Importing Medical Devices into the United States

FDA Small Business
Regulatory Education for Industry (REdI)
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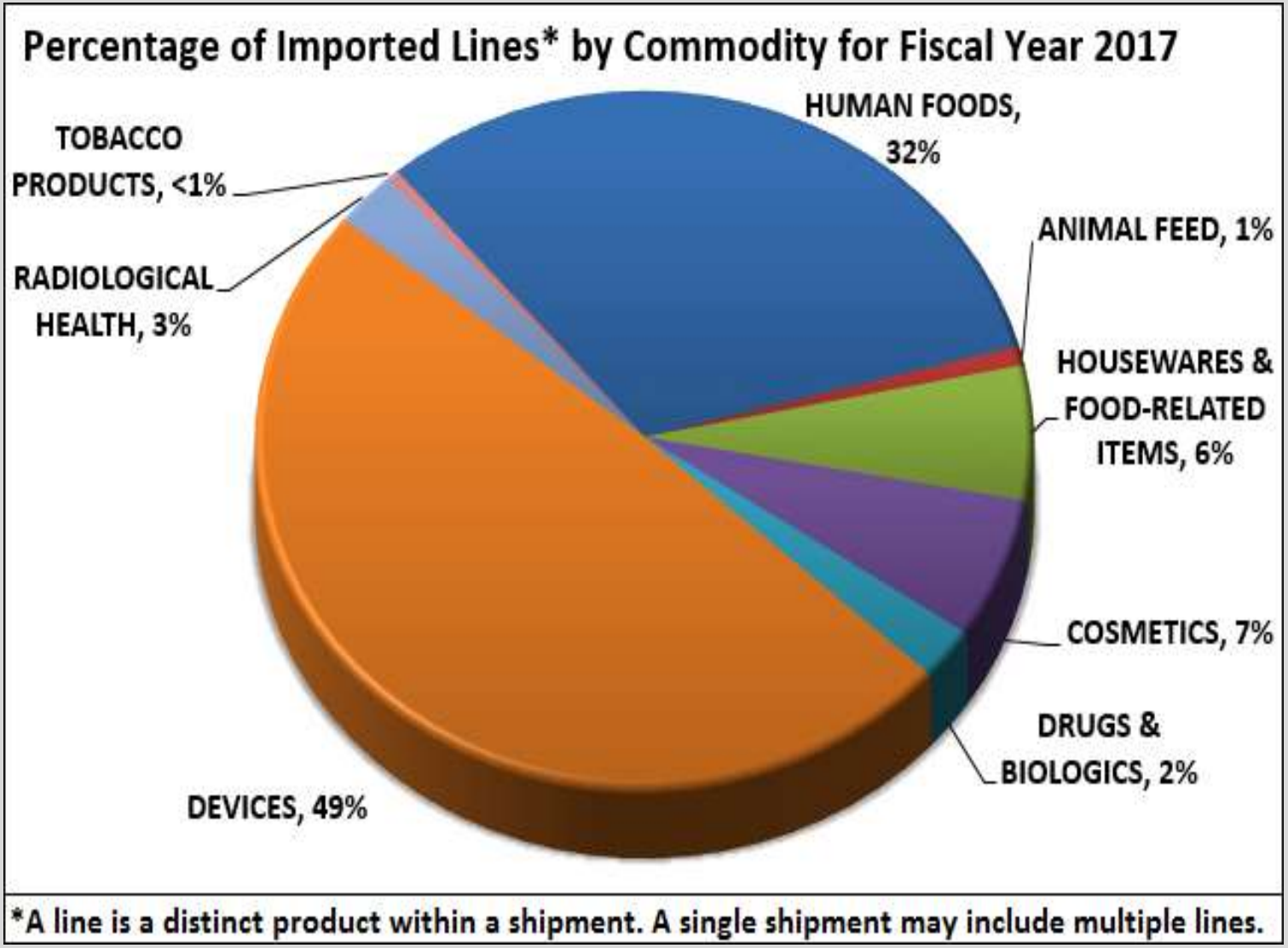
Annual Percentage of Imported FDA Commodities



Learning Objectives

- Describe the entry process for medical devices
- Recognize common errors leading to import entry delays
- Identify useful information resources

ENTRY PROCESS

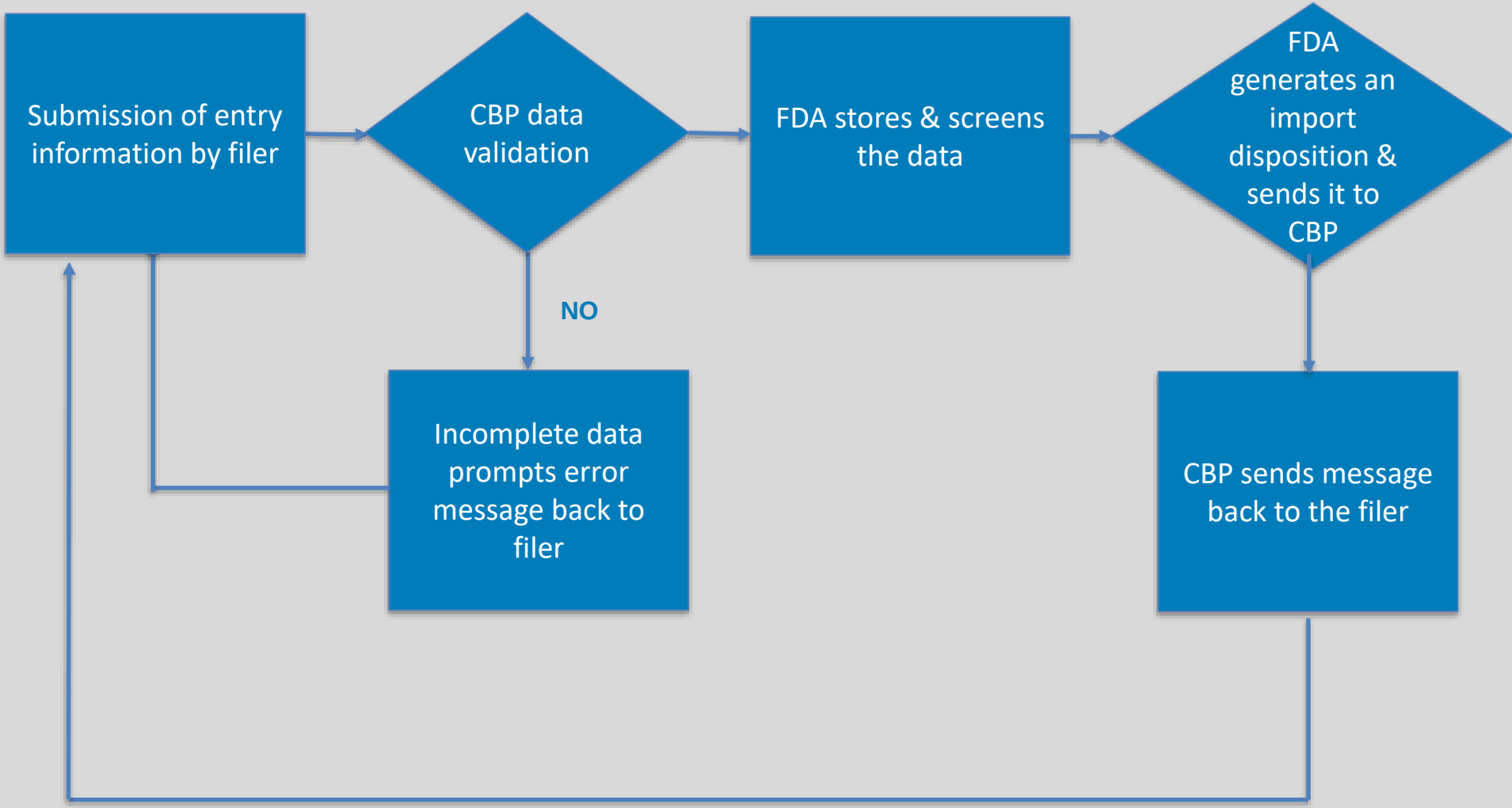
Submitting Entry Information

Filer provides mandatory information for all FDA regulated Products

Customs Broker determines Harmonized Tariff Schedule (HTS) codes, https://hts.usitc.gov/

Entries that are regulated by FDA are flagged

FDA Entry Review Process



FDA Flags

FD FLAG	Is it regulated?	Example
FD1	May or may not be regulated by FDA: If regulated by FDA, submit entry information; if not regulated by FDA, disclaim	Certain chemicals used in manufacturing drug products vs. industrial use; safety goggles for medical use vs. non-medical use
FD2	**Regulated by FDA, but is not food: Submit entry information**	**Medical Devices, Drugs, Tobacco, and Cosmetics**
FD3	May or may not be a food product: If yes, submit Prior Notice (PN) and entry information; if no, disclaim	Salt used for flavoring food vs salt used for treating road surfaces
FD4	Food product: Submit PN and entry information	Fish and seafood, live food animals, dairy products, shell eggs, fruits, vegetables, food and feed ingredients, food and feed additives, infant formula, beverages (including alcoholic beverages and bottled water), bakery goods, snack foods, candy, canned foods, and dietary supplements and dietary ingredients.

Mandatory Information

- Name and addresses
  - ✓manufacturer
  - ✓shipper
  - ✓importer
  - ✓delivered to party
  - ✓Consignee
- Quantity and Packaging

  Mandatory if the product requires Form 2877
- Estimated arrival date and time of the product

Mandatory Information

- Product information
  - ✓Commodity and subtype
  - ✓Product description
  - ✓Contact information
  - ✓Country of Origin
  - ✓Product code*

*Link to Product Code Builder Tool Aids

Mandatory *Device* Information

- CBP Intended Use Code
- Country of Production or Source
- Name and Address of Device Initial Importer (medical devices only)
- Affirmations of Compliance

Affirmations of Compliance (AofC)

- AofC codes correspond with certain regulatory requirements
- Determine the regulatory requirements based on product classification
- Use CDRH's Product Classification Database to identify product classification

CDRH Regulatory Requirements

CDRH Device Information

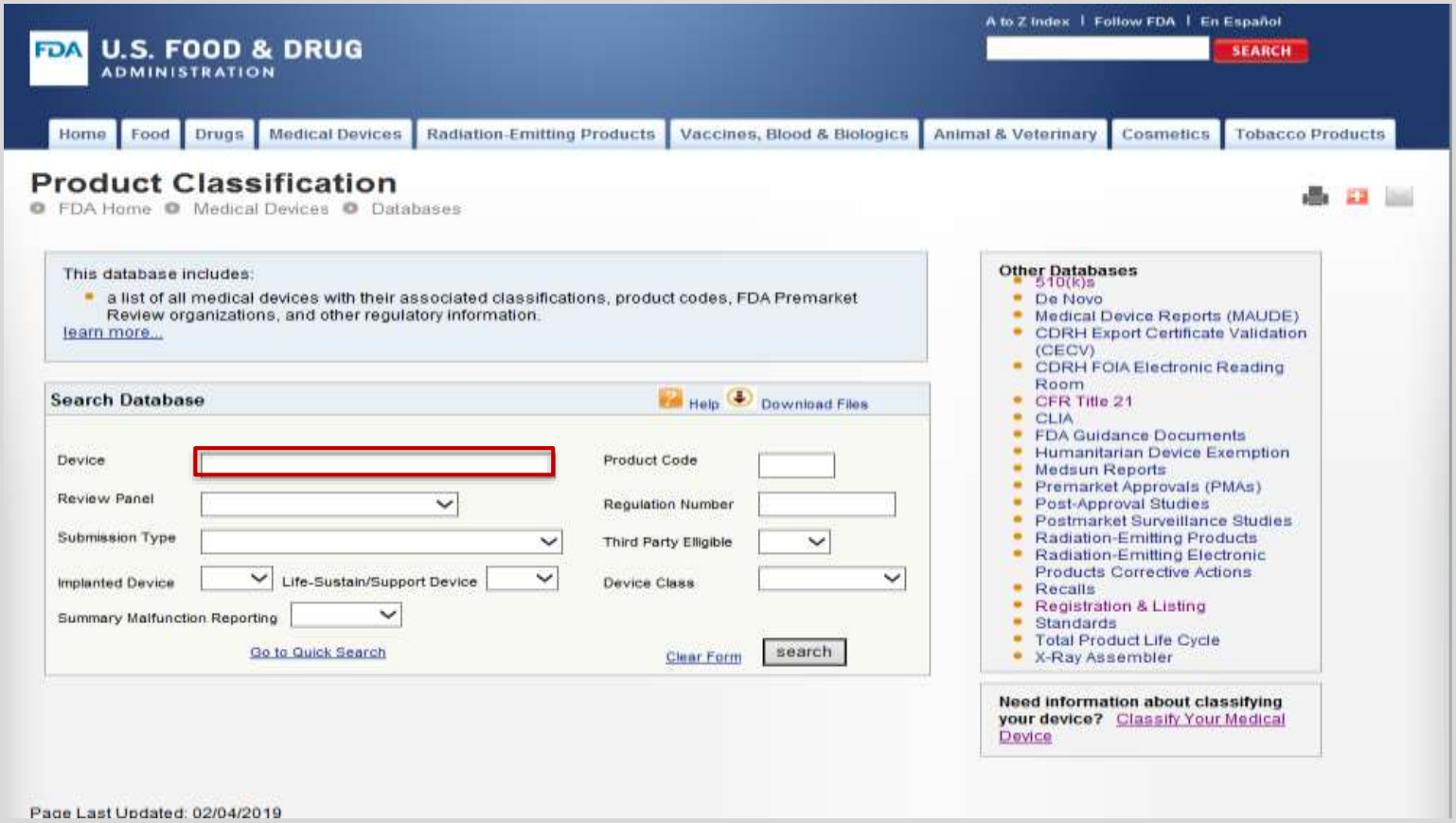
- If exempt from premarket review submission
  - ✓Product Code
- Submission Types:
  - ✓510(k)
  - ✓PMA

CDRH Regulatory Requirements

CDRH Device Information

- Registration and Listing
  - ✓Foreign Manufacturer
  - ✓Foreign Exporter
  - ✓Initial Importer (registration only)

CDRH: Product Classification Database



[Product Classification Database]

CDRH: Product Code Classification

New Search | Back to Search Results

Device	Orthosis, Corrective Shoe
Regulation Description	Limb orthosis.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	KNP
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Rehabilitation Devices Branch (PMDB)
Submission Type	510(K) Exempt
Regulation Number	890.3475
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes

Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), *as long as the device is not labeled or otherwise represented as sterile*.

Summary Malfunction Reporting	Eligible

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 Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Affirmations of Compliance

Devices		
Code	**Affirmation of Compliance**	**Qualifier?**
CPT	Component Identifier	N
DA	New Drug Application Number or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number	Y
DDM	Device Domestic Manufacturer	Y
DEV	Device Foreign Manufacturer Registration Number	Y
DFE	Device Foreign Exporter Registration Number	Y
DI	Device Identifier	Y
ERR	Entry Review Requested	N
IDE	Investigational Device Exemption Number	Y
IFE	Import For Export	N
IND	Investigation New Drug Application Number	Y
IRC	Device Impact Resistance Lens Certification	N
KIT	Device Imported Kit of Finished Devices	N
LST	Device Listing Number	Y
LWC	Electrode Lead Wire or Patient Cable	N
PM#	Device Premarket Number	Y

Affirmations of Compliance

Radiological Health Products		
Code	Affirmation of Compliance	Qualifier?
ACC	Accession Number	Y
ANC	Annual Report Accession Number	Y
CCM	Name of the Certified Component Manufacturer	Y
ERR	Entry Review Requested	N
IFE	Import For Export	N
MDL	Model Number	Y
RA1, RA2, RA5, RA7	Rad Health Product Affirmation A (FD2877)	Y
RA3, RA4, RA6	Rad Health Product Affirmation A (FD2877)	N
RB1	Rad Health Product Affirmation B (FD 2877) - transmit with ANC or ACC	N
RB2	Rad Health Product Affirmation B (FD 2877)	Y
RC1	Rad Health Product Affirmation C (FD 2877)	N
RC2	Rad Health Product Affirmation C (FD 2877)	Y
RD1, RD2	Rad Health Product Affirmation D (FD 2877)	N
RD3	Rad Health Product Affirmation D (FD 2877)	Y

FDA Entry Review

- FDA reviews the entry data
- Determines if regulatory requirements are met
- FDA may request additional information or documents
  - Documentation can be uploaded electronically using FDA's Import Trade Auxiliary Communications System (ITACS)
  - ITACS can also be used to check the status of your entry

Import Scenarios

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional* Affirmations	Optional Affirmations
081.001 or UNK	-Standard import of a foreign-manufactured device, accessories, or components regulated as a finished device -Import of refurbished device -Import of a reprocessed device	DEV, DFE, LST	IRC, LWC, PM#	DI
081.002**	Import of a foreign-manufactured device for domestic refurbishing	DEV, DFE, LST	IRC, LWC, PM#	DI

*Conditional affirmations are required if applicable to the product being declared

**Additional info may be needed at time of entry for FDA to make a final admissibility decision

Import Scenarios

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional* Affirmations	Optional Affirmations
180.014**	-Import of a device for non-clinical use/bench testing -Import of device sample for customer evaluation			
180.015**	Import of a medical device for clinical investigational use	IDE		
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	DDM, LST	DFE, IRC, LWC, PM#	DI
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	IRC, LWC, PM#	DI
950.001**	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, IRC, LWC, PM#	DI
950.002**	Import of a multi-use device for domestic reprocessing		DDM, DFE, IRC, LST, LWC, PM#	DI

*Conditional affirmations are required if applicable to the product being declared

**Additional info may be needed at time of entry for FDA to make a final admissibility decision

COMMON ENTRY ERRORS

Common Entry Errors

- Submitting the incorrect Affirmation of Compliance (AofC)
- Submitting the incorrect manufacturer information
- Submitting the incorrect product code
- Submitting the incorrect product quantity

Import Resources

FDA ACE Affirmations of Compliance and Affirmations of Compliance Quick Reference

FDA ACE/ITDS Webpage (including FDA Supplemental Guide)

Product Code Builder Tool and Tutorial

For more information about FDA's Import Program

Summary

- FDA reviews medical device import information
- Affirmation of Compliance Codes identify the Regulatory Requirement
- ITACS allows you to check the status of your import entry
- ITACS allows you to upload missing documents

Question and Answers

Your Call to Action

- Register and list prior to importing if required
- Ensure the imported product meets US Marketing Requirements
- Provide the Applicable Entry information to your customs broker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