U.S. FOOD & DRUG ADMINISTRATION

Importation Process of FDA Regulated Products

Medical Devices

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FDA Responsibility

- Ensuring that food is safe, wholesome and sanitary
- Human & Veterinary drugs, medical devices & human biologics are safe and effective
- Cosmetics and electronic products that emit radiation are safe;
- Tobacco products comply with regulations; and
- Labeling of these products honestly represent them to the users and their instructions for use are adequate

•Review, investigate, inspect, examine, collect samples, if applicable, and make admissibility decisions on all FDA regulated products offered for entry and sale into the United States from foreign and domestic sources coming through its ports of coverage to achieve compliance through applicable laws and regulations, and science based decisions;

FDA Responsibility

- Make admissibility decisions on all FDA regulated products offered for entry and sale into the United States from foreign and domestic sources coming through its ports of coverage to achieve compliance through applicable laws and regulations, and science based decisions.

- Manage the determination of the acceptability of products, subject to the Agency's jurisdiction, for entry into the United States through examination of available records, electronic entry submissions, product inspection, and/or by sampling and laboratory examination of the product followed by release, detention, and/or refusal

FDA Import Law

Federal Food, Drug, and Cosmetic Act

-FDA may detain on the appearance of a violation.

-Articles are expected and required to be in compliance at the time of entry

-The intent of the law is to deny importation of products in violation.

-Why does FDA ask for documentation?

What Is a Medical Device?

The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, 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 man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Device Classification

- Device classification depends on the *intended use* of the device and also upon *indications for use*.

- For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication for use is added in the device's labeling such as, "for making incisions in the cornea".

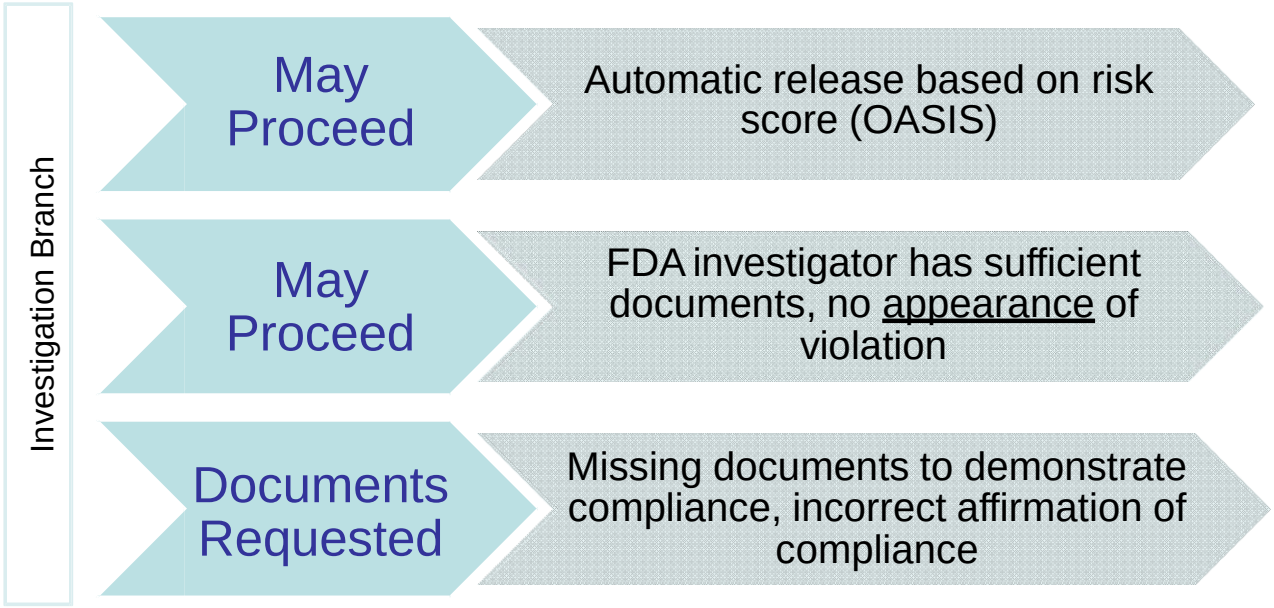
What is the intended use of Gloves?

Medical Device

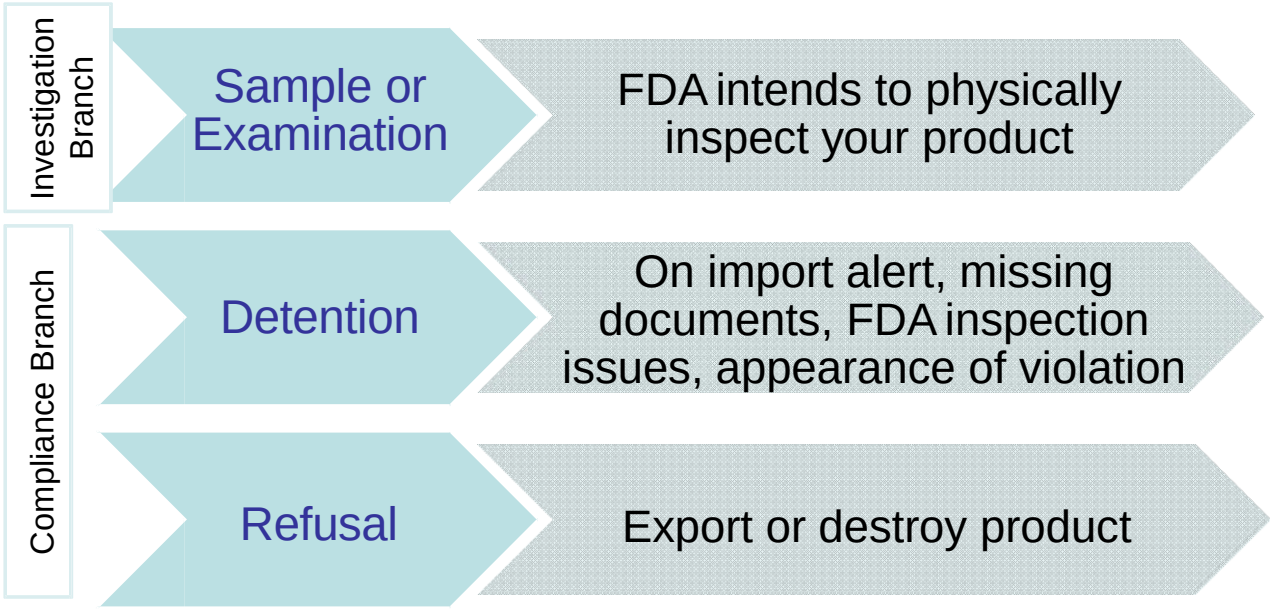
Manufacturer must list

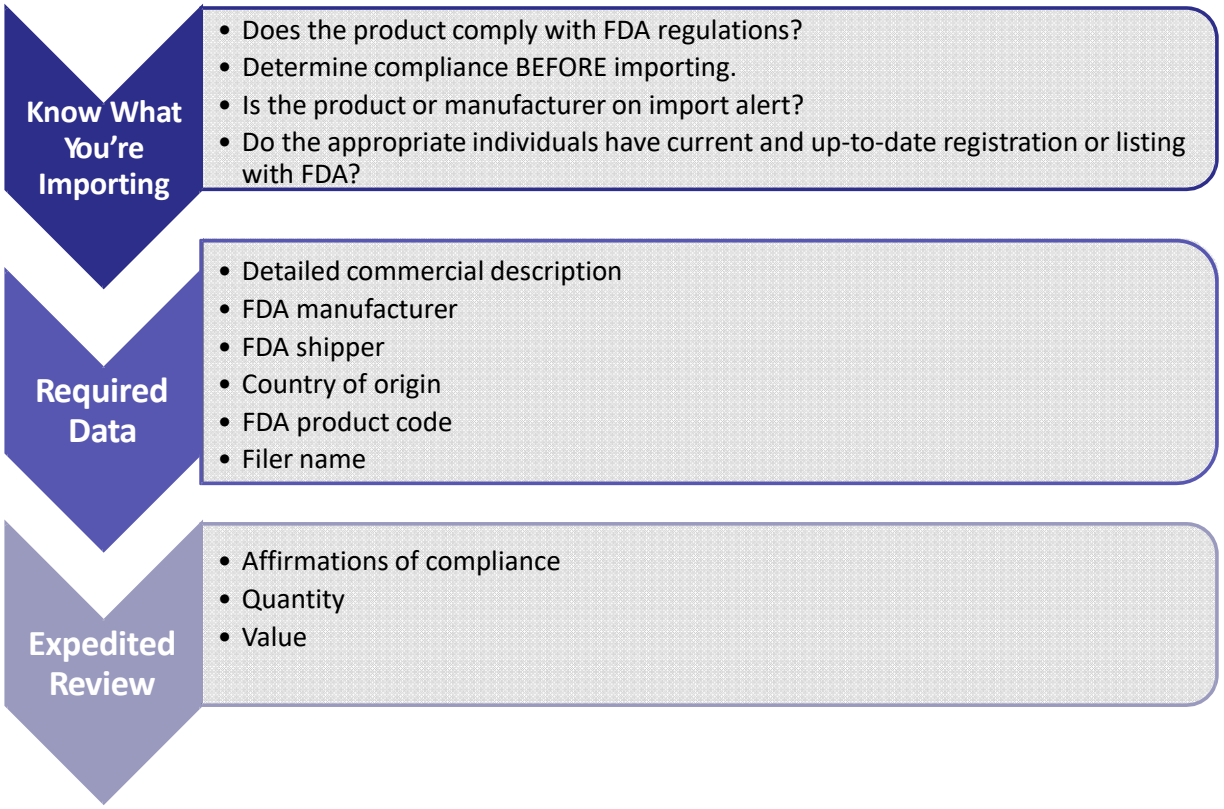
Non-Medical Device

FDA Entry Decisions



FDA Entry Decisions




Know What You're Importing
• Does the product comply with FDA regulations?
• Determine compliance BEFORE importing.
• Is the product or manufacturer on import alert?
• Do the appropriate individuals have current and up-to-date registration or listing with FDA?
Required Data
• Detailed commercial description
• FDA manufacturer
• FDA shipper
• Country of origin
• FDA product code
• Filer name
Expedited Review
• Affirmations of compliance
• Quantity
• Value

FDA BASIC IMPORT CHECKLIST

BEFORE YOU IMPORT

Is the product, manufacturer, or country on import alert?

Is this product a medical device? A component of a medical device?

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Do you have a CBP bond of three times the value of the product?

Do you have the product's FDA listing number, if applicable? Search FDA's website to determine listing.

Does this product have current registration with FDA? Search FDA's website to determine if registration is

Δ current.

Do you have the marketing application number such as a 510K, PMA, PMN, or IDE?

FILING YOUR MEDICAL DEVICE ENTRY WITH FDA

Are you declaring the proper FDA manufacturer?

Are you declaring the FDA country of origin?

Is this a U.S. returned good?

- Send FDA the reason for return and information on if you plan to destroy or recondition.

Do you have the proper FDA product code? Search FDA's site for medical device product codes.

- If you have the PMN or PMA number you can search for the product code.

Are you using an FDA affirmation of compliance code to expedite entry review?

Is this a class I, II or III medical device? Search FDA's website for classifications and associated specific

Δ regulations.

Is this a radiation-emitting product? Do you have the FDA Form 2877?

- Do you have the accession number for the product? This may be located on a product report, annual report, or abbreviated report

Does this product have impact-resistant lens certification documentation?

Does this product need electrode lead wires and patient cable certification?

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Who Is the FDA Manufacturer?

- Site-specific location where the product is manufactured, produced or grown.
  - This may be different than the CBP manufacturer
- Foreign and Domestic manufacturers are required to register with FDA **(21 CFR Part 807)**
- FDA requires the actual manufacturer of the product not the invoicing firm, which may or may not be the manufacturer.

EXAMPLE:

ABC Co, in Hong Kong manufacturers and labels canned mushrooms under contract for XYZ Corp. in Peoples Republic of China.

- *XYZ Corp. invoices and ships the product to the U.S.*
- *RESULT: FDA considers ABC Co. to be the manufacturer; CBP considers it to be XYZ Corp.*

What Is Medical Device Registration?

- Owners or operators of places of business involved in the production and distribution of medical devices intended for use in the U.S. are required to register annually with the FDA.
- Congress has authorized FDA to collect an annual establishment registration fee for device establishments.
- There are no reductions in annual establishment registration fees for small businesses or any other group.
- Takes 24-48 hours

What Is Medical Device Listing?

- Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices.
- This helps FDA locate the problem in the event of emergencies or device problem, such as death.

What is a 510(k)/ PMN?

If your device requires the submission of a Premarket Notification 510(k), you cannot 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.

- Most Class I devices and some Class II devices are exempt from the Premarket Notification 510(k) submission.

What Is a Device PMA?

Premarket Approval (PMA) - 21 CFR Part 814

Class III devices are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device.

Components and Accessories

21 CFR 820.3(c) Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

21 CFR 820.3(l) Finished device means any device ***or accessory*** to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

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Component AofCs

- If the component is being imported for further processing into a finished device, then the foreign manufacturer is not required to register and list under 807.65(a)
- Excludes certain wheelchair, cast, and exercise device components (see next slide)
- Use of the following Affirmation of Compliance codes will expedite the entry review process and increase the likelihood that your shipment may be processed based on import system screening:

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  - Component (CPT), no qualifier
  - Device Initial Importer (DII) and qualifier
  - Device Listing (LST) and qualifier for the finished medical device
  - PMN or PMA and qualifier, if applicable

Accessory AofCs

- If the component/accessory is packaged or labeled for commercial distribution to an end user, then the foreign manufacturer ***is*** required to register and list
- Certain wheelchair, cast, and exercise device components are regulated as finished medical devices
- Use of the following Affirmation of Compliance codes will expedite the entry review process and increase the likelihood that your shipment may be processed based on import system screening:
  - Device Foreign Manufacturer (DEV) or Device Foreign Exporter (DFE) and qualifier
  - Device Listing (LST) and qualifier
  - Device Initial Importer (DII) and qualifier
  - PMN or PMA and qualifier, if applicable

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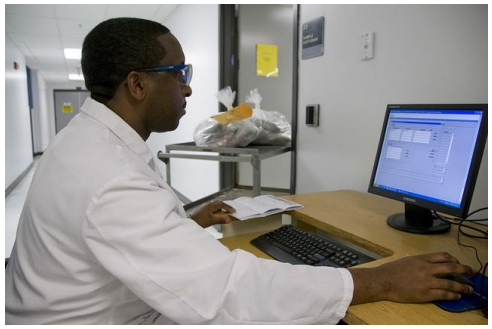
My Product Is “Detained.” What Does that Mean?

- This is an **initial** determination that the product **appears** to violate FDA's requirements.
- FDA detention is an administrative process
  - Not a physical hold of the product
  - Importer has the right to take possession of the articles



My Product Is Detained. What Does that Mean?

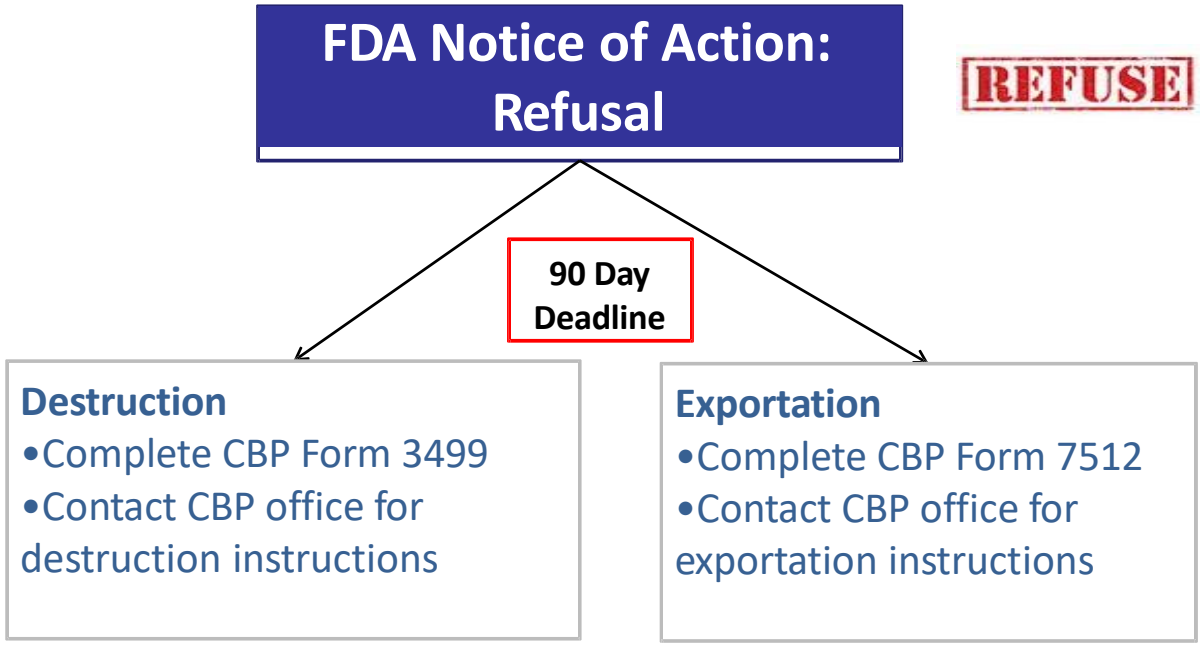
- FDA can detain based upon 'appearance' of a violation
  - Importer has the right to give evidence to refute this appearance
  - This is known as the 'Detention and Hearing Process'

- Based on the evidence, the detention will either stand (refusal) or be overturned (release)

Notice of FDA Action (Refusal)

- FDA determines product appears to not be in compliance with the Food, Drug, and Cosmetic Act.
- This is a FINAL Agency action.
- FDA Notice of Refusal Action (NORA) issued to importer of record (IOR), consignee, and filer
- Product must be exported or destroyed within 90 days

FDA Refusal
Importer Options

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