U.S. FOOD & DRUG ADMINISTRATION

CDRH Medical Device Import Overview

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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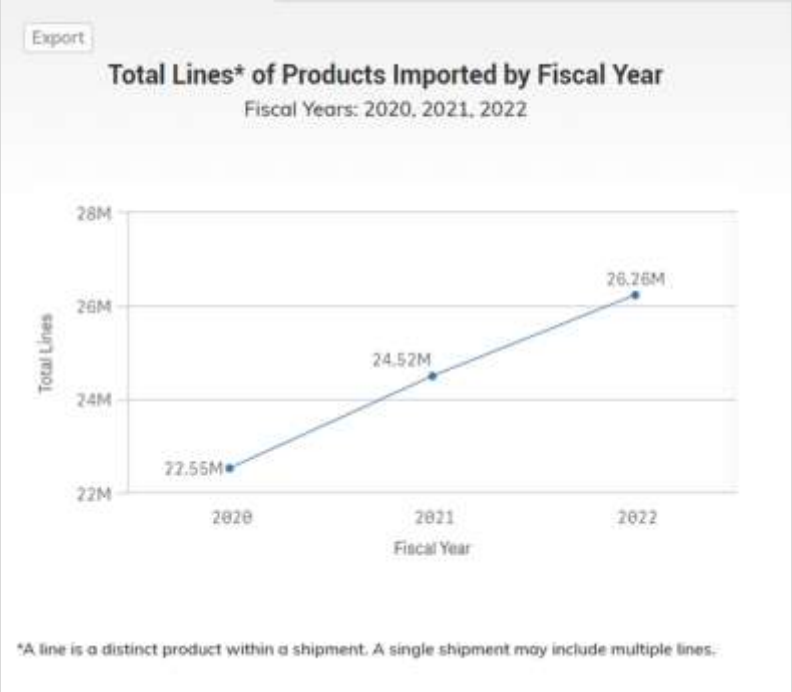
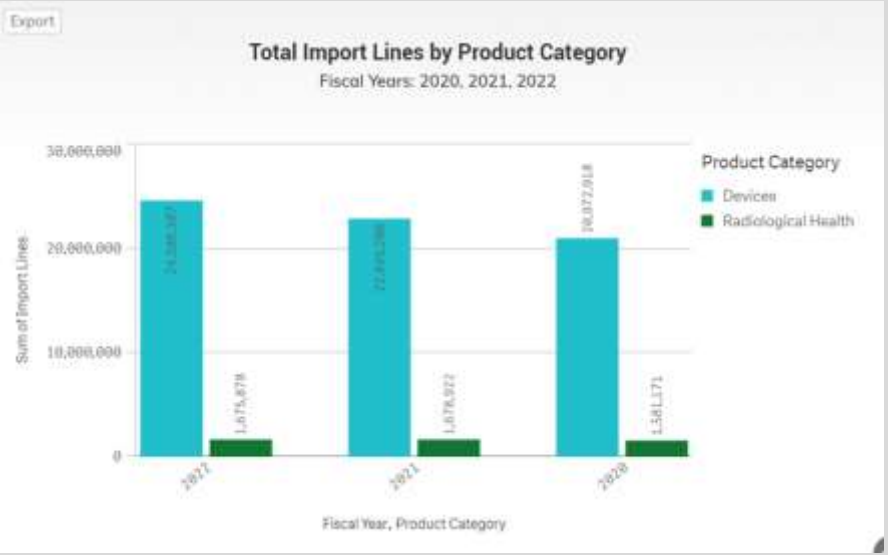
Imports Growth



All Import Lines	Refused Lines	Examined Lines	Sampled Lines
73,334,476	11,674	35,748	655

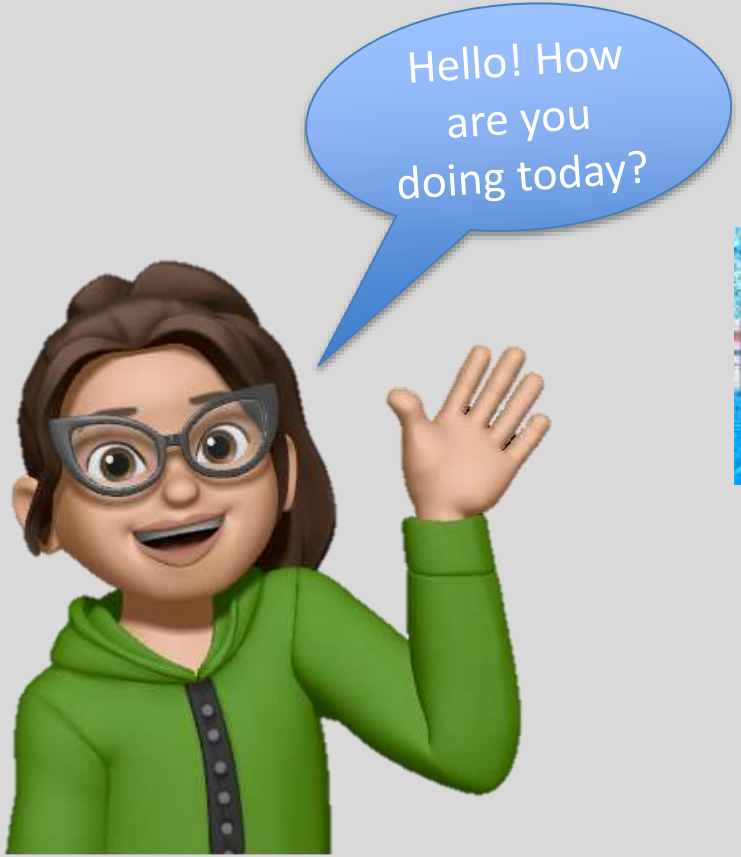


* FDA Dashboard

Learning Objectives

- Describe the importation process
- Gain knowledge and an understanding of common import lingo

Importation Process


Hello! How are you doing today?

Entry Review Overview

Preparation

Preparation

As an Initial Importer I must have a deep understanding of my supply chain.

- Must identify manufacturers of the device.
- Registration and listing information
- Clearance or approval information
- Product code
- Proprietary names
- Device intended use
- Assure product meets applicable standards

Import Program – Food and Drug Administration (FDA) | FDA

Electronic Transmission

Electronic Transmission

- 47 Partner Government Agencies (PGA)
- Quantity and value does not impact the admissibility review process.
- Automated Commercial Environment (ACE)

Shipment aka Entry XXX-1234567-8

1. Device A
2. Device B
3. Device C
4. Device D

FDA Admissibility Review

FDA Affirmations of Compliance

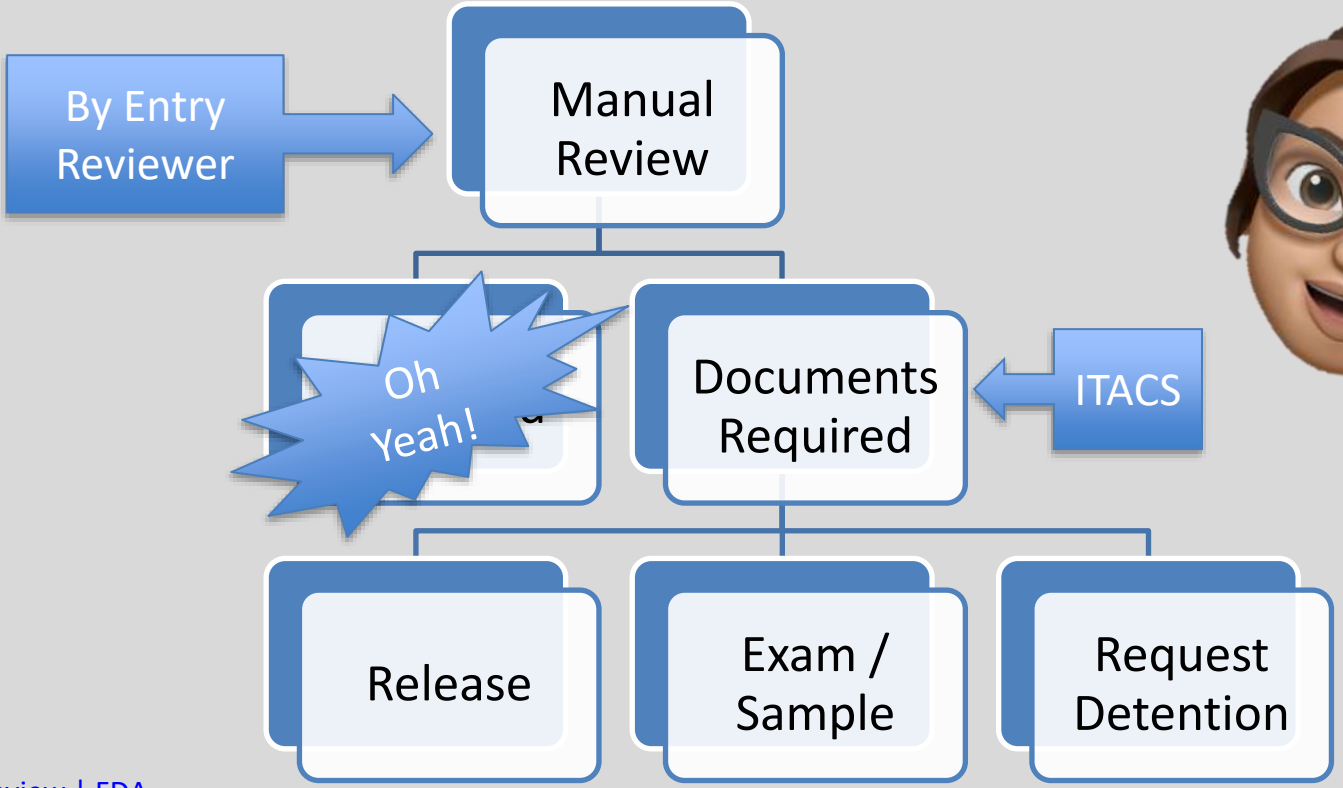
- Affirmation of Compliance (AofC) information can help expedite FDA review
- AofC can be submitted via electronic submission
- FDA can affirm compliance

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

FDA Affirmations of Compliance - Quick Reference
FDA Supplemental Guide | U.S. Customs and Border Protection (cbp.gov)

Admissibility

Admissibility Process



[Entry Review | FDA]
[ITACS | FDA]

Examination and Sampling

Examination and Sampling

- Consists of label and field exam and/or sample collection
  - Quantity confirmation
  - In transmit or storage damage
  - Storage temperature conditions
  - Product integrity or water damage

Labeling Requirements - Other Labeling Exemptions | FDA

Examination and Sampling

- Prelabeled product as “sterile” but not yet “sterile”
  - Written agreement between the parties must be in effect [21 CFR 801.150(e)]
  - Each pallet, carton, or other designated unit is conspicuously marked to indicate its nonsterile nature

Compliance Review

Compliance Review

- Conducted by a Compliance Officer
- Review may consist of:
  - ❑ Documents provided and labeling collected
  - ❑ Physical evidence
  - ❑ Laboratory results (FDA lab and private labs)
  - ❑ Photos
- Release or detain
- Review of reconditioning process
- Point of contact for detention and hearing period

Admissibility, Detention, and Hearing

- FDA finds no apparent violation = Release
- Exam or analytical result(s) in violation = Detention
- Hearing process
  - ❑ Submit evidence to overcome the appearance of a violation.
  - ❑ Submit a request to recondition (766), allowance to correct the violation
- After review of the evidence/reconditioning, the detention will either stand (refusal) or be overturned (release)

Detention & Hearing | FDA
Chapter 9 Import Operations And Actions (fda.gov)

Reconditioning

- Request authorization to recondition or relabel (FDA 766)
  - Timeframe & Summary
  - New labeling? Make sure to include a copy
  - Compliance and center review
  - FDA supervision and charges may apply
- Request refusal
  - Export or destroy

Refusals

- Violation is not overcome = Refusal
- Must be either exported or destroyed
- FDA to witness exportation or destruction
- CBP issues redelivery
- Product not exported or destroyed = Liquidated damages

Import Refusals | FDA
CBP liquidated damages

Import Alerts

Import Alerts

Import Alerts | FDA

IA #

Name

Reason

Guidance

Date/Type

U.S. Department of Health and Human Services

U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

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Home > Import Program > Import Alerts > Imports Alerts by Number

Import Alert 89-08

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(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(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 # 89-08

Published Date: 03/27/2023

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of Devices without Approved PMA's or IDE's and Other Devices Not Substantially Equivalent or Without a 510(k)"

Reason for Alert:

Note: The revision of this Import Alert (IA) dated 03/13/2023 updates the reason for alert and guidance section. Changes to the import alert are bracketed by asterisks (***).

Devices listed on the Red List of this alert ***are either devices or which a 510(k) application has not been filed and/or determined substantially equivalent, Class III medical device for which there is no Pre-Market Approval (PMA) for commercial distribution, or investigational device that lacks an Investigational Device Exemption (IDE).***

Guidance:

Divisions may detain, without physical examination, shipments of the products identified on the Red List of this alert.

Recommendations for addition to detention without physical examination under this Import alert, including analytical worksheets (if the product was analyzed), labeling, package inserts, user manuals, photographic evidence, website information, entry documents, etc., should be forwarded to the Division of Import Operations (DIO). DIO will coordinate a review of all recommendations with ***FDA's Center for Device and Radiological Health (CDRH) Imports and Registration & Listing Team (IRLT).***

Release of Articles Subject to Detention Without Physical Examination under this Import Alert:

In order to secure release of an individual shipment subject to detention without physical examination under this import alert, the owner, consignee and/or another responsible party for the affected goods should provide a written application (Form FDA 766) requesting authorization to bring a device into compliance by relabeling or other action (reconditioning). ***Records should be submitted to the appropriate FDA Division compliance officer for consideration per the notice of detention.*** Divisions will refer such applications related to this alert to CDRH Imports and Registration & Listing Team, for concurrence.

Recap

1. Preparation
2. Electronic submission
3. Admissibility Process
4. Examination and Sampling
5. Compliance Review
6. Import Alerts

Knowledge Check

Which is the first step in the importation process?

1. Electronic submission
2. Preparation
3. Examination

Knowledge Check

How can I submit entry documents to the FDA?

1. PREDICT
2. OASIS
3. ITACS

Knowledge Check

I export low quantity and value medical device shipments. I don't need to transmit to FDA, right?

1. True
2. False

Summary

- Gain high level understanding of importation process
  - Preparation
  - Electronic submission
  - Admissibility process
  - Examination and sampling
  - Compliance review

- Gain knowledge and an understanding of common import lingo
  - DWPE, ITACS, PREDICT, ACE, AofC, DEV, LST, Notice of Action (NOA)

Resources

Resources

Topics	Website	Details
Division of Industry and Consumer Education (DICE)	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice	The Division of Industry and Consumer Education (DICE) answers questions (by phone and email) from the medical device industry and consumers of medical devices and radiation-emitting electronic products. In addition, DICE develops educational resources for the FDA website to help the medical device industry understand FDA regulations and policies.
Importing Medical Devices	www.fda.gov/industry/importing-fda-regulated-products/importing-medical-devices	This page provides an overview of medical devices and the requirements that the FDA verifies/enforces at the time they are imported or offered for import into the United States.
Importing Medical Devices and Radiation-Emitting Electronic Products into the U.S.	www.fda.gov/medical-devices/importing-and-exporting-medical-devices/importing-medical-devices-and-radiation-emitting-electronic-products-us	This page provides an overview of medical devices and the requirements that the FDA verifies/enforces at the time they are imported or offered for import into the United States.
Import Trade Auxiliary Communication System (ITACS)	www.fda.gov/industry/import-systems/itacs	Communication between the FDA and the import trade community

Resources

Topics	Website	Details
Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)	www.fda.gov/media/155039/download	This guidance applies to devices that have been issued an EUA under section 564 of the FD&C Act on the basis of a device EUA declaration related to COVID-19.
Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	www.fda.gov/media/155038/download	This guidance applies to devices that fall within the enforcement policies. For a full list please refer to the website.
Automated Commercial Environment/International Trade Data System (ACE/ITDS)	www.fda.gov/industry/import-systems/automated-commercial-environmentinternational-trade-data-system-aceitds	Industry Quick Reference Guide to the FDA ACE Supplemental Guide ACE Affirmations of Compliance Codes ACE AofC Code Quick Reference Information for FDA Entry Filings
FDA Import Alerts	www.fda.gov/industry/actions-enforcement/import-alerts	This page provides information on what an import alert is and how to interpret it. For information on how to be removed from an import alert, please see the import alert removal page.

Resources

Topics	Website	Details
Examination & Sample Collection	www.fda.gov/industry/fda-import-process/examination-sample-collection	The FDA has the authority to conduct examinations and/or sample collections to determine if the product offered for import is in compliance with the FDA regulations and laws. This examination may consist of any combination of a field examination, label examination, and/or sample collection.
Quality System Regulation Labeling Requirements	www.fda.gov/medical-devices/device-labeling/quality-system-regulation-labeling-requirements#sterile	Medical device manufacturers must incorporate in their quality assurance (QA) program several elements that relate to labeling in order to meet the Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. The QA program must be adequate to ensure that labeling meets all GMP requirements.
Reconditioning of Imported FDA-Regulated Products	www.fda.gov/industry/fda-import-process/reconditioning-imported-fda-regulated-products	Information regarding the reconditioning process. If the IOR wishes to submit an application to the FDA requesting permission to re-label or recondition the product in an attempt to bring it into compliance.

Contacts

- For questions regarding the regulatory requirements for the medical device being offered for import, please contact the CDRH Imports and Registration & Listing Team at: cdrhimport@fda.hhs.gov.
- For assistance with general import procedures regarding personal protective equipment, test kits, or other products related to the public health emergency, please contact: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.
- For general import questions: FDA Imports Inquiry FDAImportsInquiry@fda.hhs.gov
- Inquiries related to a specific import entry are most appropriately routed to the FDA Import Division handling the entry.
  - www.fda.gov/industry/contact-fda-import-program/import-offices-and-ports-entry

Questions