chief, Penalties Branch, Regulations & Rulings, Office of International Trade, CBP Headquarters in Washington, DC:

- ✓ Cases where the value of the merchandise is over \$100,000.
- ✓ Novel or complex issues concerning a Ruling, policy or procedure.

HQ Recommendation sent to FP&F and Decision issued by FP&F.

Supplemental Petition Process:

1. FP&F
2. National Seizures & Penalties Office (in San Francisco)
3. Chief Counsel's Office

Typical Mitigating Factors:

- Prior good record of violator,
- Inexperience in importing, and/or
- Cooperation with Customs' investigation.



Typical Aggravating Factors:

- Criminal conviction relating to transaction;
- Repetitive violation of the same import restriction; and/or
- Evidence of intentional importation contrary to U.S. law.



Petition for Relief is Granted:



- ✓ Decision providing for remittance is valid for limited period of time (30 days).
- ✓ Execution and submission of Hold Harmless Agreement by Petitioner.
- ✓ Payment of assessed penalty, if any.
- ✓ Provide contact name and information of designated authorized agent to retrieve goods.
- ✓ Payment of storage fees.

Cancellation of Claims Involving Failure to Redeliver Merchandise into Customs Custody or Failure to Comply with a Notice of Refusal of Admission Issued by another Agency

- The provisions of 21 C.F.R. 1.97 (FDA Regulations) require that the District Director of the FDA be in agreement as to the amount acceptable to cancel the claim for liquidated damages.
- All petitions for relief received in FDA cases must be referred by Customs to an FDA Compliance Officer for recommendation.
- By regulation, Customs must follow the recommendation of FDA.

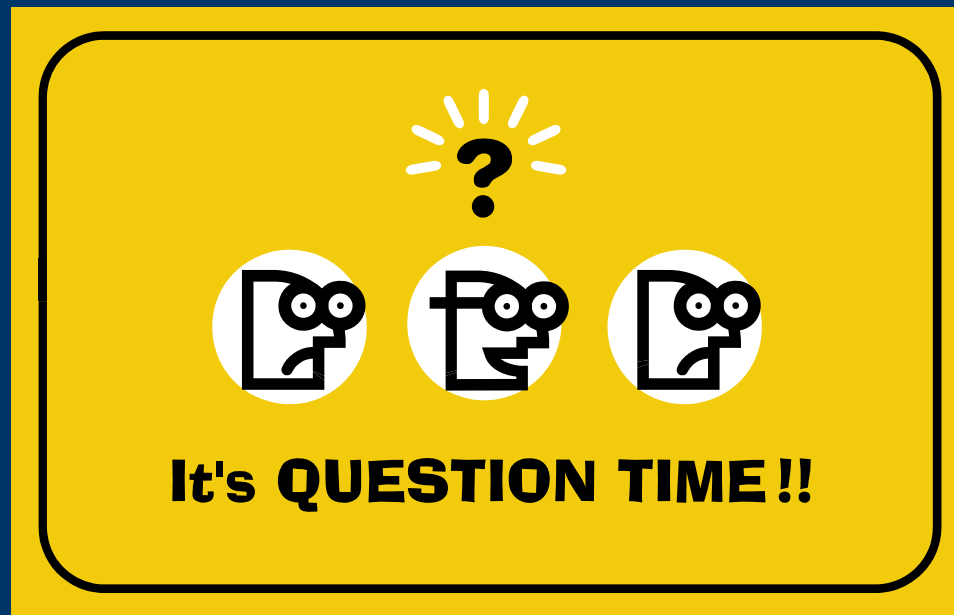
Fraud Penalties

- 19 U.S.C. 1592
- Fraud
- Gross Negligence
- Negligence

- 19 CFR Part 171
- Appendix B
- Offer in Compromise



Questions



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