

Medmarc Insurance Risk Management Webinar Series



Importing Medical Devices into the U.S. in Compliance with the U.S. FDA

OUR DISTINGUISHED SPEAKER



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AGENDA

- Medical Device Basics
- FDA Laws/Regulations
- FDA Import Process
 - What You Need to Know to Import
 - How to determine if your product is a medical device
 - How to determine if your medical device is a Class I, II, or III
 - How to determine your product code
 - How to determine whether or not your manufacturer is registered with the FDA (and their enforcement history)



POLL TIME!

- Which best describes you?
 - A. Importers
 - B. Customs Brokers
 - C. Regulatory Affairs Professionals
 - D. In-house Legal Counsel
 - E. Product Development Managers
 - F. Consultants
 - G. Others Interested in FDA and Imports



WHAT IS A MEDICAL DEVICE?



1. Instrument
 2. Apparatus
 3. Implement
 4. Machine
 5. Implant
 6. Another similar/related article
 7. Or part/accessory
- Recognized by National Formulary, or the US Pharmacopeia...
 - 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
 - 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.

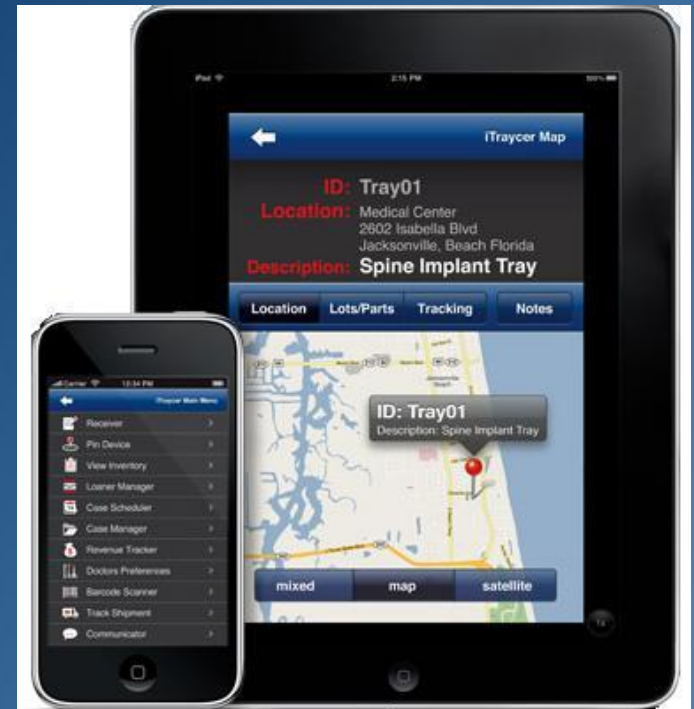
WHAT IS A MEDICAL DEVICE?

- Examples of Medical Devices:
 - Facemasks / Respirators
 - Needles
 - Ventilators
 - Sterilizers
 - Thermometer
 - Gloves
 - Hospital Beds
 - Defibrillators
 - Disposable bedsheets/
pillows/ pillowcases/blankets



MOBILE MEDICAL APPLICATIONS

- Improve health care
- Provide consumers and health care professionals with valuable health information
- FDA released draft guidance on July 19, 2011
 - updated in 2015, 2019, and 2022
- The final guidance issued on September 28, 2022 is the latest revision



POLL TIME!

- Which of the following products is NOT a medical device?
 - A. Dental Floss
 - B. SPF Moisturizer
 - C. Sunglasses
 - D. Hospital Beds





U.S. FOOD AND DRUG ADMINISTRATION

- Federal Food, Drug and Cosmetic Act
 - **Comply before U.S. Customs releases shipment**
- 21 U.S.C. 381 – Imports and Exports
 - Imports
 - List of registered foreign establishments
 - Disposition of refused articles
 - Reimportation
 - Exports
 - Temporary holds at ports of entry
 - Warning notice
 - Prior Notice



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. 21 U.S.C. 301
- For further information, see FDA's Office of Regulatory Affairs Import Start Page accessible at: [Import Program – Food and Drug Administration \(FDA\) | FDA](#)



FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

- CDRH regulates companies which
 - manufacture
 - repackaging
 - relabel
 - import
- medical devices sold in the United States.

<u>Distribution of Full-Time Equivalent (FTE)</u> <u>Employment Program Level</u>	<u>Total</u>
Center for Food Safety and Applied Nutrition	1,230
Center for Drug Evaluation and Research	5,624
Center for Biologics Evaluation and Research	1,191
Center for Veterinary Medicine	659
Center for Devices and Radiological Health	1,887
National Center for Toxicological Research	301
Office of Regulatory Affairs	4,997
Headquarters and Office of the Commissioner.....	1,018
Export Certification	26
Color Certification	37
Family Smoking Prevention and Tobacco Control Act.....	992
Priority Review Vouchers (PRV) Pediatric Disease	---
MCMi - No Year.....	---
Opioids - No Year.....	---
21st Century Cures (BA Only).....	100
Total.....	18,062

CHECKLIST TO IMPORT MEDICAL DEVICES

1. Identify Product Code & Device Class
2. Is a 510(k) or PMA needed?
3. All Establishments (IOR/ Manuf/ Exporter) Registered?
 - Foreign Facilities list a U.S. Designated Agent?
4. Device Listing #
5. Quality System Regulation (QSR)
 - (aka GMPs)
6. Labeling Requirements
 - Unique Device Identification (UDI) requirement.
7. Medical Device Reporting



MEDICAL DEVICES CLASSES

Class I	Class II	Class III
Low Risk	Moderate Risk	High Risk
Examples: <ul style="list-style-type: none">- elastic bandages- examination gloves- hand-held surgical instruments	Examples: <ul style="list-style-type: none">- powered wheelchairs- needles- surgical drapes	Examples: <ul style="list-style-type: none">- Pacemaker- Orthopedic Implants- silicone gel-filled breast implants
Most (93%) are exempt from Premarket Notification 510(k)	Most (80%) require a Premarket Notification 510(k)	Support or sustain human life. Most require a Premarket Approval (PMA).

DEVICE CLASSIFICATION

- Devices are classified into 19 medical specialties
- 21 C.F.R. 862-892:

Medical Specialty (Advisory Committee)	Regulation No.
Clinical Chemistry	Part 862
Clinical Toxicology	Part 862
Hematology	Part 864
Pathology	Part 864
Immunology	Part 866
Microbiology	Part 866
Anesthesiology	Part 868
Cardiovascular	Part 870
Dental	Part 872
Ear, Nose, & Throat	Part 874
Gastroenterology & Urology	Part 876
General & Plastic Surgery	Part 878
General Hospital	Part 880
Neurology	Part 882
Obstetrics/Gynecology	Part 884
Ophthalmic	Part 886
Orthopedic	Part 888
Physical Medicine	Part 890
Radiology	Part 892

Code of Federal Regulations
A point in time eCFR system

Title 21

Displaying title 21, up to date as of 5/18/2023. Title 21 was last amended 5/12/2023. [view historical versions](#)

Enter a search term or CFR reference (eg, fishing or 1 CFR 1.1)

Title 21 / Chapter I / Subchapter H

CFR CONTENT

Details	▼ Title 21 Food and Drugs	Part / Section
Print	▼ Chapter I Food and Drug Administration, Department of Health and Human Services	1 – 1299
Search	▼ Subchapter H Medical Devices	800 – 898
Subscribe	► Part 800 General	800.10 – 800.75
Timeline	► Part 801 Labeling	801.1 – 801.437
Go to Date	► Part 803 Medical Device Reporting	803.1 – 803.58
Published Edition	► Part 806 Medical Devices, Reports of Corrections and Removals	806.1 – 806.40
Developer Tools	► Part 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices	807.3 – 807.100
	► Part 808 Exemptions from Federal Preemption of State and Local Medical Device Requirements	808.1 – 808.101
	► Part 809 In Vitro Diagnostic Products for Human Use	809.3 – 809.40
	► Part 810 Medical Device Recall Authority	810.1 – 810.18
	► Part 812 Investigational Device Exemptions	812.1 – 812.150
	Part 813 [Reserved]	
	► Part 814 Premarket Approval of Medical Devices	814.1 – 814.126
	► Part 820 Quality System Regulation	820.1 – 820.250
	► Part 821 Medical Device Tracking Requirements	821.1 – 821.60
	► Part 822 Postmarket Surveillance	822.1 – 822.36
	► Part 830 Unique Device Identification	830.3 – 830.360
	► Part 860 Medical Device Classification Procedures	860.1 – 860.260
	► Part 861 Procedures for Performance Standards Development	861.1 – 861.38
	► Part 862 Clinical Chemistry and Clinical Toxicology Devices	862.1 – 862.3950
	► Part 864 Hematology and Pathology Devices	864.1 – 864.9900
	► Part 866 Immunology and Microbiology Devices	866.1 – 866.6080
	► Part 868 Anesthesiology Devices	868.1 – 868.6885
	► Part 870 Cardiovascular Devices	870.1 – 870.5925
	► Part 872 Dental Devices	872.1 – 872.6890
	► Part 874 Ear, Nose, and Throat Devices	874.1 – 874.5900
	► Part 876 Gastroenterology-Urology Devices	876.1 – 876.5990
	► Part 878 General and Plastic Surgery Devices	878.1 – 878.5910
	► Part 880 General Hospital and Personal Use Devices	880.1 – 880.6992
	► Part 882 Neurological Devices	882.1 – 882.5970
	► Part 884 Obstetrical and Gynecological Devices	884.1 – 884.6200
	► Part 886 Ophthalmic Devices	886.1 – 886.5933
	► Part 888 Orthopedic Devices	888.1 – 888.5980
	► Part 890 Physical Medicine Devices	890.1 – 890.5975
	► Part 892 Radiology Devices	892.1 – 892.6500
	► Part 895 Banned Devices	895.1 – 895.105
	► Part 898 Performance Standard for Electrode Lead Wires and	898.11 – 898.14

HOW TO FIND YOUR “PRODUCT CODE” AND “DEVICE CLASS”

The screenshot shows the FDA's "Establishment Registration & Device Listing" database search interface. At the top is the FDA logo and navigation tabs for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, and Vaccines, Blood & Biologics. The page title is "Establishment Registration & Device Listing" with breadcrumb links for FDA Home, Medical Devices, and Databases. A section titled "This database includes:" lists medical device manufacturers and devices listed with FDA, with a note that registration does not denote approval. Below this is a "Search Database" section with a "Help" icon and a "Download Files" button. The search form contains two columns of input fields: Establishment or Trade Name, Owner/Operator Name, Proprietary Name, Product Code, Establishment State (U.S.), Registration or FEI Number, Owner/Operator Number, Classification Device Name, Establishment Type, and Establishment Country *. There are "Quick Search", "Clear Form", and "Search" buttons at the bottom.

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

Search Database

Help Download Files

Establishment or Trade Name	<input type="text"/>	Registration or FEI Number	<input type="text"/>
Owner/Operator Name	<input type="text"/>	Owner/Operator Number	<input type="text"/>
Proprietary Name	<input type="text"/>	Classification Device Name	<input type="text"/>
Product Code	<input type="text"/>	Establishment Type	<input type="text"/>
Establishment State (U.S.)	<input type="text"/>	Establishment Country *	<input type="text"/>

[Quick Search](#) [Clear Form](#)

- Product Codes = 6704
- Devices = 6704
 - Class I = 2378
 - Class II = 3328
 - Class III = 484
- Remaining
 - Humanitarian Device Exemption (48)
 - For Export Only (361)
 - Unclassified (105)

CLASS I MEDICAL DEVICE

Device	Sunglasses (Non-Prescription Including Photosensitive)
Regulation Description	Sunglasses (nonprescription).
Regulation Medical Specialty	Ophthalmic
Review Panel	Ophthalmic
Product Code	HQY
Premarket Review	Ophthalmic Devices (DHT1A) Ophthalmic Devices (DHT1A)
Submission Type	510(K) Exempt
Regulation Number	886.5850
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
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

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Did You Know That Sunglasses Are Regulated by The FDA As Medical Devices?

By Jennifer Diaz | May 30, 2019

Did You Know That Sunglasses Are Regulated by The FDA As Medical Devices?



Whether you import sunglasses into the United States or sell sunglasses in the U.S. commerce, you are required to comply with the laws and regulations of the [U.S. Food & Drug Administration \(FDA\)](#). [The FDA regulates sunglasses products to ensure their safety and impact resistance.](#) These products are regulated as medical devices as they are intended to mitigate or prevent the effect of the sun's ultraviolet (UV) rays on the eyes of a person. The term "[Medical Device](#)" is defined in 21 CFR 201 (h).

The following are FDA regulations that apply sunglasses. Failure to comply with them may result in [CBP and FDA detaining](#) your sunglasses at the U.S. port of entry.

- Register with the FDA;
- Foreign Manufacturers Must Name a U.S. Agent;
- Manufacturers Must List Their Devices With FDA;
- Manufacturers Must Meet Quality System (QS) Requirements Set Forth in 21 CFR 820,
- The Lens for Spectacles And/or Sunglasses Must Be Certified As Impact Resistant Under 21 CFR Part 801.410.

ANNUAL ESTABLISHMENT REGISTRATION USER FEE

Year	FY 2021	FY 2022	FY 2023	FY 2024
Fee	\$5,546	\$5,672	\$6,493	\$7,653

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Breaking News

ARE YOU A MEDICAL DEVICE
IMPORTER, MANUFACTURER, OR
EXPORTER? FY2023 Registration
fees are out:

- \$6,493 for each establishment.

WHO MUST REGISTER, LIST & PAY THE FEE

Domestic establishments

Activity	Register	List	Pay Fee
Contract manufacturer (including contract packagers)	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Contract sterilizer	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Device being investigated under IDE	NO	NO 807.40(c)	NO
Domestic Distributor that does not import devices	NO 807.20(c)(3)	NO	NO
Any establishment located in a foreign trade zone involved with the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for commercial distribution in the United States	YES	YES	YES
Import agent, broker, and other parties who do not take first possession of a device imported into the United States	NO	NO	NO
Initial Importer	YES 807.40(a)	NO Identify manufacturers per 807.20(a)(5)	YES
Maintains complaint files as required under 21 CFR 820.198	YES	YES	YES
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES 807.20(a)(6)	YES 807.20(a)(6)	YES
Manufacturer of components, that are not otherwise classified as a finished device, that are distributed only to a finished device manufacturer	NO 807.65(a)	NO	NO
Manufacturer (including Kit Assemblers)	YES 807.20(a)	YES 807.20(a)	YES
Manufactures a custom device	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Refurbishers or remarketers of used devices already in commercial distribution in the United States.	NO	NO	NO
Relabeler or Repackager	YES 807.20(a)(3)	YES 807.20(a)(3)	YES
Remanufacturer	YES	YES	YES
Reprocessor of single use devices	YES 807.20	YES 807.20	YES
Specification Consultant Only	NO	NO	NO
Specification Developer	YES 807.20(a)(1)	YES 807.20(a)(1)	YES
U.S. Manufacturer of export only devices	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Wholesale distributor that is not a manufacturer or importer	NO	NO	NO

Foreign Establishments

Activity	Register	List	Pay Fee
Contract Manufacturer (including contract packagers)	YES 807.40(a)	YES 807.40(a)	YES
Contract Sterilizer	YES 807.40(a)	YES 807.40(a)	YES
Custom Device Manufacturers	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Device Being Investigated under IDE	NO 812.1 (a)	NO 812.1(a), 807.40(c)	NO
Foreign Exporter of devices located in a foreign country	YES 807.40 (a)	YES 807.40 (a)	YES
Foreign Manufacturers (including Kit Assemblers)	YES 807.40(a)	YES 807.40(a)	YES
Maintains complaint files as required under 21 CFR 820.198	YES	YES	YES
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES 807.20(a)(5)	YES 807.20(a)(5)	YES
Manufacturer of components that are distributed only to a finished device manufacturer	NO 807.65(a)	NO	NO
Relabeler or Repackager	YES 807.20(a)(3)	YES 807.20(a)(3)	YES
Remanufacturer	YES	YES	YES
Reprocessor of Single-use Device	YES 807.20(a)	YES 807.20(a)	YES
Specification Developer	YES	YES	YES

Foreign establishments must also designate a U.S. Agent.

<https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>

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TRUST, BUT VERIFY

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

U.S. Department of Health & Human Services

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Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

This database includes:

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- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

Search Database Help Download Files

Establishment or Trade Name	<input type="text"/>	Registration or FEI Number	<input type="text"/>
Owner/Operator Name	<input type="text"/>	Owner/Operator Number	<input type="text"/>
Proprietary Name	<input type="text"/>	Classification Device Name	<input type="text"/>
Product Code	<input type="text"/>	Establishment Type	<input type="text"/>
Establishment State (U.S.)	<input type="text"/>	Establishment Country *	<input type="text"/>

[Quick Search](#) [Clear Form](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Poll Time!

- What Device Class is a Ng5 respirator?
 - A. I
 - B. II
 - C. III
 - D. None of the above



MEDICAL DEVICE "PRODUCT CODE" RELATED TO COVID-19

Establishment Registration & Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)

[New Search](#)

[Back To Search Results](#)

Classification Name:	RESPIRATOR, SURGICAL
Product Code:	MSH
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	3M COMPANY
Registered Establishment Number:	2110898
Premarket Submission Number:	K063023
Owner/Operator:	3M COMPANY
Owner/Operator Number:	2110898
Establishment Operations:	Specification Developer; Complaint File Establishment

CLASS II – 510(K) EXEMPT

Device	Respirator, Surgical
Regulation Description	Surgical apparel.
Definition	<p>A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures subject to 21 CFR 878.9 and the conditions for exemption identified in 21 CFR 878.4040(b)(1).</p>
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General Hospital
Product Code	MSH
Premarket Review	Infection Control and Plastic Surgery Devices (DHT4B) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(K) Exempt
Regulation Number	878.4040
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
<p>Note: Class II devices the Food and Drug Administration (FDA) has also published a list of class II (special controls) devices subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.</p>	
Implanted Device?	No
Life-Sustain/Support Device?	No

CLASS II – 510(K)

Device	Wheelchair, Powered
Regulation Description	Powered wheelchair.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	ITI
Premarket Review	Neuromodulation and Physical Medicine Devices (DHT5B) Neuromodulation and Physical Medicine Devices (DHT5B)
Submission Type	510(k)
Regulation Number	890.3860
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

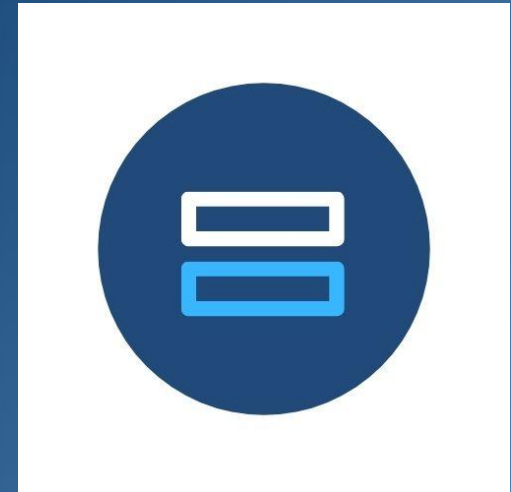
Sec. 890.3860 Powered wheelchair.

(a) *Identification.* A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class II (performance standards).

510(K) – SUBSTANTIAL EQUIVALENCE (SE)

- A device is substantially equivalent if, in comparison to a predicate it:
 - has the same intended use; **and**
 - has the same technological characteristics; OR
 - has the same intended use; **and**
 - has different technological characteristics **and** the information submitted to FDA;
 - does not raise new questions of safety and effectiveness; **and**
 - demonstrates that the device is at least as safe and effective as the legally marketed device.



CLASS II – 510(K)

- **Who must submit a 510(k)?**
 - Domestic manufacturers introducing a device to the U.S. market;
 - Specification developers introducing a device to the U.S. market;
 - Repackers or relabelers who make labeling changes or whose operations significantly affect the device.
 - Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market



CLASS II – PREMARKET NOTIFICATION – 510(K)

- Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device.
- Once the device is determined to be SE, it can then be marketed in the U.S.
 - Pro Tip → Register after receiving SE
- SE determination
 - 90 days
 - Plan for much longer
 - Based on the information submitted by the submitter.



CLASS III - PREMARKET APPROVAL (PMA)

- High risk devices that pose a significant risk of illness or injury
- The PMA process is more involved and includes the submission of clinical data to support claims made for the device.
- Approval of the device by FDA.
- 180 days to review and approve



OTHER FEES FOR FISCAL YEAR 2024

Application Type	Standard Fee	Small Business Fee†
510(k)	\$21,760	\$5,440
PMA	\$483,560	\$120,890

WANT A HAPPY BROKER?

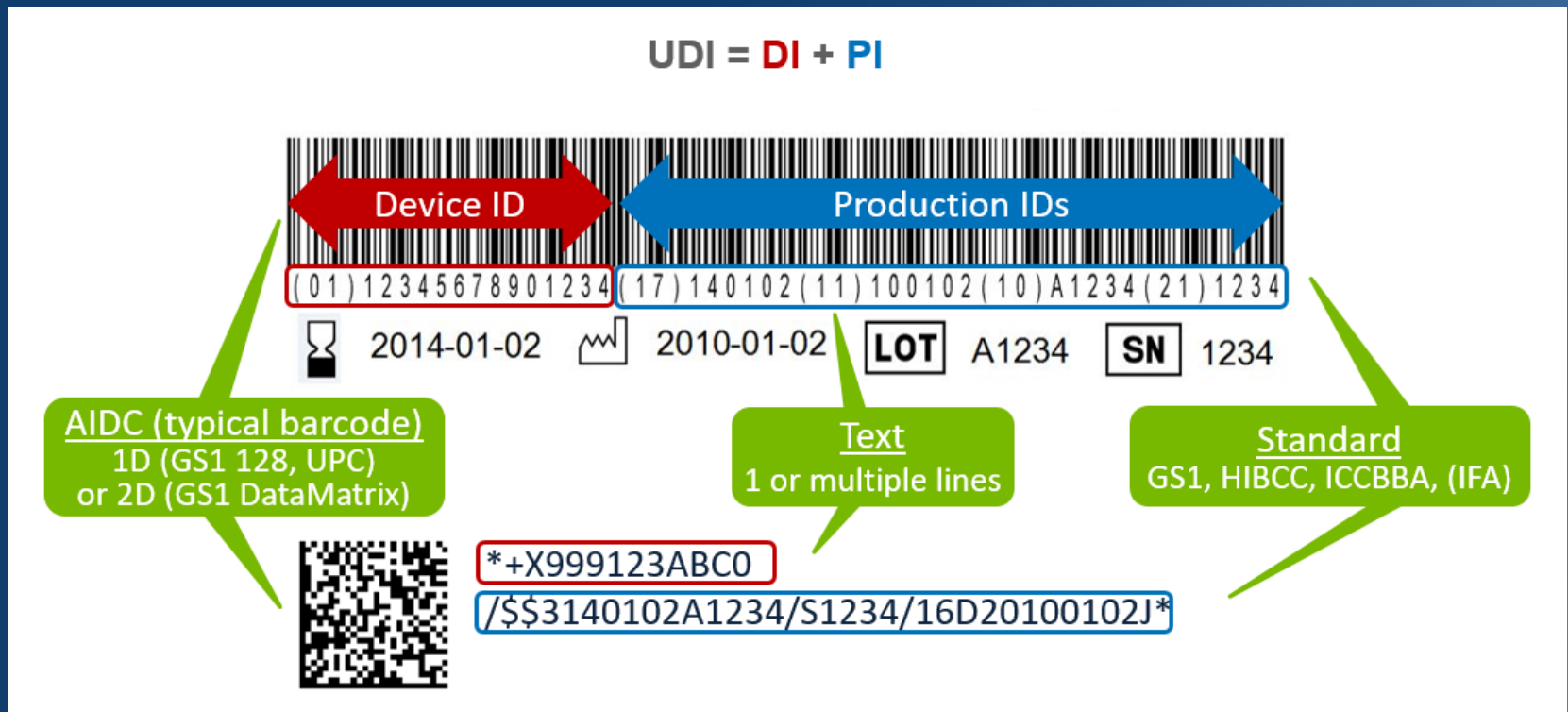
- Prior to Importing – Send your Broker:
 - 1. Product Code
 - 2. Device Class
 - 3. Device Listing #
 - 4. 510k / PMA # if applicable
 - 5. Manufacturer Establishment Registration No.
 - 6. If Exporter is different than Manufacturer – Registration No.
 - 7. Importer Registration No.

MEDICAL DEVICE LABELING BASICS



- General Device Labeling - [21 CFR Part 801](#)
 - Use of Symbols - [21 CFR Part 801.15](#)
- In Vitro Diagnostic Products - [21 CFR Part 809](#)
- Investigational Device Exemptions - [21 CFR Part 812](#)
- Unique Device Identification - [21 CFR Part 830](#)
- Good Manufacturing Practices - [21 CFR Part 820](#)
- General Electronic Products - [21 CFR Part 1010](#)

UDI LABELING REQUIREMENTS



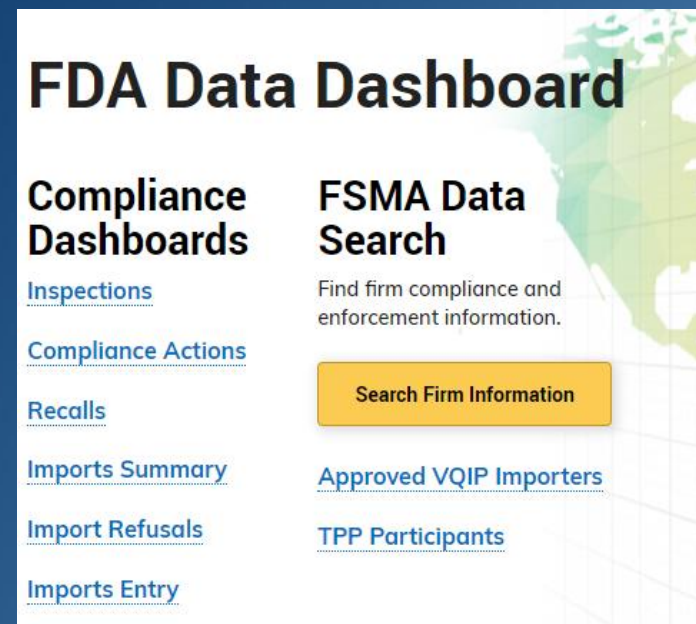
Source: Reedtech.com

UDIs must be issued under a system operated by an FDA-accredited issuing agency

DUE DILIGENCE

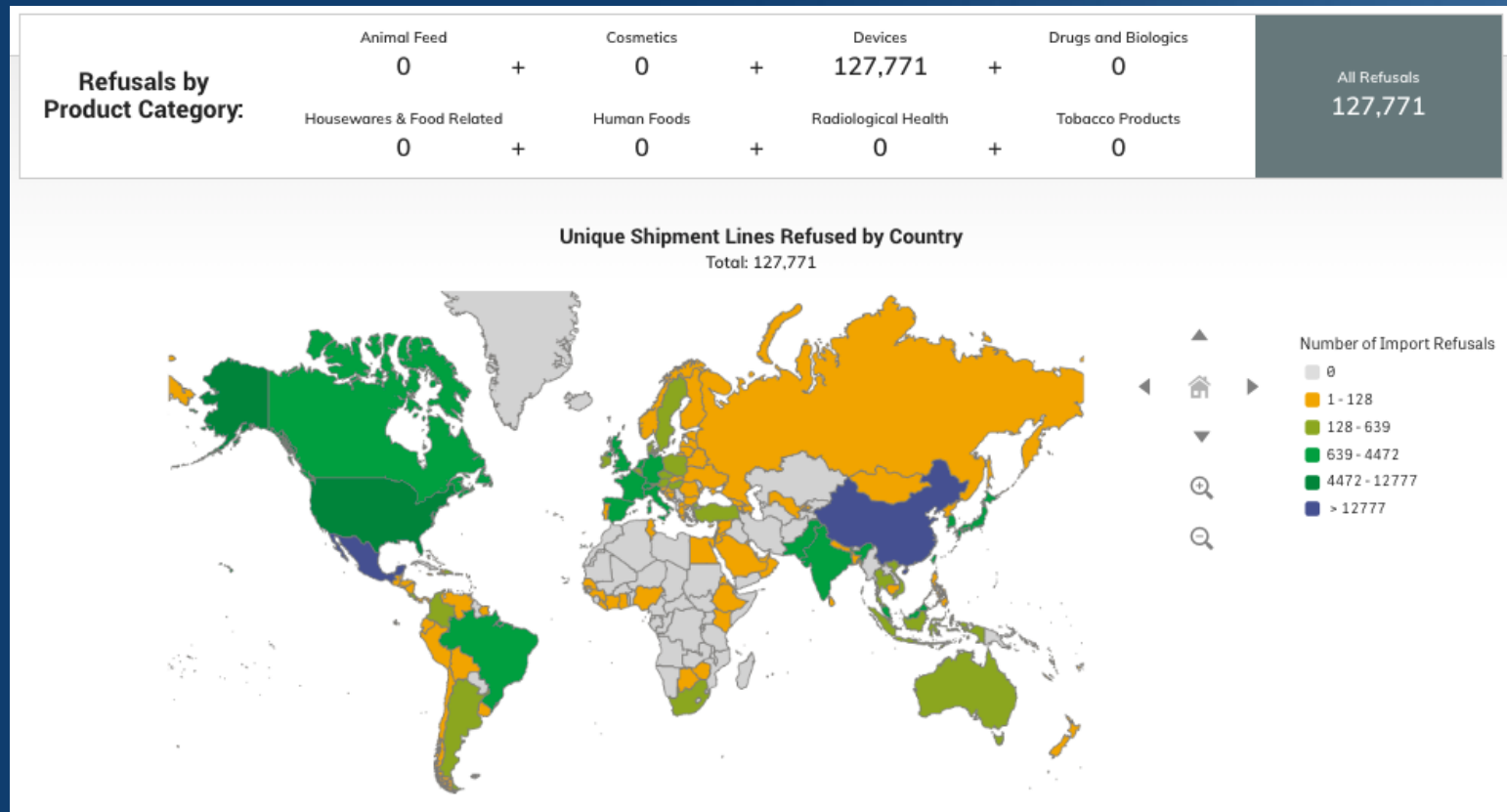
COMPLIANCE HISTORY OF MANUFACTURER

- What is the compliance history of the manufacturer, importer, and device?
- FDA Data Dashboard (datadashboard.fda.gov)
 - Previous Inspections
 - Recalls
 - Warning Letters
 - Import Alerts
 - Refusals



<https://datadashboard.fda.gov/ora/index.htm>

FDA Compliance Actions: FDA Data Dashboard



POLL TIME!

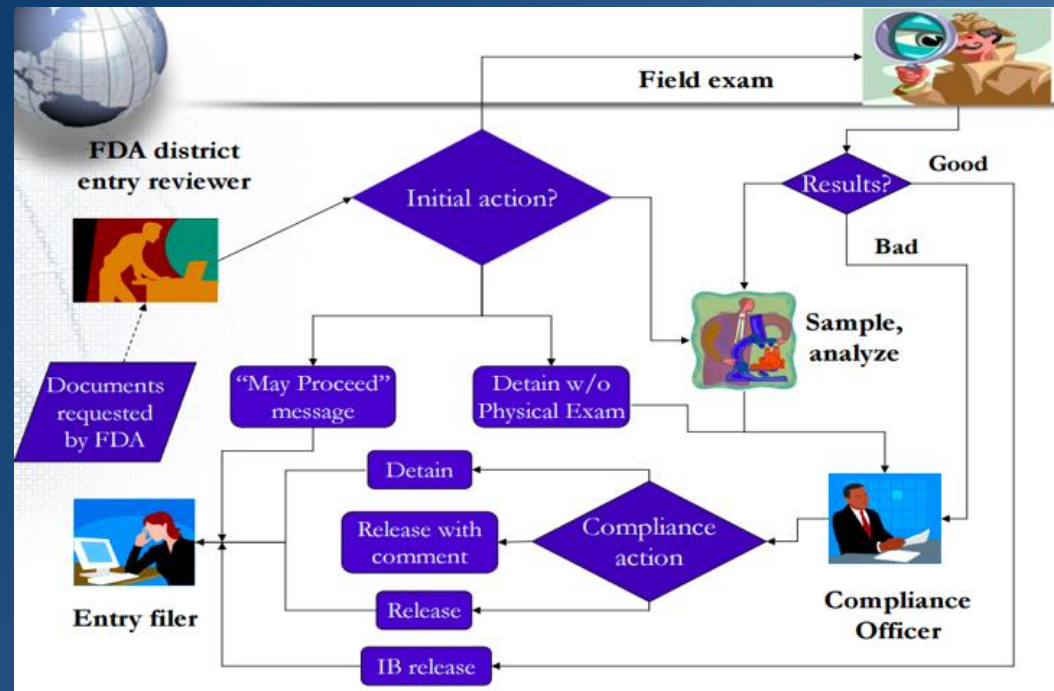
Which of the following enforcement actions have you seen FDA and/or CBP take?

- A. Notice of Action
- B. Notice of Refusal
- C. Liquidated Damages Claim from CBP
- D. Warning Letter
- E. Import Alert
- F. Recall



TYPICAL FDA/CBP ENFORCEMENT ACTIONS

- Notice of Action
- Notice of Refusal
- CBP / Liquidated Damages
- Warning Letter
- Import Alert
- Recall



<https://diaztradelaw.com/fda-discusses-top-reasons-for-detention-of-goods-2/>

ITACS



Import Trade Auxiliary Communications System

[ITACS Account Log-in\(FURLS\)](#)

Welcome to Import Trade Auxiliary Communications System

ITACS allows the Import Trade Community to:

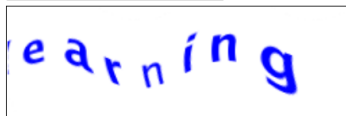
1) Check status of Entries 2) Input Line Availability 3) Submit Requested Documents



To get started, at a minimum please enter an Entry Number. If you would like to narrow your entry search, please provide a Line Number. The security letters are required for entry, when provided by the system.

*
are required fields

Entry Number* (Example: xxx-xxxxxx-x)
CBP Line Number
FDA Line Number



Hear a set of letters



Get a new set of letters

Please enter the letters provided*

SUBMIT

RESET

Select	Entry/CBP-FDA[Selfa]?	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date
<input type="checkbox"/>				Total: 3000000.0 Pieces (3000000.0 Pieces)	Vietnam	Refused Inform FDAAfter Export or Destruction	08/05/2021	Document Submitted	08/05/2021

[Export as PDF for Print](#) [Select All Lines](#) [Clear Selected](#)

[Export as PDF for Print](#) [Select All Lines](#) [Clear Selected](#)

Actions



If an action needs to be taken for the lines selected above, please choose the appropriate action option and press the Take Action button. The action taken will be applied to all of the selected lines.

Note: If you opt to submit entry level documents, ITACS will automatically select all of the lines of the entry for you.

- ☐ Input Line Availability (location of goods for examination) for the selected item(s)
- ☐ Submit Entry Level Documents
- ☐ Submit Line Level Documents for the selected item(s)
- ☐ View Expected Lab Completion Date

TAKE ACTION

REFRESH

FINISHED

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HOW TO CREATE YOUR ITACS ACCOUNT

- Step by Step Instructions:
- <https://www.fda.gov/media/106771/download>

Creating an ITACS Account

**ONLINE ACCOUNT
ADMINISTRATION (OAA)**

FDA Industry Systems System Status

Login

Existing account holders, enter your account ID & password.

Account ID

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I understand.

Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government Information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

Choose create new account

New User

POLL TIME

FDA may detain medical devices that “appear” to be in violation with FDA regulations?

- True or False?



NOTICES OF FDA ACTION

- Products that appear (from examination or otherwise) to be violative may be detained and refused entry into the U.S.
- Standard for detention and refusal is extremely low

United States Food and Drug Administration
Division of West Coast Imports
Notice of FDA Action

Entry Number: [REDACTED] Notice Number: 6
August 5, 2021

Filer: [REDACTED] Attention: [REDACTED]
Broker Box: [REDACTED]

Port of Entry: [REDACTED]
Carrier: [REDACTED]
Date Received: [REDACTED]
Arrival Date: [REDACTED]
Importer of Record: [REDACTED]
Consignee: [REDACTED]

HOLD DESIGNATED
Summary of Current Status of Individual Lines

Line	ACSI/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	POWDER FREE NITRILE EXAM GLOVES	3000000 PCT	Refuse 08-05-2021

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCG conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

REJECTION OF PRIVATE LABORATORY RESULTS
The laboratory results received by this office are rejected and no further laboratory submissions will be accepted.

Line	ACSI/ACE/FDA	Product Description	Respond By
11/1		POWDER FREE NITRILE EXAM	August 5, 2021

FDA NOTICE OF ACTION

- You have the right to provide oral or written testimony to the FDA, regarding the admissibility of the article or the manner in which the article can be brought into compliance.
- Request extension from the FDA NOW!

FDA Discusses TOP Reasons for Detention of Goods

At today's Import Operations Training, sponsored by the U.S. Food and Drug Administration (FDA) and the Florida Customs Brokers and Forwarders Association (FCBF), top officials from FDA traveled to Miami to educate importers and brokers. Topics ranged from a general overview of FDA compliance, TOP rationales for FDA detentions, Food Safety and Modernization Act (FSMA) updates, an overview of the newly re-organized (now DIO) Division of Import Operations (formerly DIOP – policy has now been removed), an overview of CBP & FDA's Joint Team 488 – which handles liquidated damages claims for underlying FDA violations and much more. Highlights of the TOP rationale for detentions follows, as I feel this is of most value to you to know and is arranged by commodity.

Medical Devices Top Rationales for Detention

- The manufacturers is not registered with the FDA
- The initial importer is not registered with the FDA
- The device is not listed with the FDA
- The product does not contain a 510k or PMA
- Product labeling is not compliant (FDA does not pre-approve medical device labeling, it is up to importers to assure it is compliant before importing)
- Common labeling violations include:
 - 1.Label is not in English
 - 2.Label is false or misleading

[FDA Discusses TOP Reasons for Detention of Goods - Customs & International Trade Law Firm \(diaztradelaw.com\)](http://diaztradelaw.com)

CBP Conditional Release

- A CBP release of any food, drug, device, or cosmetic product is conditional.
- The conditional release period terminates upon the earliest occurring of the following events:
 - (i) The date that FDA issues a notice of refusal of admission;
 - (ii) The date that FDA issues a notice that the merchandise may proceed; or
 - (iii) Upon the end of the 30-day period following the date of release.

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection

CUSTOMS BOND
19 CFR Part 113

BOND NUMBER (Assigned by CBP)
[REDACTED]

CBP USE ONLY

Do not file this bond confirmation CBP Surety Reference Number: [REDACTED]

In order to secure payment of any duty, tax or charge and compliance with law or regulation as a result of activity covered by any condition referenced below, we, the below name principal(s) and surety(ies), bind ourselves to the United States in the amount or amounts, as set forth below.

SECTION I – Select Single Transaction OR Continuous Bond (not both) and fill in the applicable blank spaces.

<input type="checkbox"/> SINGLE TRANSACTION BOND	Identification of transaction secured by this bond (e.g., entry number, seizure number, etc.)	Transaction Date	Port Code
<input checked="" type="checkbox"/> CONTINUOUS BOND	Effective Date 12/31/2020	This bond remains in force for one year beginning with the effective date and for each succeeding annual period, or until terminated. This bond constitutes a separate bond for each period in the amounts listed below for liabilities that accrue in each period. The interest to terminate this bond must be conveyed within the period and manner prescribed in the CBP Regulations.	

SECTION II – This bond includes the following agreements. Check one box only. (Except 3a may be checked independently or with 3.)

Activity Code	Activity Name and CBP Regulations in which conditions codified	Limit of Liability	Activity Code	Activity Name and CBP Regulations in which conditions codified	Limit of Liability
<input checked="" type="checkbox"/> 1	Importer or broker	\$113.62	<input type="checkbox"/> 8	Detention of Commercial Materials	\$113.20

NOTICE OF REFUSAL /NOTICE TO REDELIVER

United States Food and Drug Administration
Division of West Coast Imports
Notice of FDA Action

Entry Number: [REDACTED] Notice Number: 6
August 5, 2021

Importer:
[REDACTED]

> <

Port of Entry: [REDACTED]
Carrier: [REDACTED]
Date Received: February 26, 2021
Arrival Date: March 2, 2021
Filer of Record: [REDACTED]
Consignee: [REDACTED]

HOLD DESIGNATED

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	POWDER FREE NITRILE EXAM GLOVES	3000000 PCS	Refuse 08-05-2021

“You are ordered to redeliver this merchandise to CBP’s custody. This can be accomplished by exporting or destroying under CBP supervision. Forward the original copy of the signed CBPF7512 or CBPF3499 to the CBP/FDA Joint Team 488 with a copy of this notice. Failure to comply with this notice will result in the assessment of liquidated damages.”

REFUSAL INSTRUCTIONS

- 90 Days to export/destroy product!
- Guidelines to follow
- Seizure/liquidated damages



U.S. Food and Drug Administration
Office of Enforcement and Import Operations
Division of Southeast Imports
15100 NW 67th Ave., Suite 400
Miami Lakes, FL 33014
www.fda.gov

PROCEDURES FOR EXPORTATION OR DESTRUCTION

The merchandise subject to this refusal must be exported or destroyed under Customs and Border Protection (CBP) / Food and Drug Administration (FDA) supervision within (90) days of the date on the Notice of FDA Action to avoid unnecessary liquidated damages. Please comply with the following instructions:

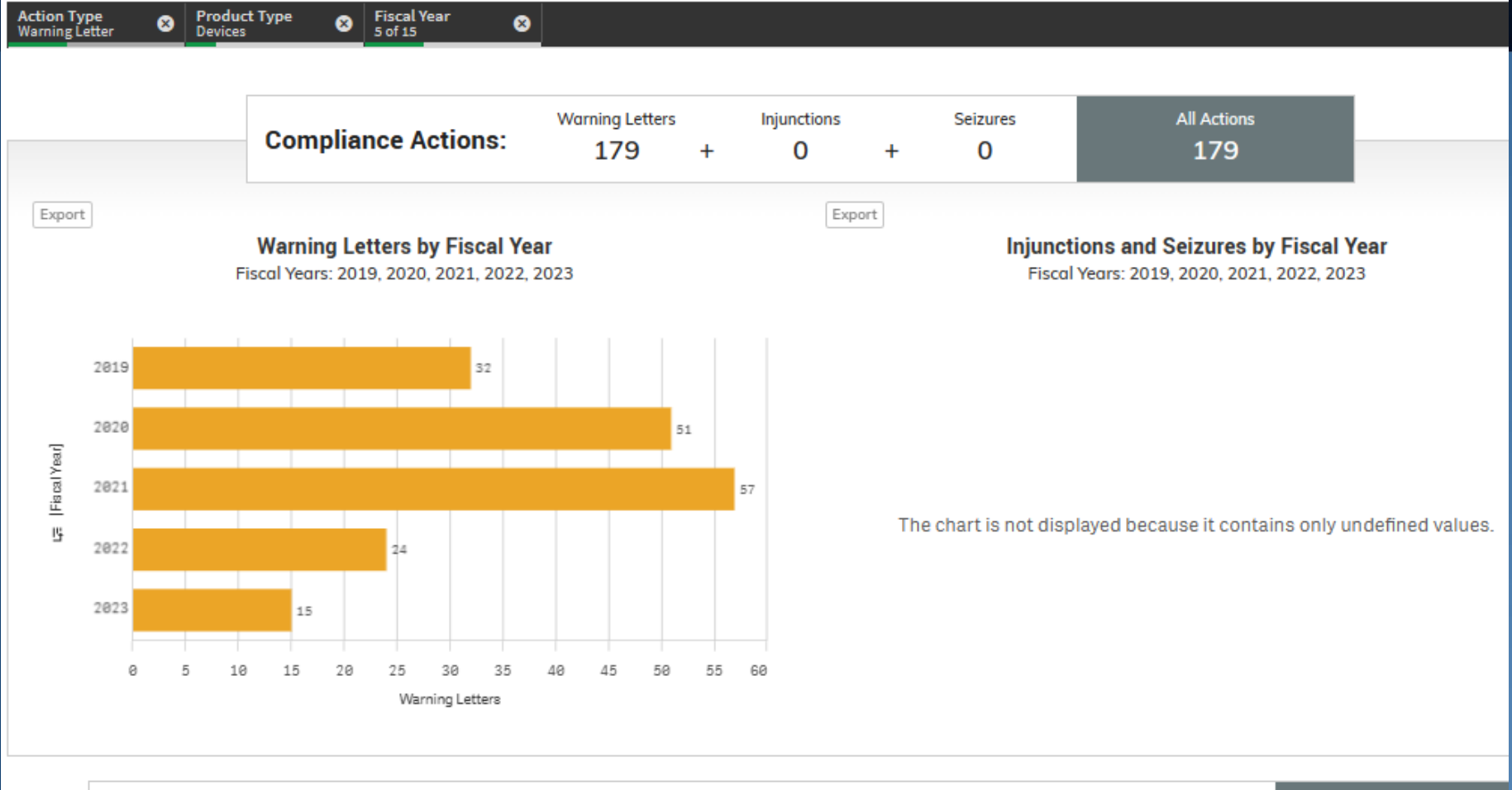
- **PORTS: 5201; 5203; 5204; 5206; MIAMI / PORT EVERGLADES** - If you intend to **DESTROY** this merchandise imported by Air or by Sea contact FDA at (305) 816-1416 Ext. 0 to schedule a destruction. Provide documents supporting the destruction (i.e., signed CBP Form 3499) to the following email: miamiimportsdestruct@fda.hhs.gov
- If you intend to **EXPORT** this merchandise by Air, contact CBP Carrier Audit Team (CAT) at MIA (305)869-2740 / 2750 to schedule a CBP Officer to supervise the lading of this merchandise at the export carrier's location.
- If you intend to **EXPORT** this merchandise thru Miami Seaport, contact CBP Miami Seaport Office at (305)869-2653 Ext. 321 or Ext. 345.
- If you intend to **EXPORT** this merchandise thru Port Everglades, contact CBP at (954)356-7361.
- If you intend to **EXPORT** this merchandise thru West Palm Beach, contact CBP Selectivity Team at (561)-844-4393 Ext. 226 or 227.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by CBP to: Joint Team 488, 6601 NW 25 St, Room 261, Miami, FL 33122 or by email at cbpfdteam488@cbp.dhs.gov.

- **PORT 1811 Tampa** - If you intend to **DESTROY** this merchandise imported by Air or by Sea contact FDA at (813) 915-7955 to arrange date and time of destruction.
- **PORT 1808 Orlando** - If you intend to **DESTROY** this merchandise imported by Air or by Sea contact FDA at (407)475-4778 to arrange date and time of destruction.
- **PORT 1803 Jacksonville** - If you intend to **DESTROY** this merchandise imported by Air or by Sea contact FDA at (904)281-1196 Ext. 117 to arrange date and time of destruction.
- **Tampa/Orlando/Jacksonville** - If you intend to **EXPORT** this merchandise contact CBP at (813) 712-6016, (813) 344-0392 or (904) 714-3100.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by CBP to: US Customs and Border Protection, ATTN: FDA Coordinator, 164 East 7th Avenue, Suite 101, Tampa, FL 33605.

WARNING LETTERS



TOP TIPS WHEN RESPONDING TO A WARNING LETTER

1. Respond On Time - 15 days! Be timely.
2. Assign A Response Team
 - Immediately secure executive leadership support & the right expertise
 - Set the emotional tone: calm and supportive.
 - Hold a regular team meeting - typically weekly to provide status updates on how observation responses are coming together from each group working on a response
 - Engage a range of internal and external stakeholders to thoroughly review the response.
3. Focus On The Importance Of The Warning
 - Write a thorough, proactive response.
4. Consult With Legal Counsel If Necessary
5. Respond In Descending Order of Importance
6. Take Responsibility
7. Address Each Item Individually
8. Identify Correct Causes Of Findings
9. Develop Corrective Action Plans
10. Set Obtainable Goals

POLL TIME!

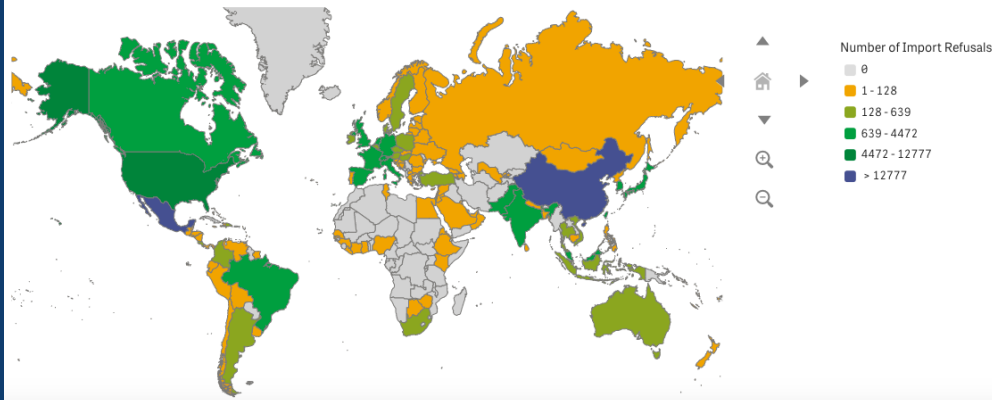
You have the right to provide **oral or written testimony** to the FDA, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance

- True or False?



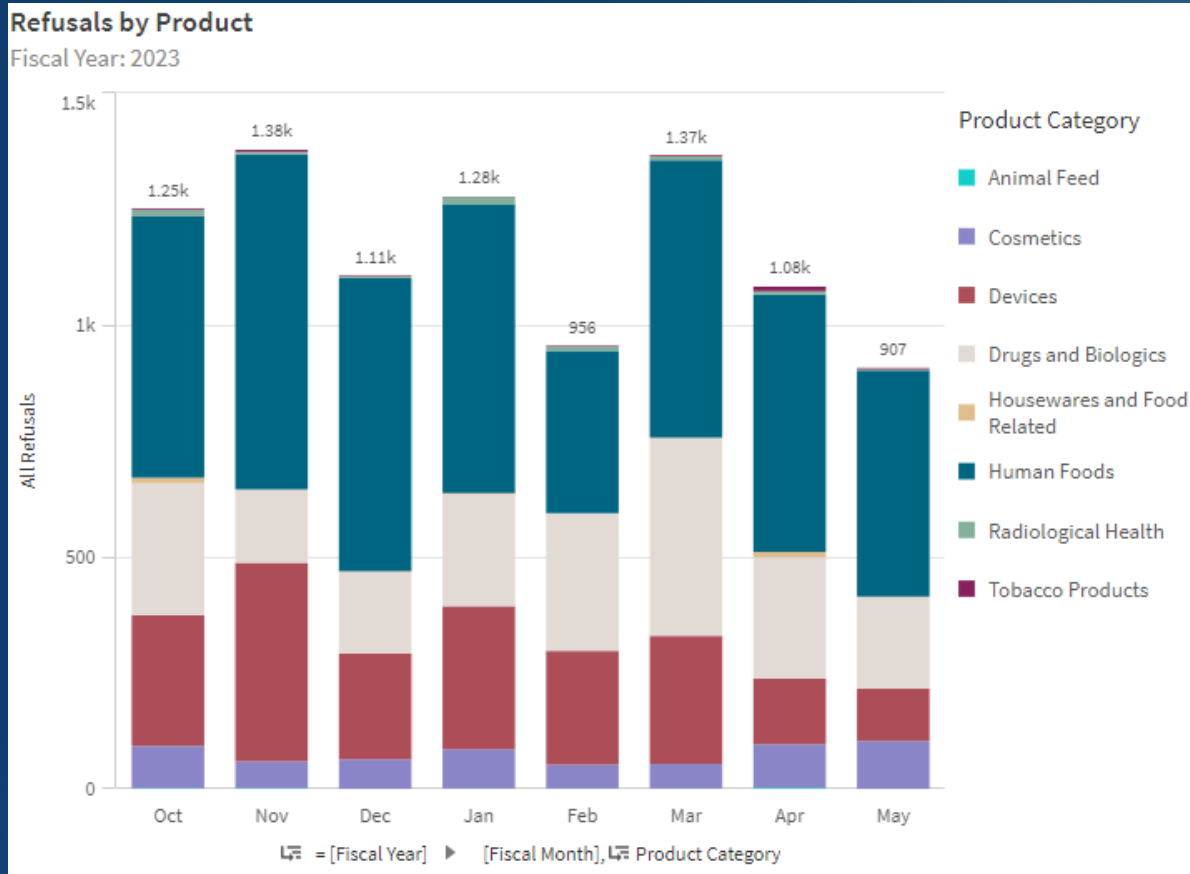
ALL MEDICAL DEVICE REFUSALS - 127,771

Unique Shipment Lines Refused by Country
Total: 127,771



Grand Total	% of total	Charge Description
118	56%	It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).
341	4%	It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(5).
118,3280	4%	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded as defined in section 502(o) of the FD&CA. It appears that it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act.
508	6%	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a post 1976 device for which a Section 510(k) application has not been determined substantially equivalent or a 510(k) has not been filed.

REFUSALS FY23



Y23 = 9,325 Refusals

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POLL TIME

Within how many days of a notice of refusal must the refused merchandise be exported or destroyed?

- A. 30
- B. 60
- C. 90
- D. immediately



LIQUIDATED DAMAGES

<p>DEPARTMENT OF HOMELAND SECURITY U.S. CUSTOMS AND BORDER PROTECTION</p> <p>NOTICE OF PENALTY OR LIQUIDATED DAMAGES INCURRED AND DEMAND FOR PAYMENT</p> <p>19 USC 1618, 19 USC 1623</p>	<p>CASE NUMBER F01</p> <hr/> <p>PORT CODE AND NAME</p> <hr/> <p>INVESTIGATION FILE NO. ID:</p> <hr/>
	<p>TEAM NUMBER:</p>
<p>DEMAND IS HEREBY MADE FOR PAYMENT OF \$50,000.00, REPRESENTING LIQUIDATED DAMAGES ASSESSED AGAINST YOU FOR VIOLATION OF LAW OR REGULATION, OR BREACH OF BOND, AS SET FORTH BELOW:</p> <p>REDELIVERY NOTICE(CF4647) ISSUED: REDELIVERY REQUIRED:</p> <p>ENTRY # MDSE REFUSED DATE</p> <p>FDA REFUSAL DATE: DESCRIBED MERCHANDISE NOT REDELIVERED INTO CUSTOMS CUSTODY AFTER REFUSED ADMISSION BY THE FOOD AND DRUG ADMINISTRATION.</p>	

FP&F PETITION PROCESS

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



POLL TIME!

- Which of the following is incorrect?
 - A. A previous record of compliance is an example of a mitigating factor
 - B. Goods must be exported or destroyed within 90 days of refusal by FDA
 - C. If goods are exported after refusal, the exportation must be done under CBP supervision
 - D. You should not bother to respond to CBP with a Petition after receiving a Liquidated Damages claim





MEC:

This is in response to your supplemental petition dated _____, filed on behalf of _____ for the above referenced claim for liquidated damages under the provisions of Title 21, United States Code, section 381 and Title 19, Code of Federal Regulations, section 141.111, in the amount of \$50,000.00.

Should you require additional information regarding this matter, please contact

Security

POLL TIME!

- Customs typically follows FDA's recommendation as to the amount acceptable to cancel the claim for liquidated damages.
- True or False?



IMPORT ALERTS

Import Alert for Industry General Hospital/Personal Use

[f SHARE](#) [TWEET](#) [in LINKEDIN](#) [PIN IT](#) [EMAIL](#) [PRINT](#)

General Hospital/Personal Use

DWPE = Detain without physical examination

Import Alert Number	Import Alert Type	Publish Date	Import Alert Name
55-03	DWPE	04/26/2023	DETENTION WITHOUT PHYSICAL EXAMINATION OF DIFFERENT FORMS OF HEPARIN AND HEPARIN-RELATED PRODUCTS
66-40	DWPE	05/08/2023	"Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs"
66-41	DWPE	05/19/2023	Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.
66-78	DWPE	05/09/2023	"Detention Without Physical Examination of Drugs, Based Upon Analytic Test Results"
66-79	DWPE	05/22/2023	"Detention Without Physical Examination of Drugs From Foreign Establishments Refusing FDA Inspection"
68-19	DWPE	08/31/2022	"DETENTION WITHOUT PHYSICAL EXAMINATION OF UNAPPROVED FINISHED NEW ANIMAL DRUGS"
76-01	DWPE	05/19/2023	Detention Without Physical Examination Of Medical Instruments from Pakistan
79-01	DWPE with Surveillance	04/02/2021	"Detention Without Physical Examination Plastic Bandages And Cotton Pads Due To Microbiological Contamination"
80-04	DWPE with Surveillance	05/08/2023	"Surveillance and Detention Without Physical Examination of Surgeon's and Patient Examination Gloves"
80-06	DWPE	12/28/2021	"Detention Without Physical Examination of Medical Devices with False or Misleading Labeling"
89-01	DWPE	02/24/2022	"Detention Without Physical Examination of Misbranded and/or Adulterated Powered Muscle Stimulators and Iontophoresis Devices"
89-04	DWPE	02/16/2023	"Detention Without Physical Examination of Devices from Firms that Have not met Device Quality System Requirements"
89-08	DWPE	05/11/2023	"Detention Without Physical Examination of Devices without Approved PMA's or IDE's and Other Devices Not Substantially Equivalent or Without a 510(k)"
89-16	DWPE	10/27/2021	Detention Without Physical Examination of Products from Medical Device Firms Refusing FDA Foreign Establishment Inspection
89-17	DWPE	05/08/2023	"Detention Without Physical Examination of Medical Devices That Appear To Be Adulterated Because Their Quality Falls Below That Which They Purport Or Are Represented to Possess"
89-18	DWPE	12/20/2022	Detention Without Physical Examination of Filtering Facepiece Respirators (FFR)

- Import Alerts are listed by Country and Industry

IMPORT ALERT

- Import Alerts are listed by Country and Industry
 - Import Alert # 76-01
 - Type: DWPE (Detention Without Physical Examination)

Import Alert 76-01

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(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(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 # 76-01

Published Date: 05/19/2023

Type: DWPE

Import Alert Name:

Detention Without Physical Examination Of Medical Instruments from Pakistan

Reason for Alert:

NOTE: The revision of this Import Alert dated 04/5/2023 updates the Guidance section, product description, and countries section. Changes are noted and bracketed with three asterisks (***)

CDRH has determined that many steel medical instruments manufactured in Pakistan appear to be violative under section 501(c) of the Act, as the quality of the instruments appear to fall below that which they were represented to possess. Documented analysis revealed great variability in chromium content, causing concern that medical instruments manufactured in Pakistan are not compliant with the quality system regulations.

REMOVAL FROM IMPORT ALERT LIST

- FDA's Regulatory Procedures Manual
 - Ch. 9 - Import Operations And Actions
- **9-6 - Detention without Physical Examination (DWPE)**
 - <https://www.fda.gov/media/71776/download>



Jennifer Diaz, Esq.
Diaz Trade Law, P.A.
12700 Biscayne Boulevard, Suite 301
North Miami, FL 33181

Email: jen@diaztradelaw.com

CASE [REDACTED]

Dear Ms. Diaz:

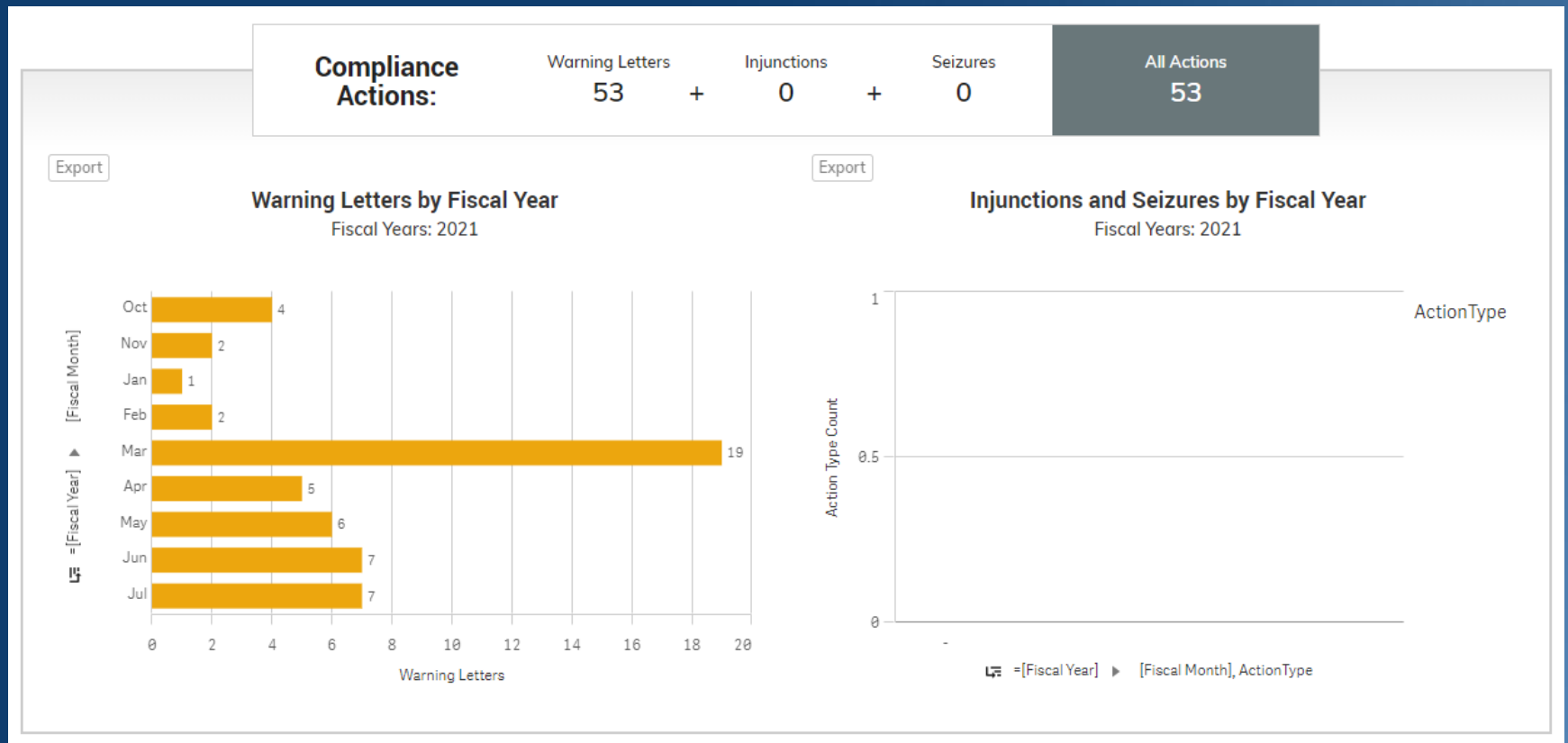
This letter is in response to your March, 2019 request to remove [REDACTED] produced by [REDACTED] from detention without physical examination under Import Alert #45-02, "Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors."

The information you provided, as well as FDA's national entry data, were reviewed. The data indicates that [REDACTED] has met the criteria for removal from detention without physical examination.

Routine coverage of entries will resume. Should detentions occur for the same or related reasons, detention without physical examination may be reinstated.

Enclosed is a copy of the advisory to our FDA field offices.

FDA Compliance Actions: FDA Data Dashboard



TOP TIPS WHEN IMPORTING MEDICAL DEVICES TO ENSURE COMPLIANCE

Learn From Over 60 Years of our Collective Experience on How to Be Proactive and Avoid Common Mistakes When Importing!

- 1 Medical Device Importation Checklist:
 - Ensure you know what Class your medical device is: I, II, or III
 - Does the manufacturer have a valid Establishment Registration?
 - Are the goods being exported by a company other than the manufacturer? If so, have you ensured they have a valid Establishment Registration?
 - Does the initial importer have a valid Establishment Registration?
 - Use the [Search Database](#)
 - Is there a valid Device Listing in place?
 - For Class II devices, is a 510k (Pre-Market Notification) necessary?
 - For Class III devices, is a PMA (Pre-Market Approval) necessary?
 - Review and assure compliance with [Labeling Requirements](#)
 - Review and assure compliance with [Good Manufacturing Practices/Quality System Regulation](#)
- 2 Protect your own Intellectual Property Rights (IPR)
 - Register your trademark with the [U.S. Patent and Trademark Office](#)
 - Record your trademarks with [CBP](#)
 - [For \\$190 U.S. Customs Will Police Your Brand](#)
- 3 Keep records proving you used Reasonable Care – Request a binding ruling from CBP!
 - [Importing into the U.S.: A Guide for Commercial Importers](#) (Includes a [reasonable care](#) checklist).
- 4 Confirm you're using the correct [Harmonized Tariff Schedule \(HTSUS\)](#)
 - [Harmonized Tariff Schedule](#)
 - [Customs Ruling Online](#)
- 5 Confirm you're using the correct value for your product. Do you use related parties?
- 6 Confirm you're using the correct country of origin. Do you source products from many countries?
- 7 If you receive a Notice from the U.S. Food and Drug Administration (FDA) or U.S. Customs Border and Protection (CBP) - **IMMEDIATELY** consult an expert to answer thoroughly.
 - If you receive a [Notice of FDA Action](#), assure you respond in a timely basis and request extensions!
 - If you receive a [Warning Letter](#) from the FDA, assure you consult an expert and respond within 15 days.
 - If you receive a notification that you are on an [Import Alert](#) List, take action through an expert to be removed.
 - If you receive a [Notice of Detention](#) or [Seizure Notice](#) from CBP, be PROACTIVE.
 - Always petition [Penalties](#) and [Liquidated Damages](#) claims.
 - [U.S. Customs Seized My Merchandise. Now What?](#)

ADDITIONAL RESOURCES FOR IMPORTING:

- [Basic Importing and Exporting](#)
- [CBP's Rulings and Legal Decisions](#)
- [FDA - Warning Letter List](#)
- [Customs and Trade Law Blog](#)
- [FDA - Import Alert List](#)
- [FDA - Regulatory Procedures Manual](#)
- [FDA - Device Advice](#)

Info@DiazTradeLaw.com

www.DiazTradeLaw.com

(305) 456-3830

*This document is provided for informational purposes only and does not constitute legal advice nor does use of this constitute the formation of an attorney-client relationship.

TOP TIPS WHEN IMPORTING /EXPORTING DEVICES



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USEFUL LINKS

- [Registration and Listing Database](#)
- [Diaz Trade Law Blog](#)
- [Diaz Trade Law Newsletter](#)
- [U.S. Agent](#)
- [Medical Device Labeling](#)
- [UDI Labeling](#)
- [FDA Data Dashboard](#)
 - [Import Alerts](#)
 - [Recalls](#)
 - [Warning Letters](#)
- [Top Tips When Importing Medical Devices](#)
- [Top Tips When Exporting to Ensure Compliance](#)

DIAZ TRADE LAW MONTHLY NEWSLETTER – SIGN UP!



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CUSTOMS & TRADE UPDATE
VOLUME 8, ISSUE 9

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Does Your Medical Device Have a Unique Device Identification (UDI)?

Call 305-456-3830 or email info@diaztradelaw.com.

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Don't be a Target, Learn Best Practices to Mitigate FDA Enforcement

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Draft Guidance on Medical Device Transition Period

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NOW THAT WE HAVE OUR PAWS DIRTY... ANY QUESTIONS?



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Importing Medical Devices into the U.S. in Compliance with the U.S. FDA

OUR DISTINGUISHED SPEAKER



Jennifer Diaz

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