Importing Medical Devices Into the United States

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Annual Percentage of Imported FDA Commodities

Percentage of Imported Lines* by Commodity for Fiscal Year 2017

- **Devices, 49%**
- **Human Foods, 32%**
- **Cosmetics, 7%**
- **Drugs & Biologics, 2%**
- **Housewares & Food-Related Items, 6%**
- **Radiological Health, 3%**
- **Animal Feed, 1%**
- **Tobacco Products, <1%**

*A line is a distinct product within a shipment. A single shipment may include multiple lines.
Learning Objectives

1. Describe the import entry process

2. Identify common entry errors that may lead to import delays
FDA Import Entry Process

Submission of entry data by the broker

CBP* data validation

FDA screens the data

NO

Incomplete data prompts error message back to filer

FDA generates an import disposition & sends it to CBP

CBP sends message back to the broker
FDA Import Entry Process:
Submitting Entry Data

1. **Filer obtains data required by Customs and Border Protection** (19 CFR* 142.3)
2. **Filer submits data to Customs Broker licensed by Customs and Border Protection (CBP)**
3. **Customs Broker assigns Harmonized Tariff Schedule (HTS) codes, enters code and mandatory product data into CBP’s ACE** **portal**

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*Code of Federal Regulations
**Automated Commercial Environment
FDA Import Entry Process

Submission of entry data by the broker

CBP* performs syntax data validation

FDA screens the data

FDA generates an import disposition & sends it to CBP

CBP sends message back to the broker

Incomplete data prompts error message back to filer

*Customs and Border Protection
CBP Data Validation

- CBP conducts syntax validation of import entry (article) lines:
  - Verify each entry (article) line for data completeness
  - Determine entry (article) status using “other government agency” (OGA) Flags
    - Entry (article) lines regulated by FDA receive FDA OGA Flag
  - If data are incomplete, entry (article) is returned to filer
## CBP Data Validation: FDA Flags

<table>
<thead>
<tr>
<th>FDA FLAG</th>
<th>Is it regulated?</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD*1</td>
<td>May or may not be regulated by FDA: If regulated by FDA, submit entry information; if not regulated by FDA, disclaim</td>
<td>Certain chemicals used in manufacturing drug products vs. industrial use; safety goggles for medical use vs. non-medical use</td>
</tr>
<tr>
<td>FD2</td>
<td>Regulated by FDA, but is not food: Submit entry information</td>
<td>Medical Devices, Drugs, Tobacco, and Cosmetics</td>
</tr>
<tr>
<td>FD3</td>
<td>May or may not be a food product: If yes, submit Prior Notice (PN) and entry information; if no, disclaim</td>
<td>Salt used for flavoring food vs salt used for treating road surfaces</td>
</tr>
<tr>
<td>FD4</td>
<td>Food product: Submit PN and entry information</td>
<td>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.</td>
</tr>
</tbody>
</table>

*An FDA flag is assigned a file descriptor (FD) number, i.e. FD1
FDA Import Entry Process

Submission of entry data by the broker

CBP performs syntax data validation

FDA screens the data

FDA generates an import disposition & sends it to CBP

CBP sends message back to the broker

Incomplete data prompts error message back to filer

NO
FDA Screens the Data

• FDA Reviews the Entry (Article) Data

• FDA determines if all required data to meet regulatory requirements have been provided
  – FDA may request additional data needed to meet regulatory requirements or request sample for examination
  – Data can be uploaded electronically using FDA’s [Import Trade Auxiliary Communications System (ITACS)](https://www.fda.gov)
  – ITACS can also be used to check the status of an entry (article)
Submission of entry data by the broker

CBP performs syntax data validation

FDA screens the data

FDA generates an import disposition and sends it to CBP

Incomplete data prompts error message back to filer

CBP sends message back to the broker

NO
Import Disposition

To generate an import disposition:

1. FDA reviews entry (article) for
   - Data required for all FDA regulated articles (products), *(21 CFR 1.72)*
   - Data Required by CDRH* for medical devices, *(21 CFR 1.76)*

*Center for Devices and Radiological Health*
Import Disposition

Data required for all FDA regulated articles (product)  
21 CFR 1.72

• **Product-identifying information:**
  – FDA country of production
  – Complete FDA product code
  – Full intended use code

• **Importer of Record Contact Information**
  – Email address and telephone number
Import Disposition

If applicable, Data required by CDRH for Medical Devices  

21 CFR 1.76

- Registration and Listing Number
- Investigational Device Information
- Premarket number
- Component affirmation
Import Disposition

If applicable, data required for Medical Devices
21 CFR 1.76
• Lead wire/patient cable performance standard affirmation
• Impact resistance lens affirmation of compliance with 21 CFR 801.40
• Convenience kit affirmation

If applicable, data required for Radiation-Emitting Electronic Products
21 CFR 1.76
• Radiation-emitting electronic products declarations in Form 2877
Data required by CDRH for Medical Devices

- Determine regulatory requirements based on product classification
- Use CDRH’s Product Classification Database to identify product classification and other regulatory requirements
- Use Affirmation of Compliance Codes (A of C) to designate regulatory requirements
CDRH Device Regulatory Requirements:
Product Classification Database
Example: Product Classification Record
Use Device Classification Information To:

• Identify Premarket Number:
  ✓ Premarket Notification [510(k)]
  ✓ Premarket Approval (PMA) Application
  ✓ Humanitarian Device Exemption (HDE)
  ✓ De Novo Classification
  ✓ Exempt (3-letter product code)
CDRH Regulatory Requirements: Product Classification Database

Use Device Classification Information To:

• Identify Registration and Listing Numbers for:
  ✓ Foreign manufacturer
  ✓ Foreign exporter
  ✓ Initial importer (registration only)
CDRH Regulatory Requirements: Affirmation of Compliance Codes

Use Affirmation of Compliance (A of C) codes to designate regulatory requirements

– A of C Codes for Medical Devices
– A of C Codes for Radiological Health Products
Example: Medical Device Affirmations of Compliance Codes

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

Affirmations of Compliance Codes

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

<table>
<thead>
<tr>
<th>Intended Use (see PG01 for definitions)</th>
<th>Import Scenarios</th>
<th>Mandatory Affirmations</th>
<th>Conditional* Affirmations</th>
<th>Optional Affirmations</th>
</tr>
</thead>
</table>
| 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 for entry

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

To generate an import disposition:

1. FDA reviews entry (article) for
   ✓ Data required for all FDA regulated articles (products), (21 CFR 1.72)
   ✓ Data Required by CDRH* for medical devices, (21 CFR 1.76)

2. FDA determines Notice of Action:
   ✓ Release the product
   ✓ Request additional information or sample evaluation; or
   ✓ Request detention of product

3. FDA issues Notice of Action to CBP and Importer of Record
FDA Import Entry Process

Submission of entry data by the broker

CBP performs syntax data validation

FDA screens the data

FDA generates an import disposition & sends it to CBP

NO

Incomplete data prompts error message back to filer

CBP sends message back to the broker
CBP Sends Message

CBP sends electronic disposition message to:

- Customs Broker
- Filer/Importer of Record
- Owner or Consignee
Common Entry Errors
Common Entry Errors

Submitting

• Incorrect Affirmation of Compliance Codes
• Incorrect Manufacturer Information
• Incorrect Product Code
• Incorrect Product Quantity
• Incomplete Information

www.fda.gov/industry/regulated-products/medical-device-common-entry-errors
Summary

• FDA reviews medical device import information
• Regulatory requirements are based partly on product classification
• Affirmation of Compliance codes correspond with regulatory requirements
• Entry errors may lead to import delays
Providing Industry Education

1. CDRH Learn – Multi-Media Industry Education
   ▪ over 100 modules - videos, audio recordings, PowerPoint presentations, software-based “how to” modules
   ▪ accessible on your portable devices: www.fda.gov/CDRHLearn

2. Device Advice – Text-Based Education
   ▪ comprehensive regulatory information on premarket and postmarket topics: www.fda.gov/DeviceAdvice

3. Division of Industry and Consumer Education (DICE)
   ▪ Email: DICE@fda.hhs.gov
   ▪ Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4:30 pm ET)
Your Call to Action

Prior to importing your products, do these three tasks:

1. Ensure your product meets U.S. regulatory requirements
2. Register and list, if required
3. Provide the applicable entry information to your custom broker