Medmarc Insurance Risk Management Webinar Series

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

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Medmarc Insurance Risk Management Webinar Series
MEDMARC

DIAZ TRADE LAW

Disclaimer

This presentation is for informational purposes only and does not purport to provide legal advice as all cases and facts are different. The information in this presentation is provided "as is" and no representations are made whatsoever.
You should not rely on the information included in this presentation as an alternative to legal advice from your attorney. For questions related to a specific matter, you should consult your attorney.

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- FDA released draft guidance on July 19, 2011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
  - repackage
  - relabel
  - import

  medical devices sold in the United States.

Distribution of Full-Time Equivalent (FTE) Employment Program Level	Total
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	---
Opiods - 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

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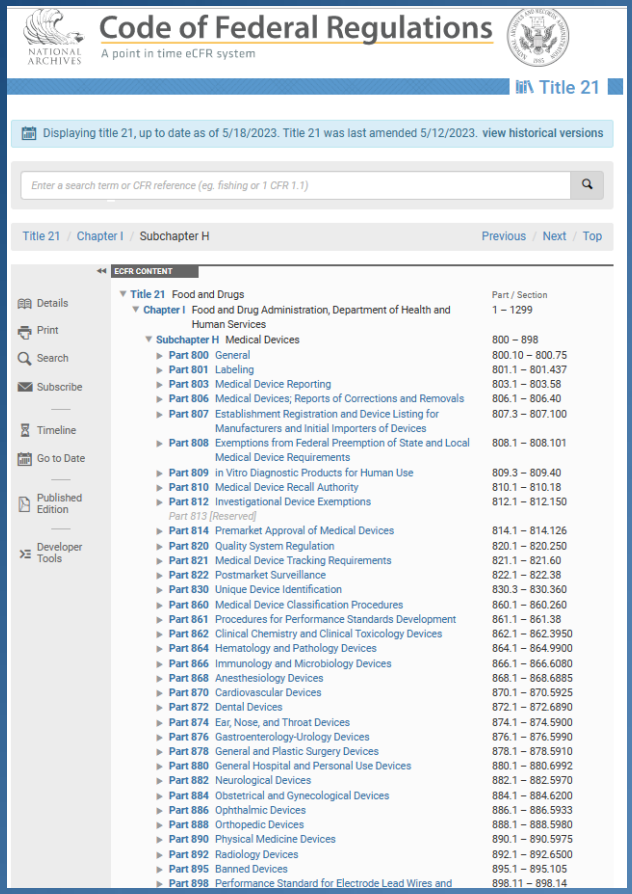
Medical Devices Classes

Class I	Class II	Class III
Low Risk	Moderate Risk	High Risk
Examples: - elastic bandages - examination gloves - hand-held surgical instruments	Examples: - powered wheelchairs - needles - surgical drapes	Examples: - 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



How to find your "product code" and "device class"

- 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

Annual Establishment Registration User Fee

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

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

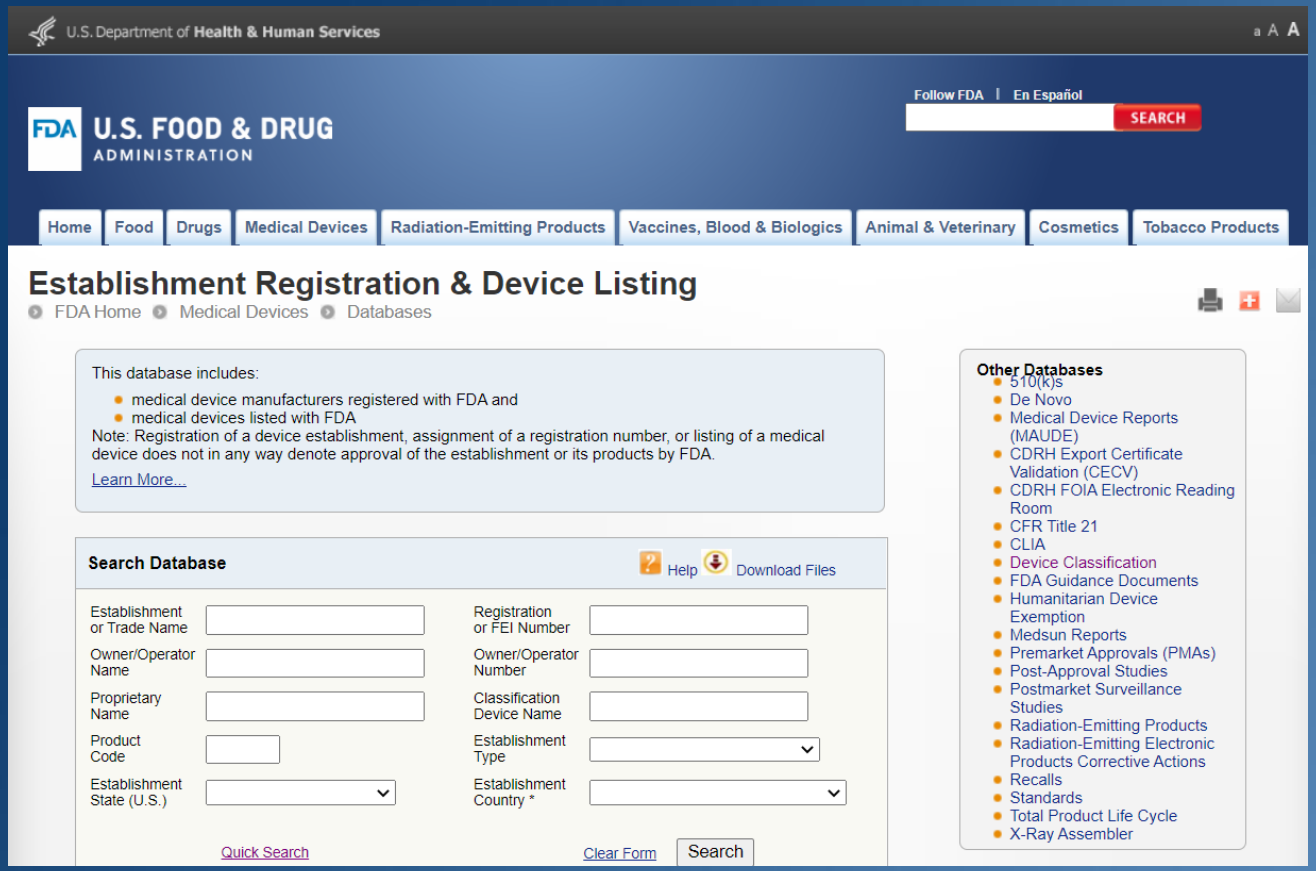
Activity	Register	List	Pay Fee
Contract Manufacturer (including contract packagers)	YES 807.40(a)	YES 807.40(a)	YES
Contract Sterilizer	YES 807.40(a)	YES 807.40(a)	YES
Custom Device Manufacturers	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Device Being Investigated under IDE	NO 812.1 (a)	NO 812.1(a), 807.40(c)	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

TRUST, BUT VERIFY

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



Poll Time!

- What Device Class is a N95 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	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).
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

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.

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

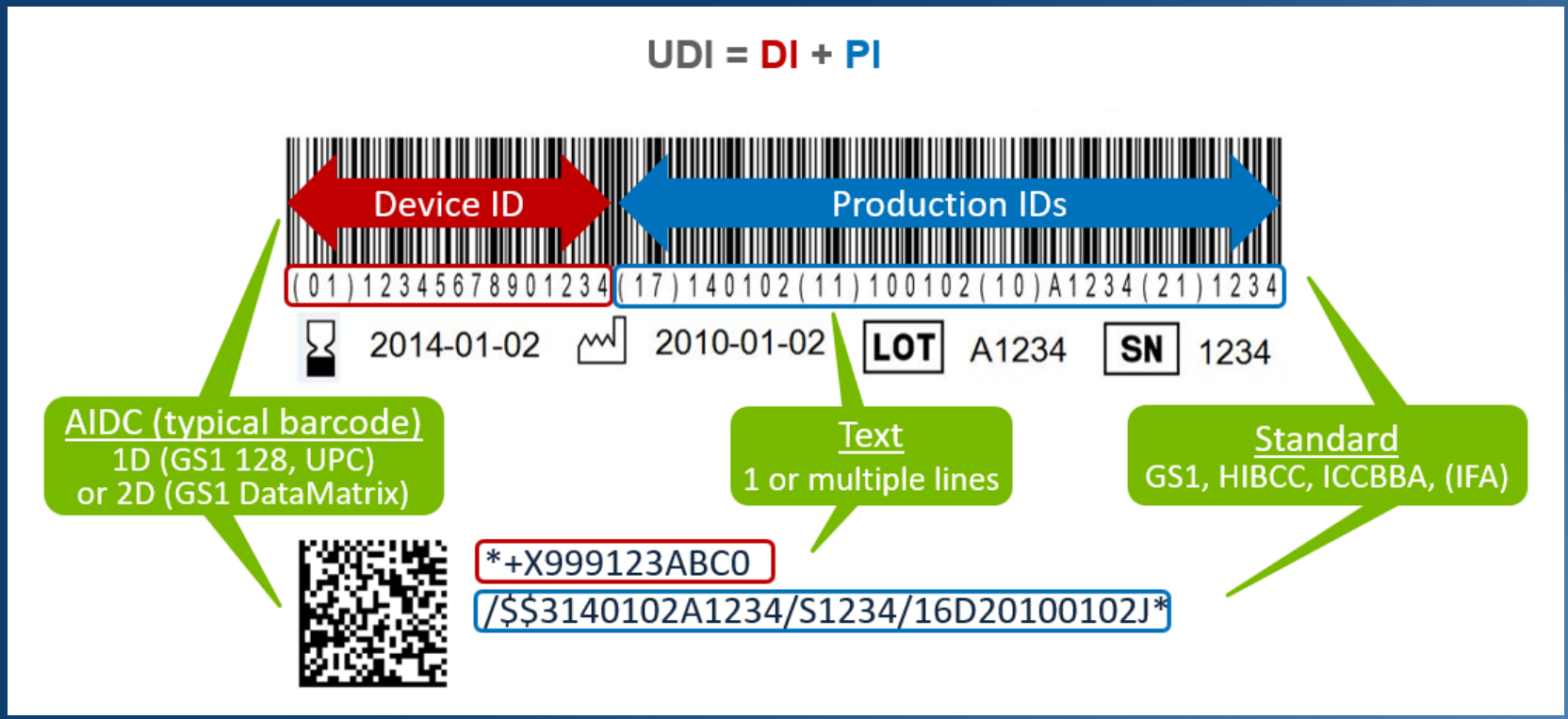
Want a Happy Broker?

- 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 - 21CFR 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

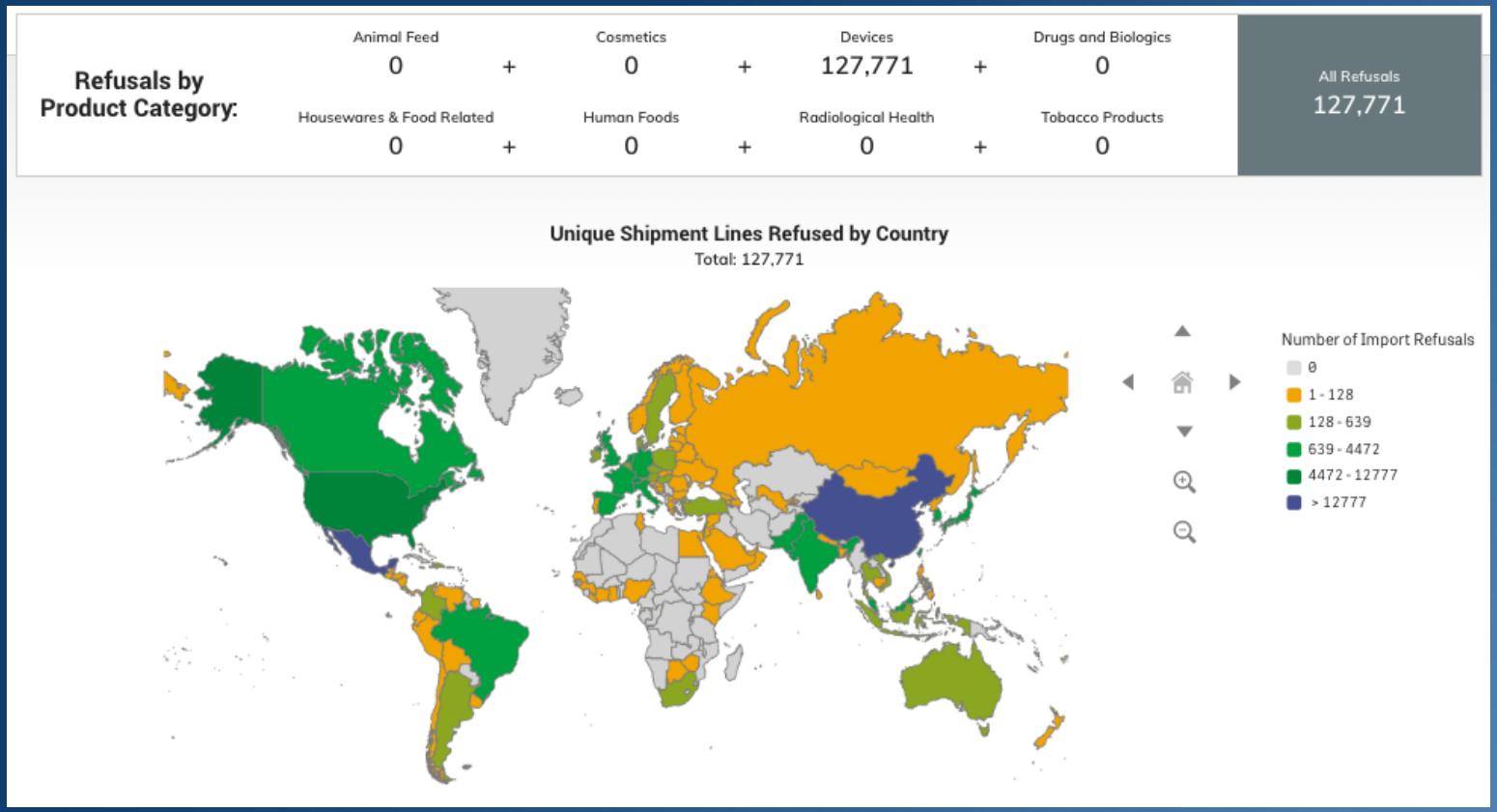
DUE DILIGENCE
COMPLIANCE HISTORY OF MANUFACTURER

- 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



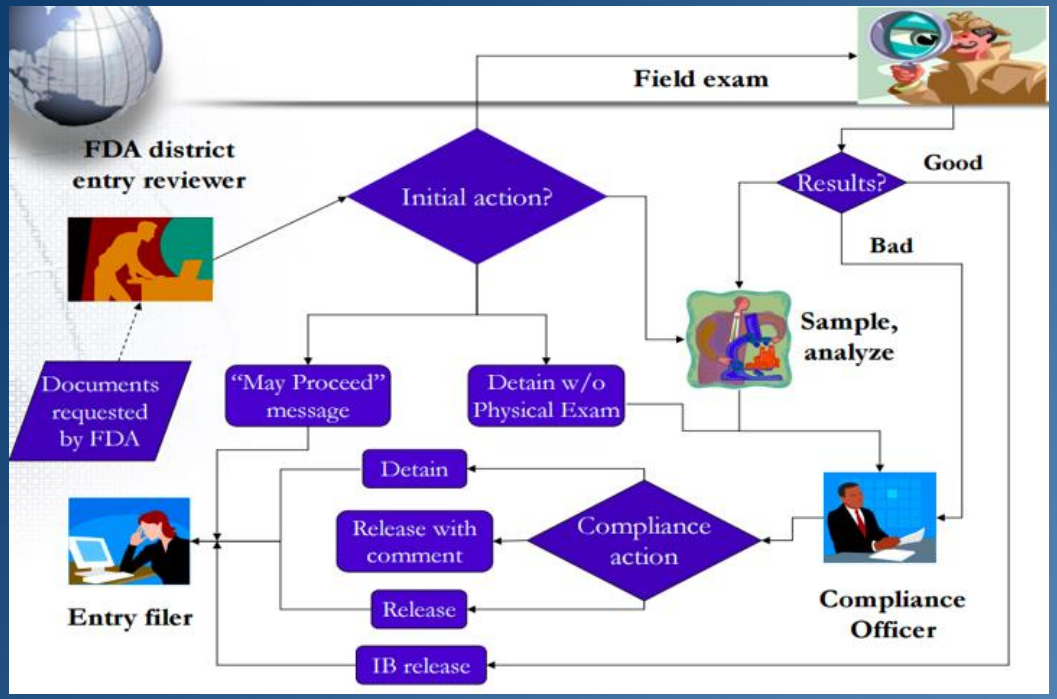
Poll Time!

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

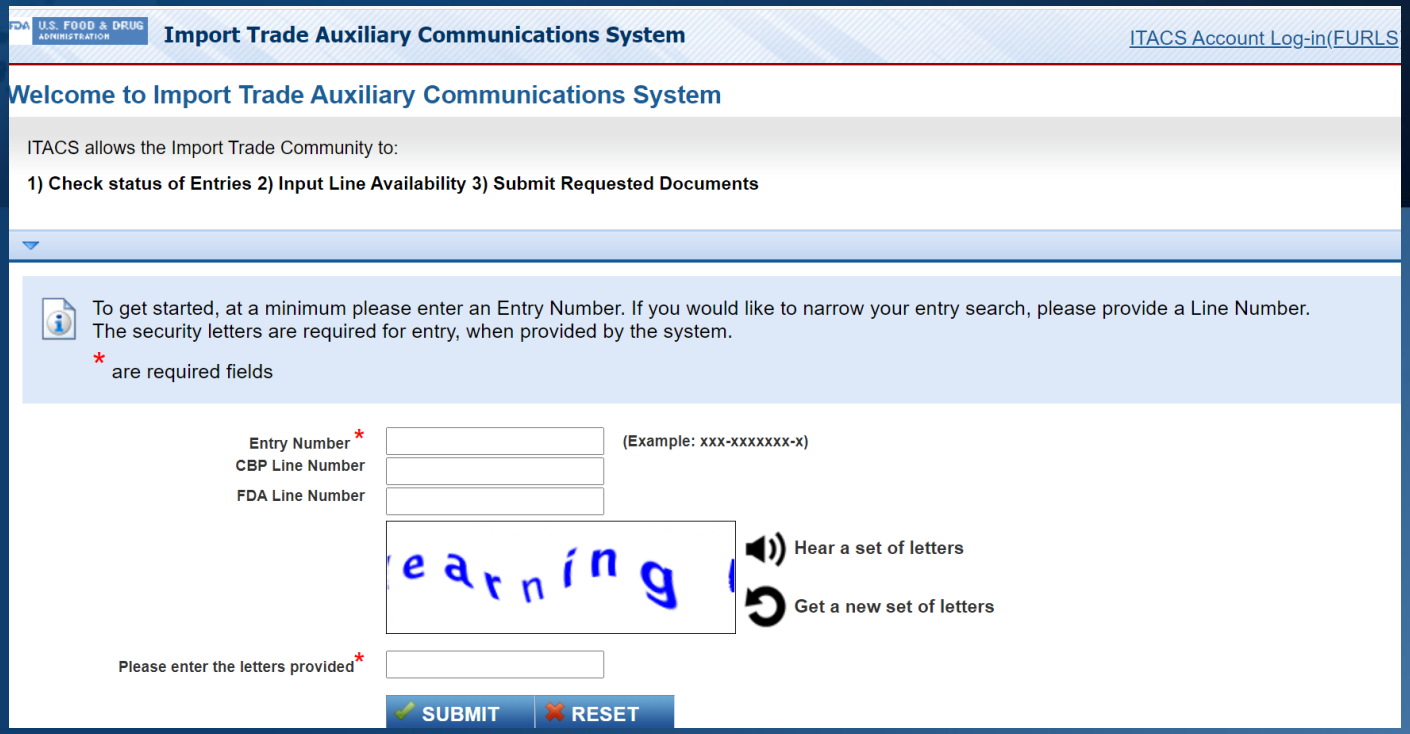
Typical FDA/CBP Enforcement Actions

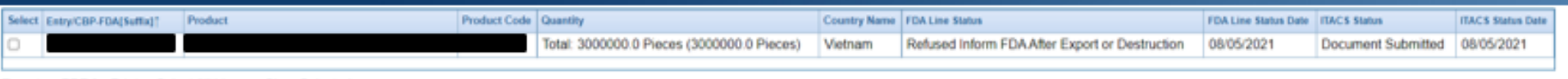
- Notice of Action
- Notice of Refusal
- CBP / Liquidated Damages
- Warning Letter
- Import Alert
- Recall



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

ITACS

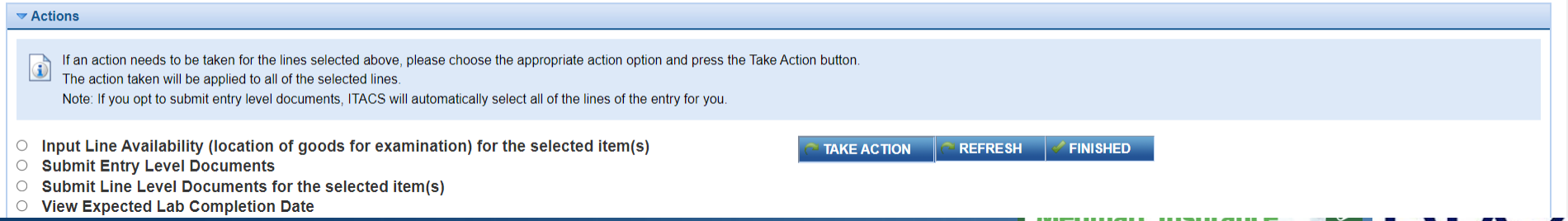




Select	Entry/CBP-FDA[Suffix]†	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date
☐	[redacted]	[redacted]		Total: 3000000.0 Pieces (3000000.0 Pieces)	Vietnam	Refused Inform FDA After Export or Destruction	08/05/2021	Document Submitted	08/05/2021

Export as PDF for Print Select All Lines Clear Selected

Export as PDF for Print Select All Lines Clear Selected



How to Create Your ITACS Account

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

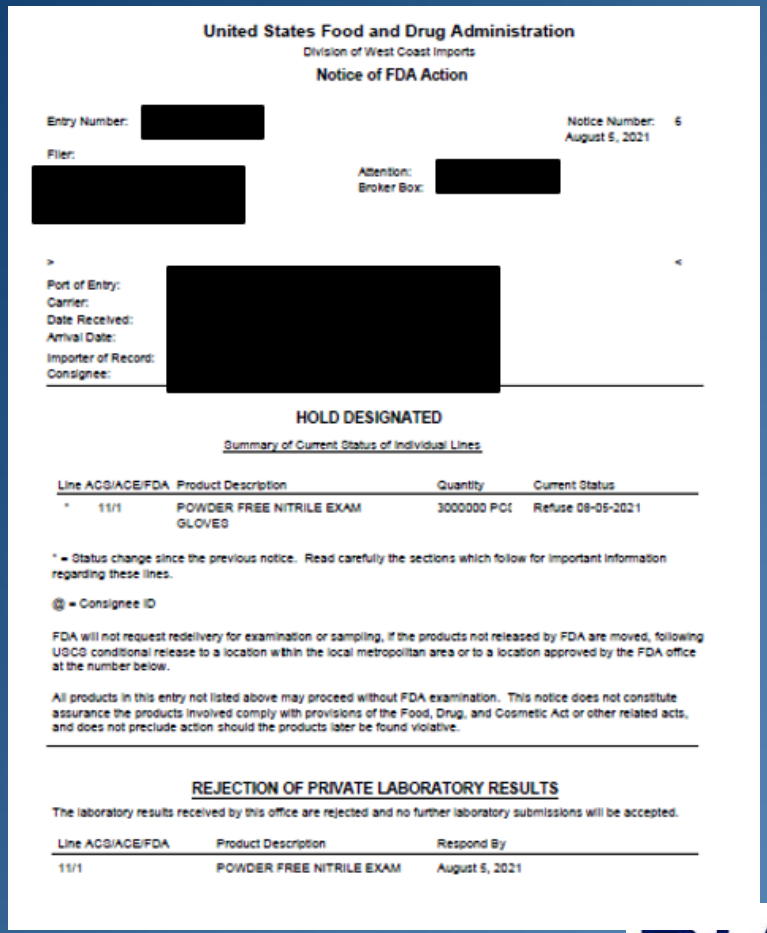
Poll Time

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:
Broker Box: [redacted]

Port of Entry:
Carrier:
Date Received:
Arrival Date:
Importer of Record:
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

* = 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 USCS 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	ACS/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:

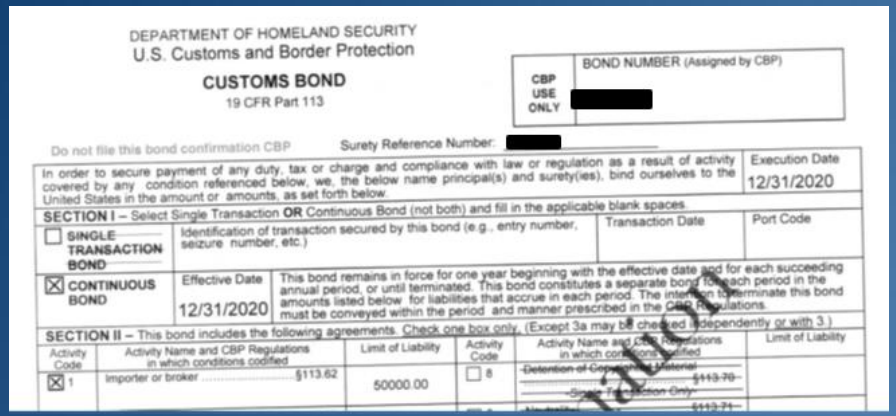
1.Label is not in English

2.Label is false or misleading

FDA Discusses TOP Reasons for Detention of Goods - Customs & International Trade Law Firm (diaztradelaw.com)

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

CBP USE ONLY — BOND NUMBER (Assigned by CBP) [redacted]

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. — Execution Date: 12/31/2020

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

☐ SINGLE TRANSACTION BOND — Identification of transaction secured by this bond (e.g., entry number, seizure number, etc.) — Transaction Date — Port Code

☒ 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 intention 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
☒ 1	Importer or broker ..... §113.62	50000.00	☐ 8	~~Detention of Commercial Merchandise ..... §113.70~~	
				~~Single Transaction Only ..... §113.71~~	

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:
Date Received: February 26, 2021
Arrival Date: March 2, 2021
Filer of Record:
Consignee: [redacted]

HOLD DESIGNATED

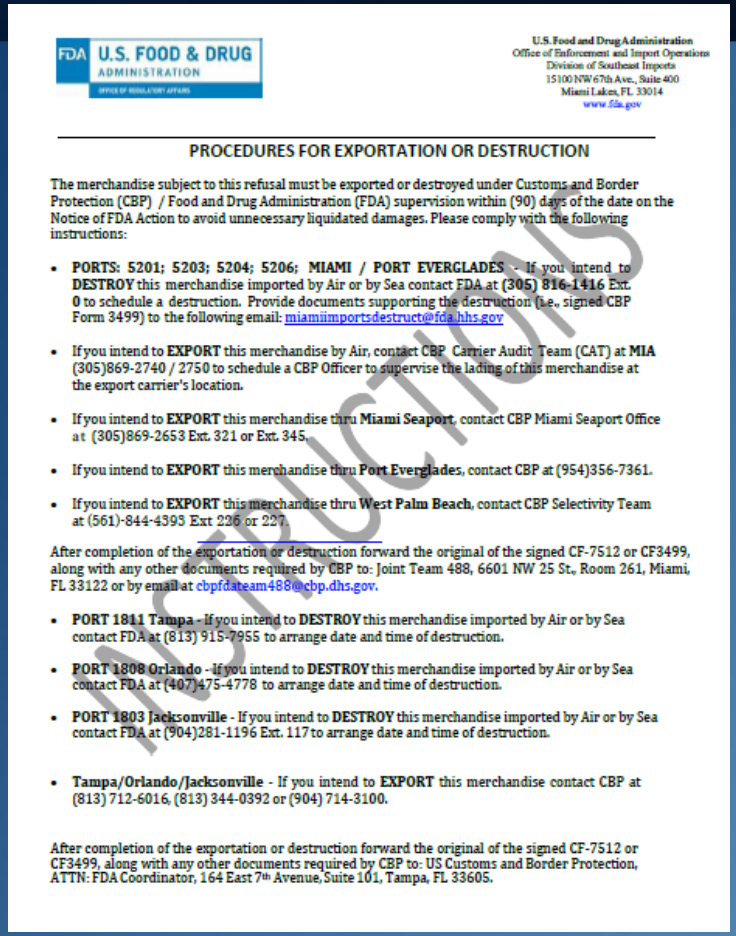
Summary of Current Status of Individual Lines

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



FDA U.S. FOOD & DRUG ADMINISTRATION

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 cbpfdateam488@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

Action Type: Warning Letter | Product Type: Devices | Fiscal Year: 5 of 15

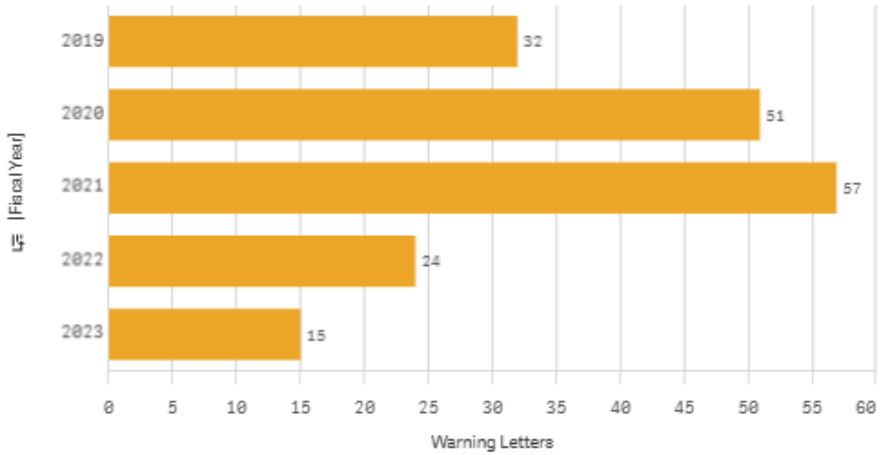
Compliance Actions:

Warning Letters		Injunctions		Seizures	All Actions
179	+	0	+	0	179

Export

Warning Letters by Fiscal Year

Fiscal Years: 2019, 2020, 2021, 2022, 2023



Export

Injunctions and Seizures by Fiscal Year

Fiscal Years: 2019, 2020, 2021, 2022, 2023

The chart is not displayed because it contains only undefined values.

Top Tips When Responding to a Warning Letter

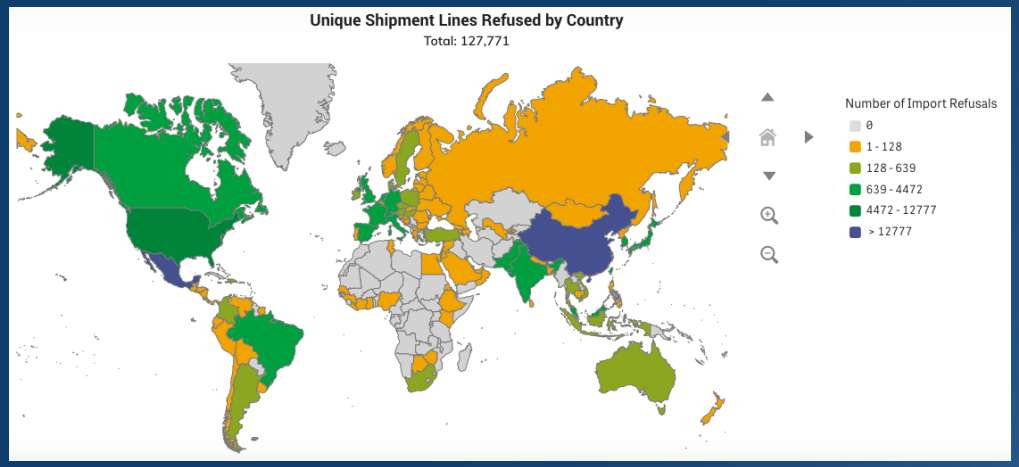
1. Respond On Time - 15 days! Be timely.
2. Assign A Response Team
   - Immediately secure executive leadership support & the right expertise
   - Set the emotional tone: calm and supportive.
   - Hold a regular team meeting - typically weekly to provide status updates on how observation responses are 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

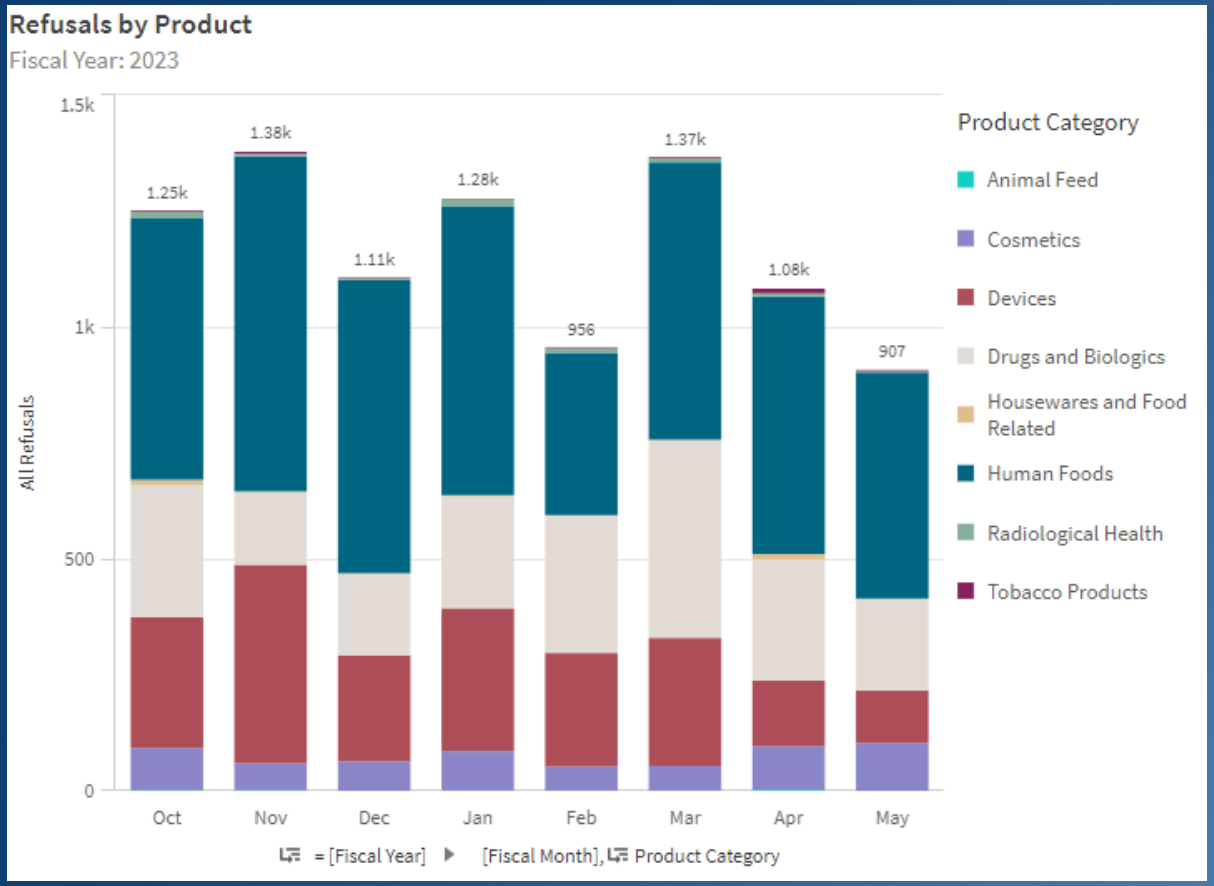
- True or False?

All Medical Device Refusals - 127,771



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

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

DEPARTMENT OF HOMELAND SECURITY
U.S. CUSTOMS AND BORDER PROTECTION

NOTICE OF PENALTY OR
LIQUIDATED DAMAGES INCURRED
AND DEMAND FOR PAYMENT

19 USC 1618, 19 USC 1623

CASE NUMBER F01

PORT CODE AND NAME

INVESTIGATION FILE NO.
ID:

TEAM NUMBER:

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:

REDELIVERY NOTICE(CF4647) ISSUED: REDELIVERY REQUIRED:

ENTRY # MDSE REFUSED DATE

FDA REFUSAL DATE:
DESCRIBED MERCHANDISE NOT REDELIVERED INTO CUSTOMS CUSTODY AFTER REFUSED ADMISSION BY THE FOOD AND DRUG ADMINISTRATION.

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

LIQUIDATED DAMAGES

[illegible]
[illegible]

U.S. Customs and Border Protection

RE:

Dear Ms. Diaz:

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 141.113*, in the amount of $50,000.00.

In accordance with regulations, your supplemental petition, along with our case file, was forwarded to our Headquarters Office for review and final determination, which we have now received (copy enclosed). Based on their findings it has been determined that cancellation is warranted. Accordingly, pursuant to *title 19, Code of Federal Regulations, section 172.11*, this claim for liquidated damages is hereby cancelled and considered closed in our records.

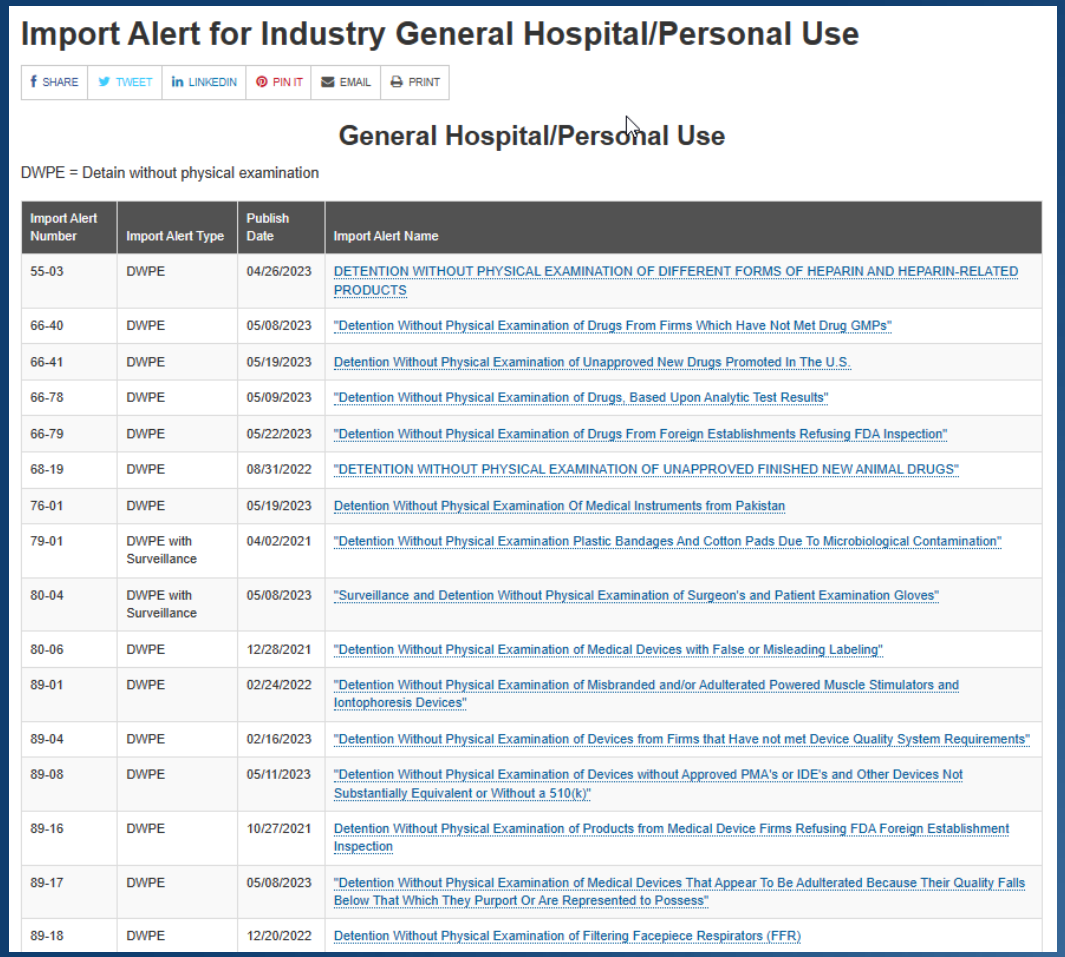
Should you require additional information regarding this matter, please contact

Sincerely,

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

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General Hospital/Personal Use

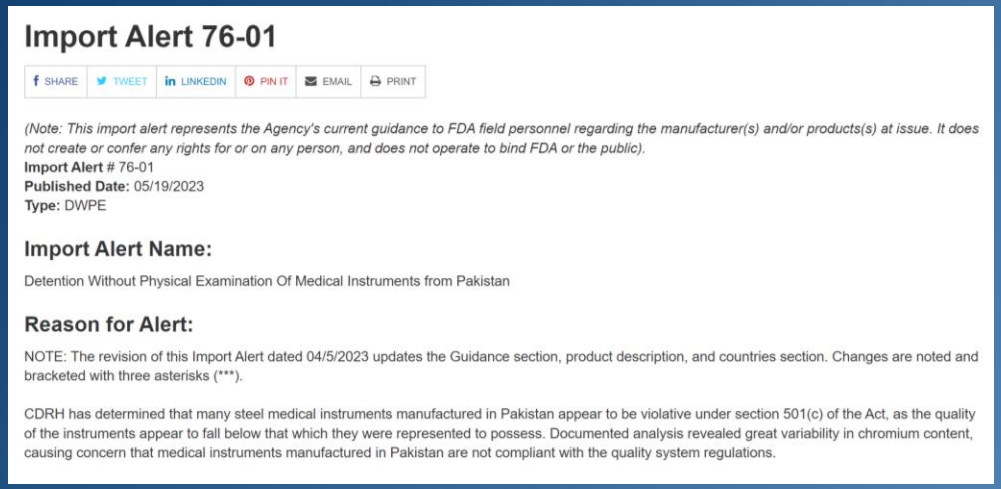
DWPE = Detain without physical examination

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

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

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:

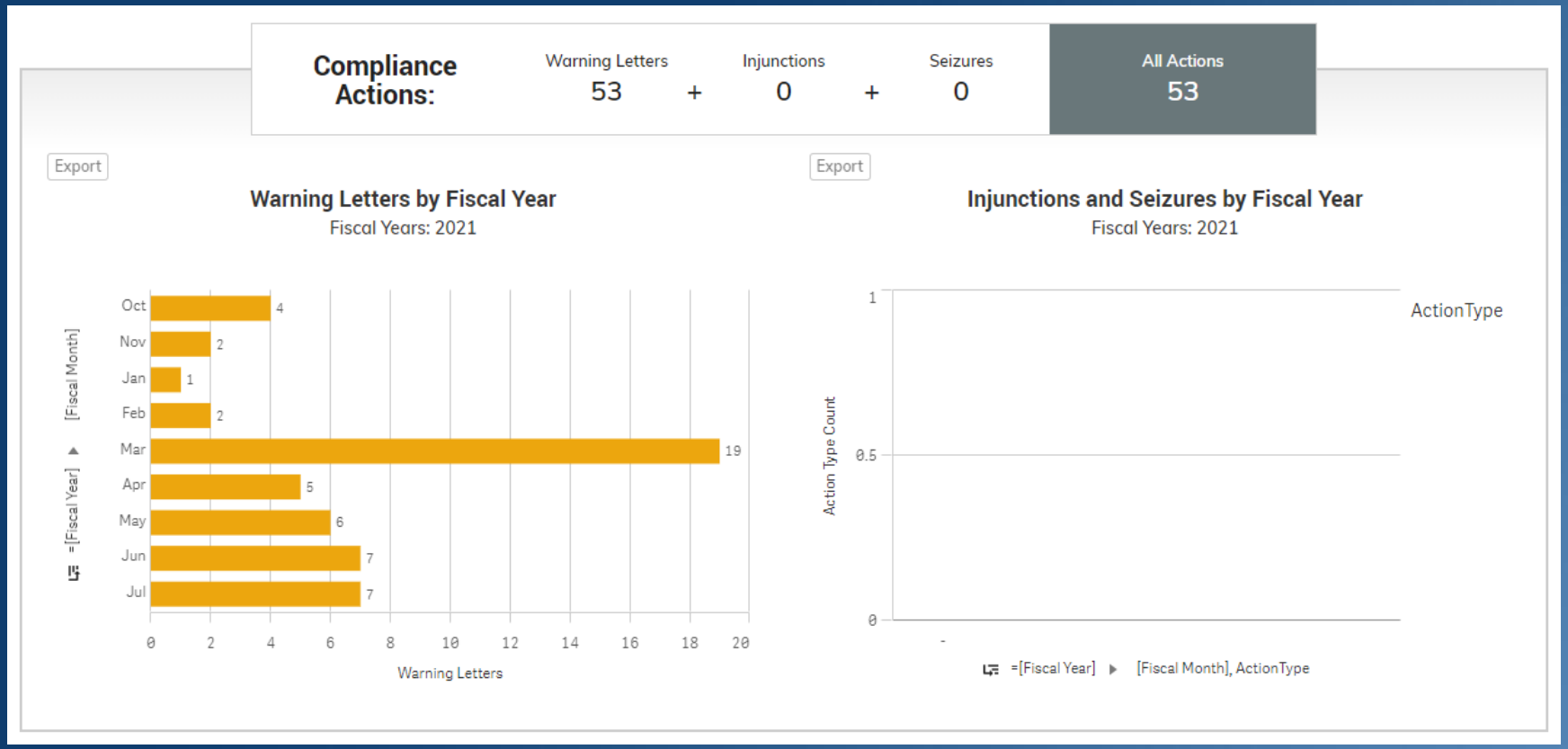
This letter is in response to your March, 2019 request to remove [redacted] produced by [redacted] from detention without physical examination under Import Alert #45-02, "Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors."

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



Medmarc Insurance Risk Management Webinar Series

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DIAZ TRADE LAW

Top Tips When Importing /Exporting Devices

DIAZ
TRADE LAW

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 – Regulatory Procedures Manual
- Customs and Trade Law Blog
- FDA - Warning Letter List
- FDA – Import Alert List
- FDA – Device Advice

Info@DiazTradeLaw.com www.DiazTradeLaw.com (305) 456-3830

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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

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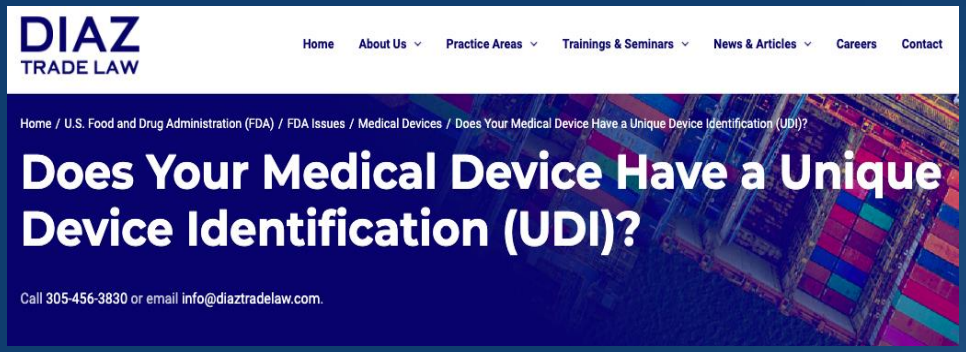

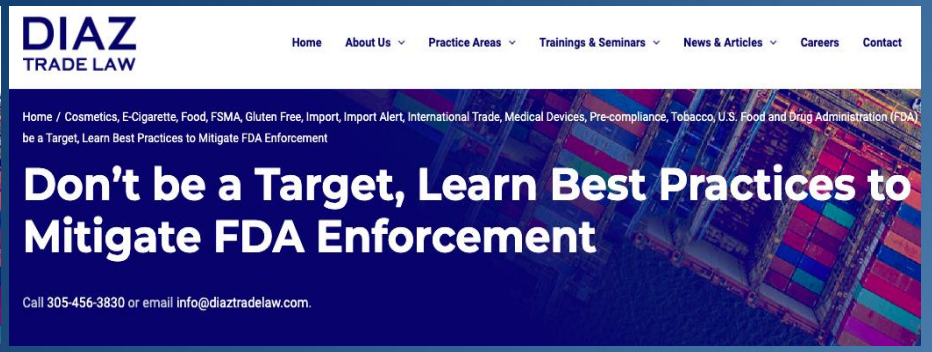

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Now That We Have Our Paws Dirty… Any Questions?

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

Email questions to
jen@diaztradelaw.com
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