Best Practice to Navigate FDA Enforcement Actions

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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.

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Agenda

- The Primary Enforcement Actions Used by the FDA.
- How to Successfully Navigate FDA Enforcement Actions.
- How to Use ITACS when Communicating with the FDA.
- Actions to Take When Your Company Receives a FDA Enforcement Action
- How to Use FDA's Databases to Perform Due Diligence

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Poll Time!

- Which best describes you?
  - Importers
  - Customs Brokers
  - Regulatory Affairs Professionals
  - In-house Legal Counsel
  - Product Development Managers
  - Consultants
  - Others Interested in FDA and Imports

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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

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Poll Time!

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

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

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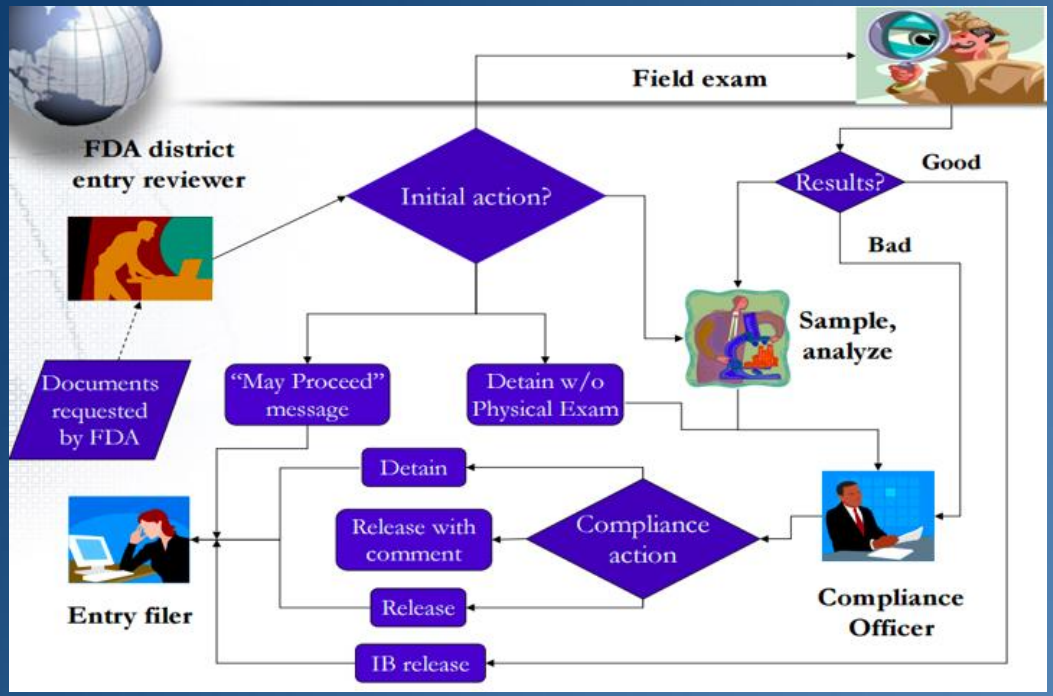
The Primary Enforcement Actions Used by the FDA

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



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

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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

Bottom line, as you can see, **it is up to you, the importer to perform pre-compliance and assure you get compliance right *before* you import**. FDA expects you to know the requirements and has little mercy if you don't. Assure you stay compliant and avoid the top rationale for FDA to detain your goods by hiring someone that is extremely knowledgeable with FDA's laws and regulations and continually stays up to date with the constant changes.

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

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Poll Time!

FDA may detain products that "appear" to be in violation with FDA regulations

- True or False?

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How to successfully navigate Notices of FDA actions

Notice of FDA Action #1

- Products that **appear** (from examination or otherwise) to be violative may be detained and ultimately refused entry into the U.S.
- The standard for detention and refusal is extremely low - detention is permissible without actual observation of a product or its labeling.
- The ability to challenge the FDA is limited almost exclusively to legal, as opposed to factual, issues.

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

Entry Number:
Importer:

Notice Number: 1
May 31, 2019

Port of Entry: 4196, UPS at Louisville, Louisville, KY
Date Received: May 30, 2019
Arrival Date: May 24, 2019
Filer of Record:
Consignee:

HOLD DESIGNATED

Notify FDA of Availability
Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	11/1	STETHOSCOPE NO DFE NOT PERSONAL	204 PCS	Detained 05-31-2019

* = 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 Customs conditional release to a location within the local metropolitan area or to a location approved by the FDA.

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.

Notify FDA upon actual availability, and include location and location identifiers, where applicable, for all designated lines.

FDA's Import Trade Auditary Communication System (ITACS) is the preferred method for submission of information related to the availability of goods for FDA examination. This submission will automatically link the information to the line designated for exam and will facilitate FDA's completion of examination. ITACS may be accessed at https://itacs.fda.gov

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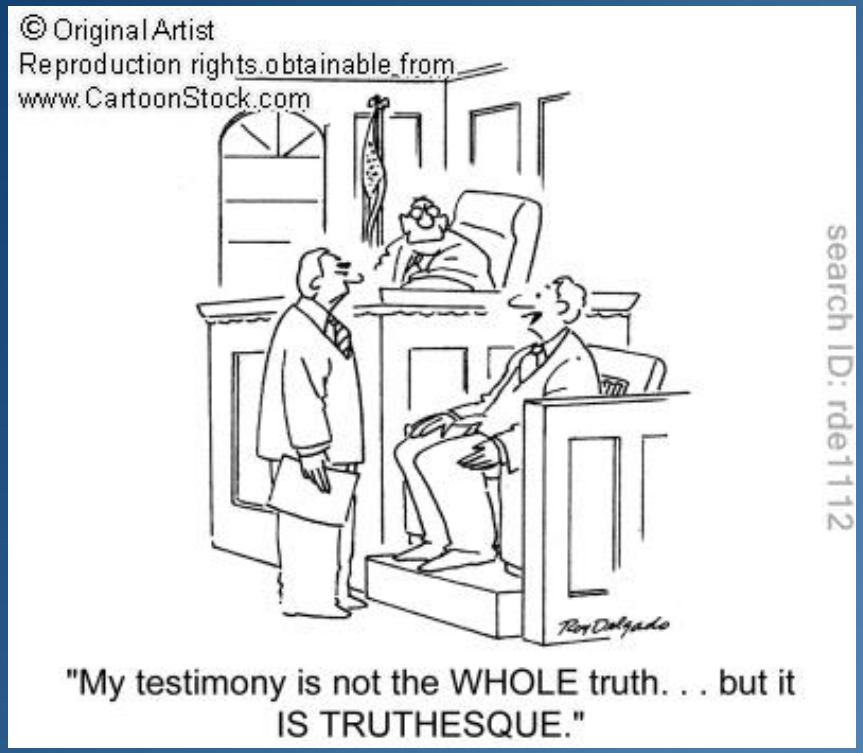
FDA Notice of Action #1

- 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!



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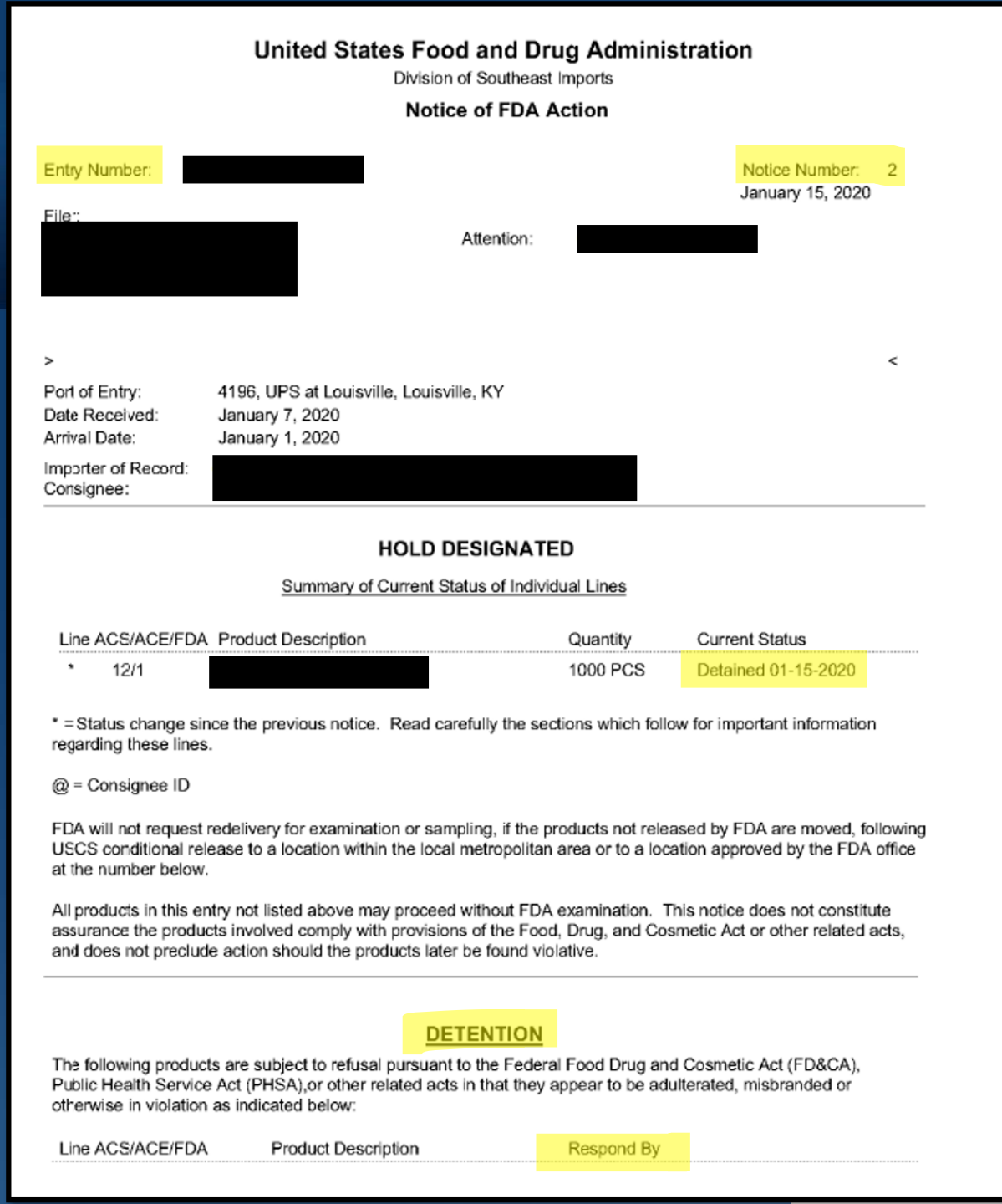
How to successfully navigate Notices of FDA actions



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

Entry Number: [redacted]

Notice Number: 2
January 15, 2020

File:: [redacted]

Attention: [redacted]

>

<

Port of Entry: 4196, UPS at Louisville, Louisville, KY
Date Received: January 7, 2020
Arrival Date: January 1, 2020
Importer of Record:
Consignee: [redacted]

HOLD DESIGNATED

Summary of Current Status of Individual Lines

Line	ACS/ACE/FDA	Product Description	Quantity	Current Status
*	12/1	[redacted]	1000 PCS	Detained 01-15-2020

* = 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.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line	ACS/ACE/FDA	Product Description	Respond By

Poll Time!

The FDA logo can be used for private sector materials.

- True or False?

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Notice of FDA Action
Entry Number [redacted]

Notice Number: 2
Page: 2

12/1 [redacted] February 5, 2020

FD&CA Section 502(a), 801(a)(3); MISBRANDING
The labeling for this article appears to be false or misleading

The FDA logo is for the official use of the U.S. Food and Drug Administration (FDA) and not for use on private sector materials. To the public, such use would send a message that FDA favors or endorses a private sector organization or the organization?s activities, products, services, and/or personnel (either overtly or tacitly), which FDA does not and cannot do. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability.

FD&CA Section 502(o), 801(a)(3); MISBRANDING
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).

No listing number found for this device.

FD&CA Section 801(a)(3); 502(o) Misbranding
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.

Please direct your response to:

Allison M. Mcgloin, Compliance Officer
U.S. Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

(513) 679-2700 ext. 2123

ALLISON.MCGLOIN@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

Notice Prepared For: The Division Director, U.S. Food and Drug Administration
Notice Prepared By: AMS

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?

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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."

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Inspections

Export

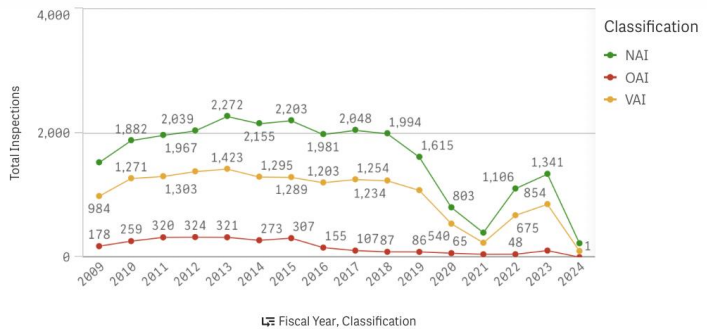
Foreign and Domestic Inspections

Fiscal Years: 2009 - 2024

Export

Inspections Classification by Fiscal Year

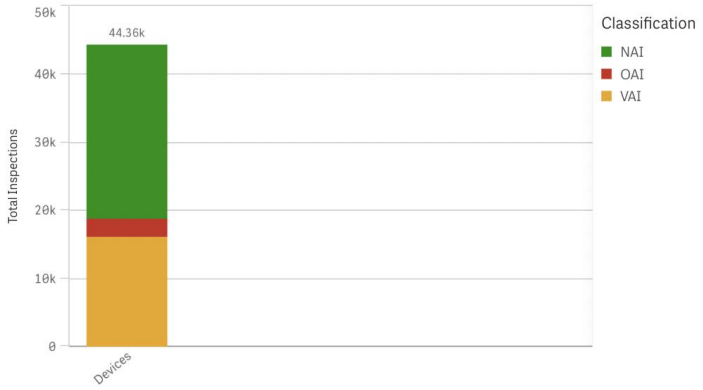
Fiscal Years: 2009 - 2024



Export

Inspections Classification by Product Type

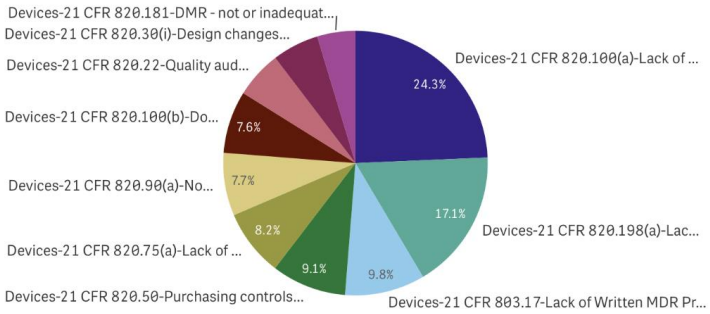
Fiscal Years: 2009 - 2024



Export

Top 10 Citations

Fiscal Years: 2009 - 2024



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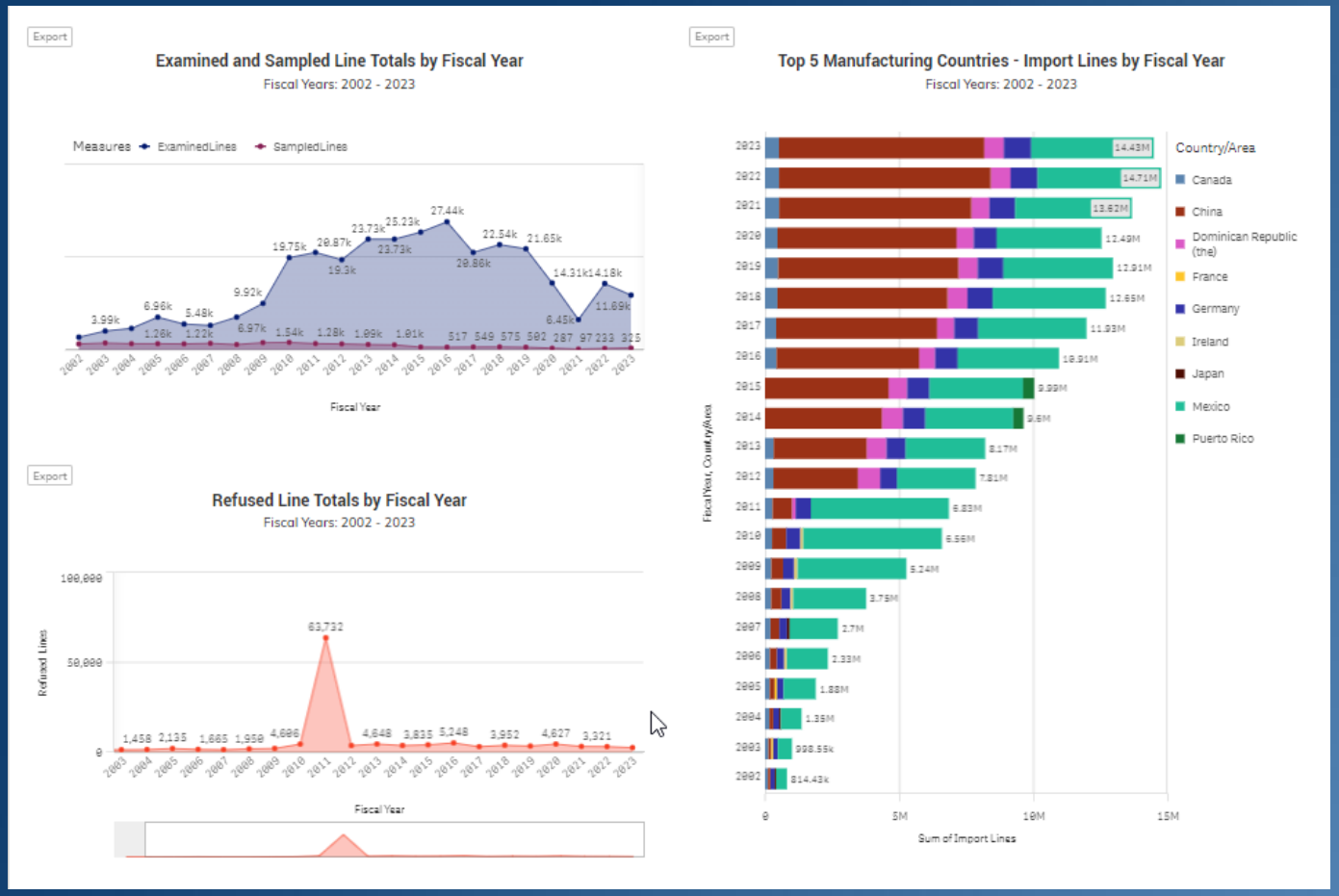
Imports Summary

All Import Lines	Refused Lines	Examined Lines	Sampled Lines
274,104,074	128,559	317,457	20,018



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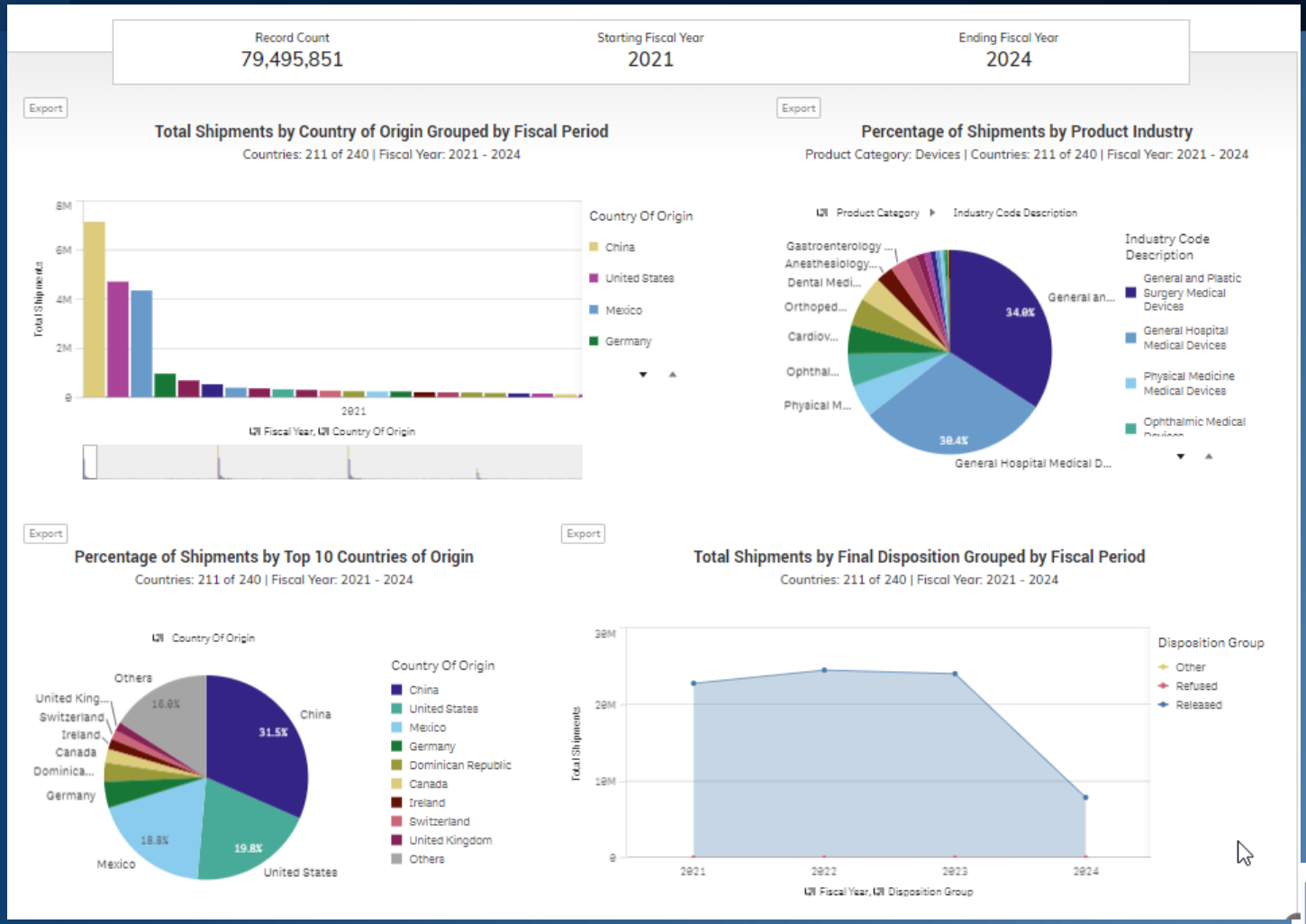
Imports Entry



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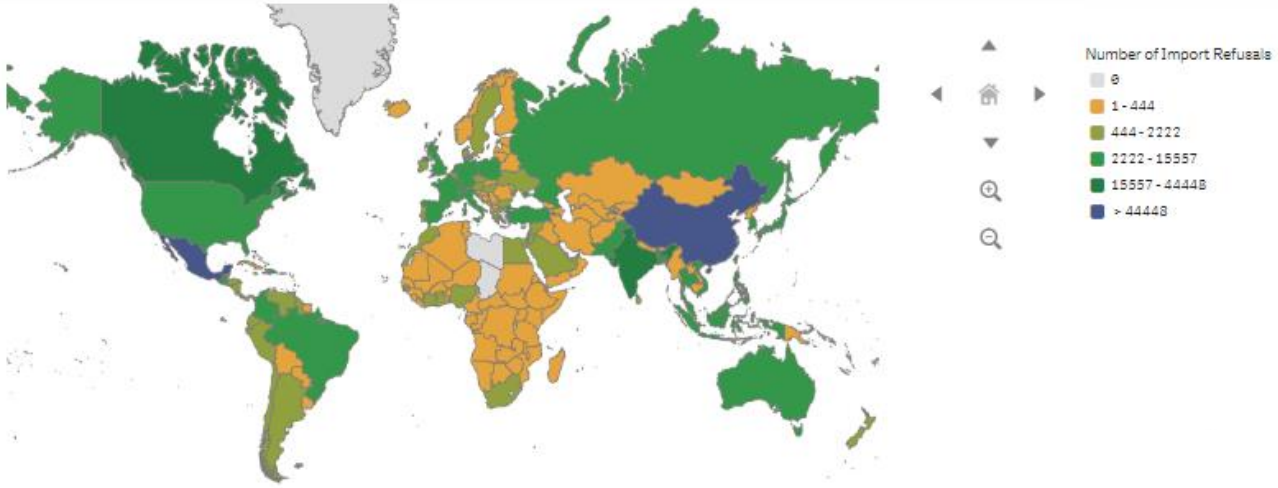
Import Refusals

Refusals by Product Category:	Animal Feed	Cosmetics	Devices	Drugs and Biologics	All Refusals
	2,651 +	24,824 +	129,463 +	72,770	444,480
	Housewares & Food Related	Human Foods	Radiological Health	Tobacco Products	
	2,168 +	204,842 +	6,577 +	1,185	

Unique Shipment Lines Refused by Country

Total: 444,480



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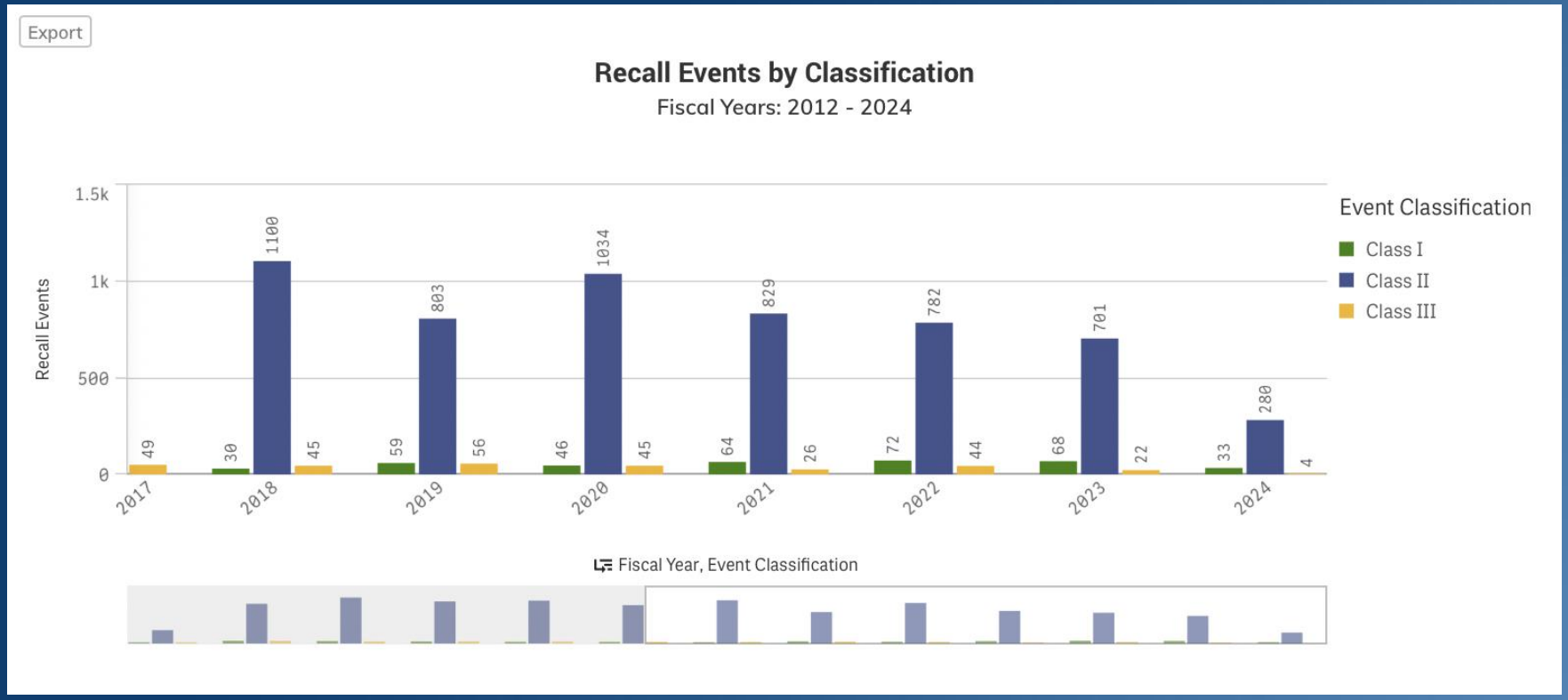
Recalls



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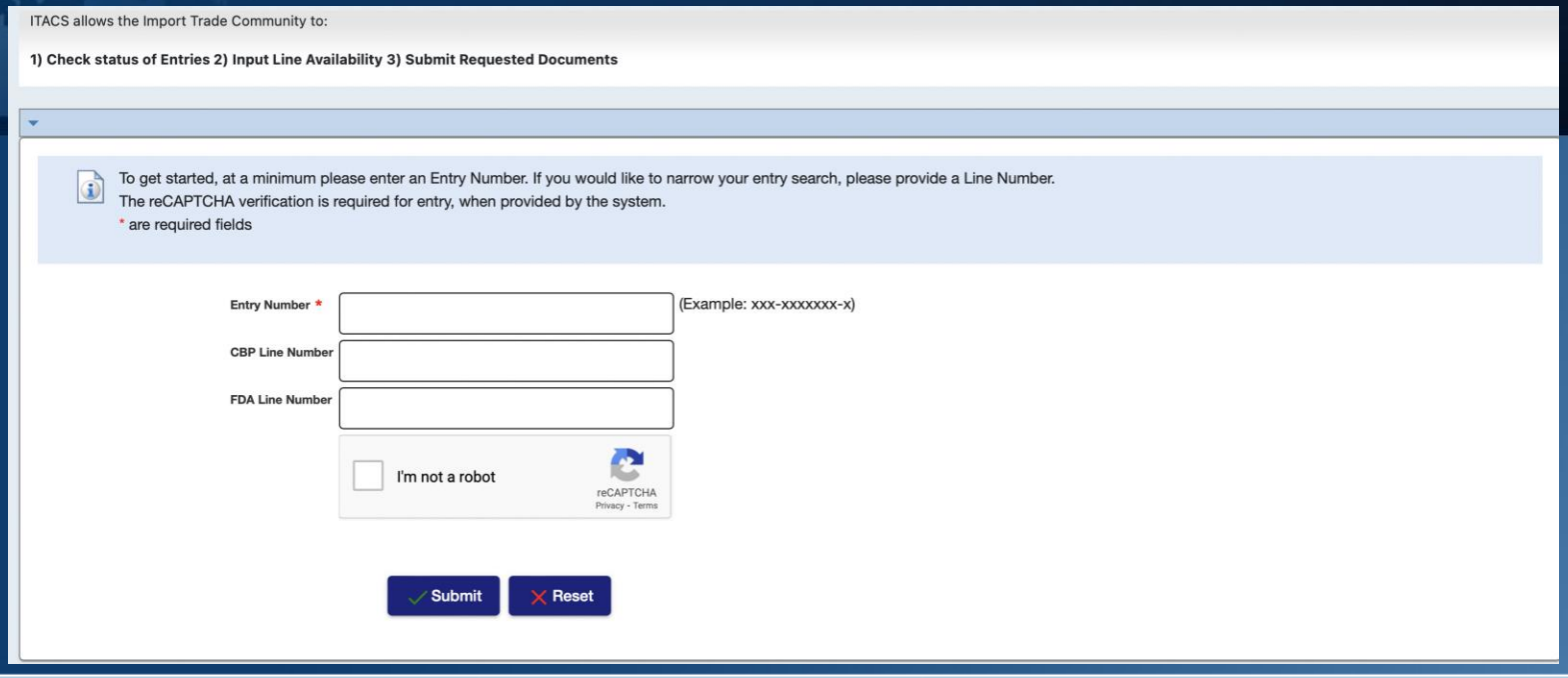
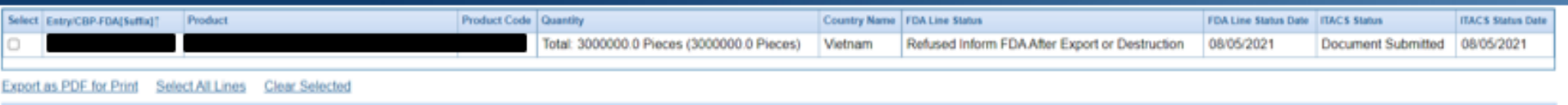
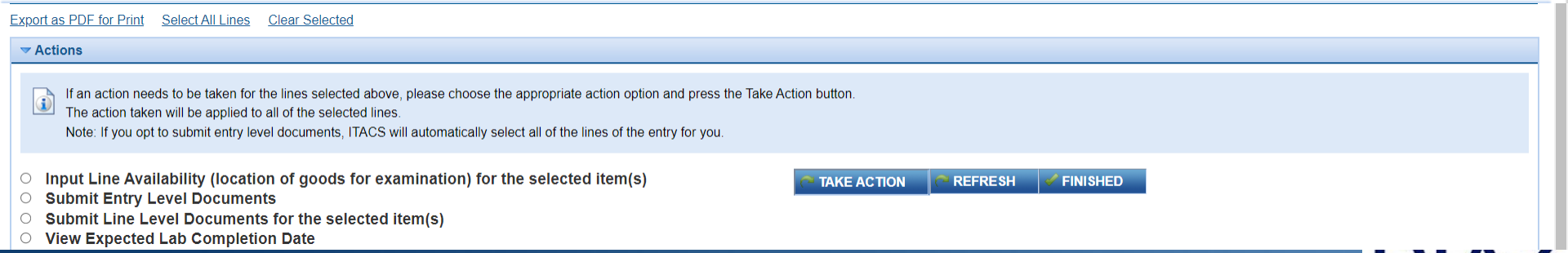
HOW TO USE ITACS







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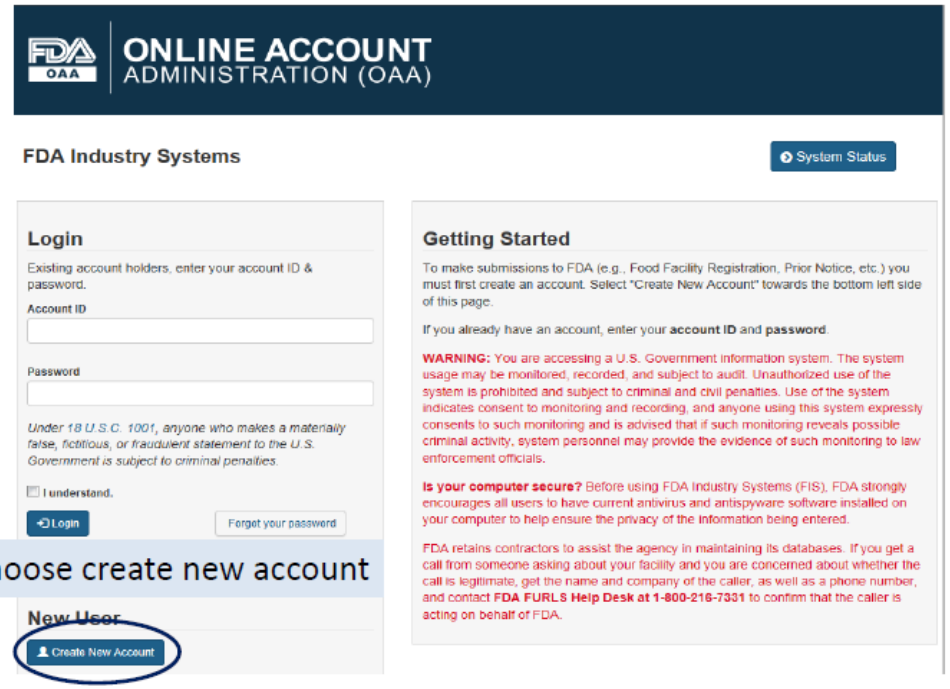
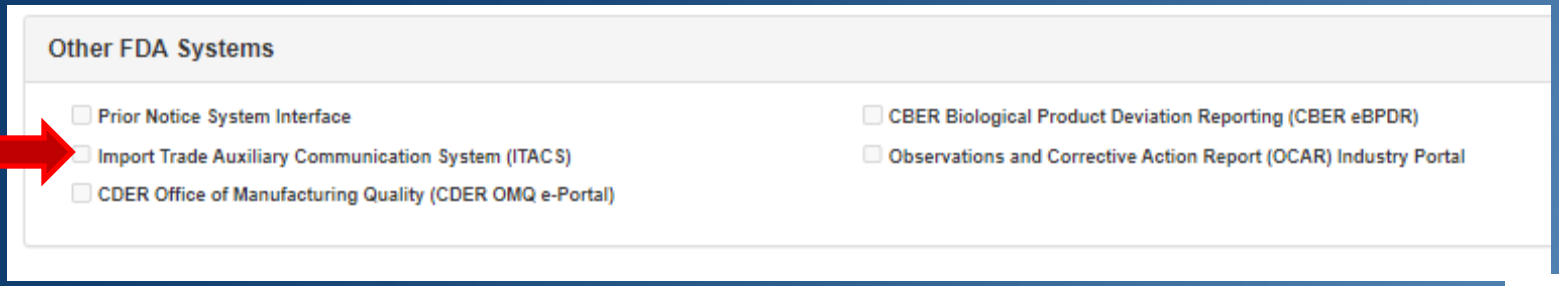
How to Create YOUR ITACS

Creating an ITACS Account





- https://www.fda.gov/media/106771/download

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NOTICE OF REFUSAL

Notice Number 3

HOLD DESIGNATED

Notify FDA of Availability

Summary of Current Status of Individual Lines

MULTILEAD BOX (NEW MACHINE)	5 NO	Refuse 10-26-20

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

(Signature) Paul R. Magdikian
FDA COMPLIANCE OFFICER

(Signature) 10/27/20
for PORT DIRECTOR OF CBP
CBP PORT NO. 5206
MIAMI INTERNATIONAL AIRPORT

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NOTICE TO REDELIVER

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

"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."

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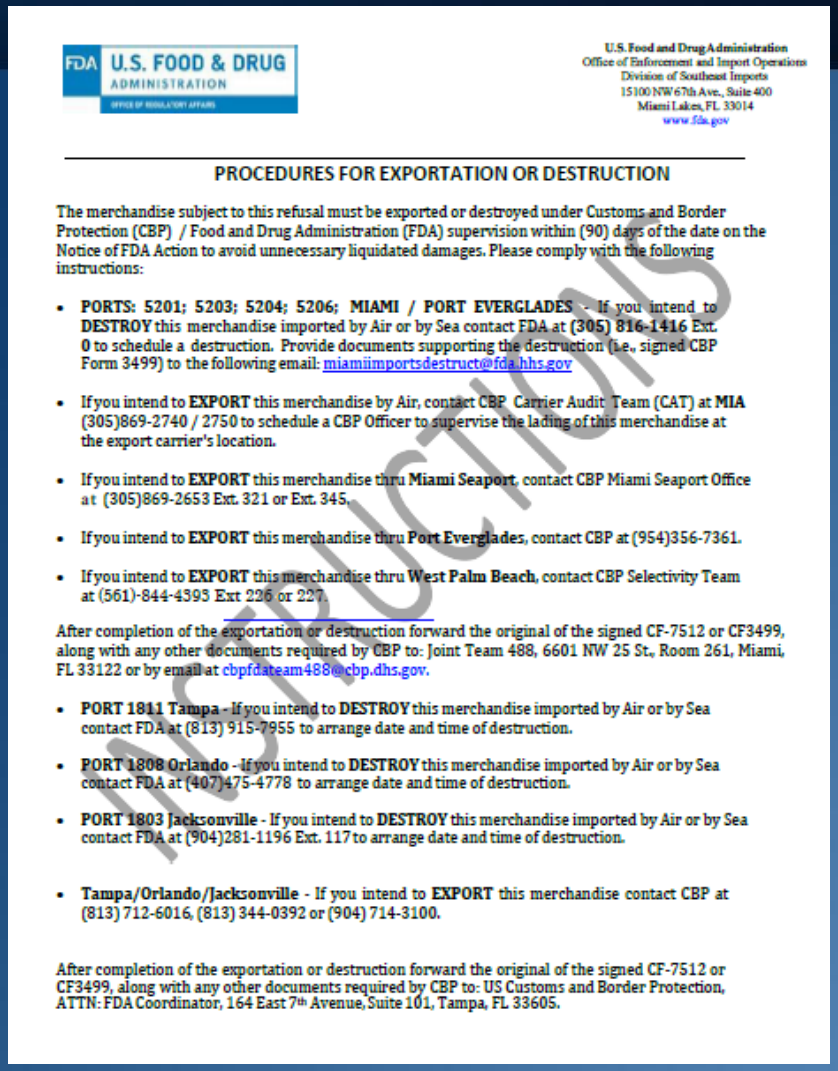
Refusal Instructions

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



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.

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Liquidated Damages

U.S. Customs and Border Protection F01

NOTICE OF PENALTY OR LIQUIDATED DAMAGES INCURRED AND DEMAND FOR PAYMENT

PAGE 1 OF 1

DEMAND IS HEREBY MADE FOR PAYMENT OF $ 50,000.00 representing ☐ Penalties or X ☐ Liquidated Damages assessed against you for violation or law or regulation, or breach of bond, as set forth below:

LIQUIDATED DAMAGES INCURRED FOR FAILURE TO EXPORT OR DESTROY SUBJECT MERCHANDISE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE IMPORTATION AND ENTRY BOND.

If you feel there are extenuating circumstances, you have the right to object to the above action. Your petition should explain why you should not be penalized for the cited violation. Write the petition as a letter or in legal form; submit in (duplicate) (triplicate), addressed to the Commissioner of Customs and Border Protection, and forward to the FP & F Officer at:

FP&F, P.O. BOX 52-2207, MIAMI, FL 33152

Unless the amount herein demanded is paid or a petition for relief is filed with the FP & F Officer within the indicated time limit, further action will be taken in connection with your bond or the matter will be referred to the United States Attorney.

TIME LIMIT FOR PAYMENT OR FILING PETITION FOR RELIEF (Days from the date of this Notice) ➡ 60

Signature | Title | Date

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Liquidated Damages

This is in response to your petition dated filed on behalf of your client claim for liquidated damages arose due to failure to redeliver into the custody of U.S. Customs and Border Protection (CBP) after being refused by the U.S. Food and Drug Administration (FDA) for misbranding. This is a violation of *Title 19, Code of Federal Regulations, section 141.113(c), 19 CFR 12.3, 21 United States Code, section 381(b) and 21 United States Code section 381(a).*

Upon review of your petition along with the facts and circumstances surrounding this case, it has been determined that a violation did in fact occur. asserts that good faith efforts were made to destroy the refused merchandise timely; however, due to a delayed response from the FDA you were unable to have the merchandise destroyed timely. You add that redelivery and destruction of the refused product was accomplished by The Notice of Action issued by FDA clearly states that the refused products must be exported or destroyed under Customs supervision within 90 days from the date of the notice. Although the refused product under entry number was destroyed under FDA supervision; destruction occurred outside the 90-day time period prescribed on the FDA which would have been

relief shall be granted, and mitigation afforded in the amount of You have 60 days from the date of this letter to comply with the decision, or, in accordance with 19 C.F.R. §172.41, to file a supplemental petition for relief. If payment or a supplemental petition is not received in this office within the specified time, this claim shall be forwarded to the surety for collection.

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Poll Time!

Customs typically follows FDA's recommendation as to the amount acceptable to cancel the claim for liquidated damages.

- True or False?

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FP&F Petition Process

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

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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. If goods are destroyed after refusal, the destruction must be done under CBP supervision

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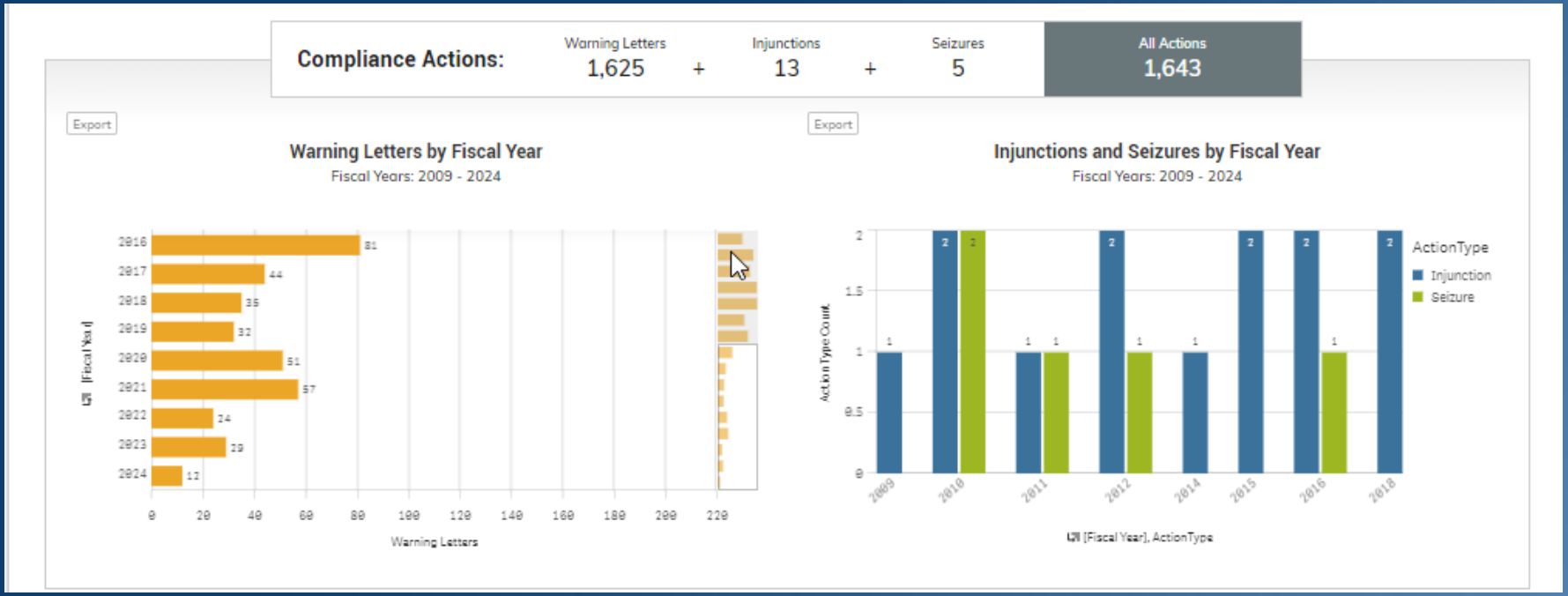
Compliance Actions



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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

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Poll Time!

Once you are placed on an import alert it is impossible to be removed.

- True or False?

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IMPORT ALERT

Where can I find a list of the FDA's import alerts?

- **Enter key word(s), firm name, product, etc. to search import alerts:**
  Search
- Browse import alerts by country/ area
- Browse import alerts by industry
- Browse import alerts by number assigned to each alert
- Browse import alerts by last published date

Back to top

How do I interpret an import alert?

Each import alert will include the following information:

Import Alert Section	Description
Import Alert #	This is the number issued by the FDA. The first 2 numbers are the industry code of the product. For example, any import alert that starts with a 16 will be related to seafood.
Published Date	This is the last date that there was an update to the alert. This is not the original date the alert was published.
Type	This describes whether the alert is DWPE or DWPE with surveillance. Import Alerts that are DWPE with surveillance include additional guidance for the field. Such as, IA 20-05 states: Surveillance of heavy metal levels in fruit juices and fruit juice concentrates from all countries is warranted.
Import Alert Name	This is the name of the alert; it is a brief description of what the alert applies to.
Reason for Alert	This section describes why the alert was issued.

Import Alert Industry Group Medical Devices & Diagnostic Products

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Industries
Anesthesiology
Cardiovascular
Chemistry
Dental
Ear,Nose And Throat
Gastroenterological & Urological
General & Plastic Surgery
General Hospital/Personal Use
Hematology
Immunology
Microbiology
Neurological
Obstetrical & Gynecological
Ophthalmic
Orthopedic
Pathology
Physical Medicine
Radiological
Toxicology

Import Alerts | FDA

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Import Alert

- Import Alerts are listed by Country and Industry
  - Import Alert # 80-06
  - Type: DWPE (Detention Without Physical Examination)
  - Import Alert Name:
    - "Detention Without Physical Examination of Medical Devices with False or Misleading Labeling"

Import Alert 80-06

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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 # 80-06
Published Date: 10/16/2023
Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of Medical Devices with False or Misleading Labeling"

Reason for Alert:

Note: The revision of this Import Alert (IA) dated 10/16/2023 updates the guidance section including agency contacts, and charge code language. Changes to the import alert are bracketed by asterisks (***).

The Food and Drug Administration has warned and/or taken action against a number of companies that have made improper claims about their products' intended use. Some may carry significant health risks.

Section 502(a) declares that a drug or device is misbranded if its labeling proves false or misleading in any particular. Section 201(n) states that if an article is alleged to be misbranded because the labeling or advertising is misleading. Then, in determining whether the labeling or advertising is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

Guidance:

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

CANADA

Europe Cosmetiques
Date Published : 09/16/2009
3471 Bou Thimens , Saint-Laurent, QC CANADA
77 - - - -- Ear,Nose And Throat
Date Published: 09/16/2009
Desc: Auricular candles with Otoska oil
Notes: Effective in treatment of ear wax build up; hearing problems; sinus congestion; frequent migraines and earaches. 4/3/96

Kencayd Consulting (aka Candela Earcandles)
Date Published : 09/16/2009
555 Ridley Drive , Victoria, BC CANADA
77 - - - -- Ear,Nose And Throat
Date Published: 09/16/2009
Desc: Ear candles
Notes: Promotes better hearing; better lymphatic circulation; pressure regulation; etc. 2/5/1997

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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

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

March 28, 2019

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.

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How to Use FDA's Databases to Perform Due Diligence

- 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

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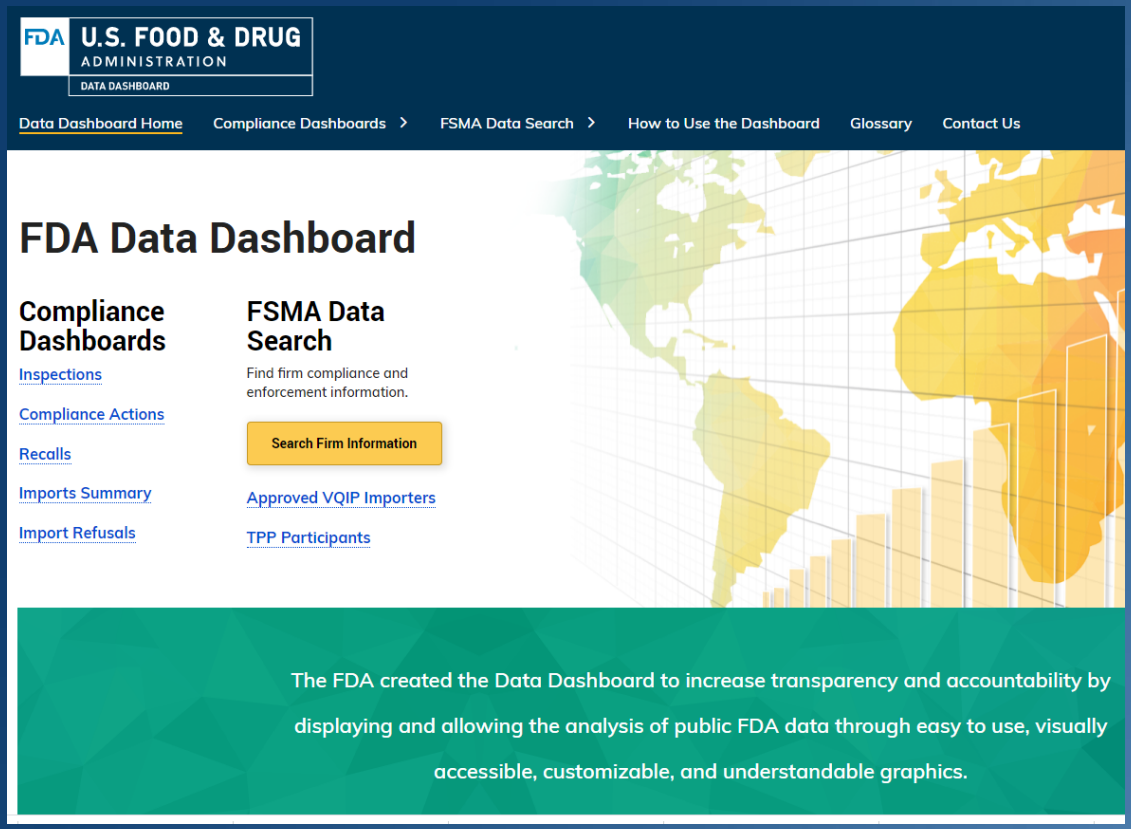
Compliance History of Manufacturer

- What is the compliance history of the manufacturer, importer, and device? https://datadashboard.fda.gov/ora/index.htm



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USEFUL LINKS

- Diaz Trade Law Blog - Home - Customs & International Trade Law Firm (diaztradelaw.com)
- Diaz Trade Law Newsletter - https://diaztradelaw.us3.list-manage.com/subscribe?u=8a54e8f0884220f2018f4e388&id=27569bf0f6
- FDA Data Dashboard - FDA Dashboards - Home
- Warning Letters - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
- Import Alerts - Import Alerts | FDA
- Recalls - https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
- FDA Regulatory Procedures Manual - Regulatory Procedures Manual | FDA
- Labeling Guide for Dietary Supplements - https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide
- Labeling Guide for Medical Devices - https://www.fda.gov/media/74034/download
- Detention of Goods- https://diaztradelaw.com/fda-discusses-top-reasons-for-detention-of-goods-2/
- ITACS- https://www.access.fda.gov/itacs/#/

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FDA Seeks Public Comments on Proposed Final Order for OTC Sunscreen Safety

FDA is proposing to amend the Over-the-Counter (OTC) Monograph which covers sunscreen drug products for OTC human use. The public has until **November 12, 2021** to submit comments on the impact the proposed changes may have on consumers and industry. This blog provides background on why FDA is considering such changes and discusses FDA's newly deemed final order for OTC sunscreens as well as the changes included in the proposed order for sunscreens. Industry is encouraged to contact Diaz Trade Law to assess the implications of the proposed changes on its products and to assist in drafting and submitting comments to FDA.

Why is FDA Taking New Steps to Enhance Sunscreen Safety?

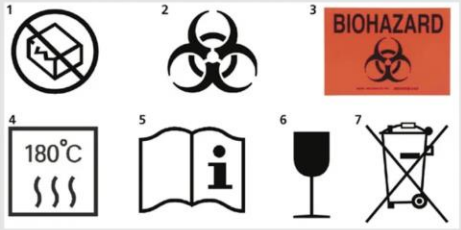
The 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act reformed and modernized the way FDA regulates certain OTC monograph drugs, including sunscreen.

The CARES Act *replaced* the rulemaking process for OTC monograph drugs with an administrative order process for issuing, revising, and amending the OTC monographs. The administrative order process gives FDA new tools to help revise the OTC monographs as science changes, innovation progresses, new data becomes available, or emerging safety signals arise.

For sunscreens specifically, in addition to establishing a deemed final order, the CARES Act requires FDA to issue a proposed order to amend and revise the deemed final order for sunscreens. The FDA believes that most sunscreens on the market will be in compliance with the deemed final order because the provisions are nearly identical to the pre-CARES Act marketing conditions for sunscreens.

FDA Launches New Webpage to Promote Use of Symbols in Labeling of Medical Device

Today the U.S. Food and Drug Administration (FDA) launched a new webpage to assist the public understand the Use of Symbols in Labeling Final Rule. The final rule was issued by the FDA in June 2016 and became effective three months later.



FDA intends the final rule to be an attempt to "harmonize the U.S. device labeling requirements for symbols with international regulatory requirements. As the medical device industry has requested the ability to use stand-alone symbols on domestic device labeling, consistent with their current use on devices manufactured for European and other foreign markets." This is exciting news for our clients who are Medical Device Manufacturers or Importers – as of September 2016 all medical device labeling may use stand-alone symbols!

MoCRA Update: Final Guidance and Launch of Electronic Submissions Portal

On December 18, 2023, the U.S. Food and Drug Administration (FDA) launched Cosmetics Direct, an electronic submission portal for product listing and facility registration required under the Modernization of Cosmetics Regulation Act (MoCRA). The agency also issued final guidance with recommendations to assist companies and individuals submitting facility registration and product listing information to the FDA.

Draft Guidance on Medical Device Transition Period

In response to the COVID-19 Pandemic, the FDA took unprecedented action in transforming its enforcement because of the declaration of a Public Health Emergency while also issuing, and continuing, Emergency Use Authorizations. These governmental actions facilitated and increased the importation of necessary medical devices needed to combat the pandemic here in the United States. And now as the U.S. relaxes its pandemic protocol, the FDA is exploring the best way to have medical devices transition back to pre-pandemic regulations and protocol. On December 23, 2021, the FDA issued two draft guidance documents in the Federal Register detailing its proposed medical device transition plans for all medical devices previously imported under the two aforementioned government declarations. And to provide further assistance, the FDA hosted a webinar "Draft Guidances on Transition Plans for COVID-19 Related Medical Devices" providing further explanations to the trade community on what can be expected from the proposed transition plans.

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Now That We Have Our Paws Dirty… Any Questions?

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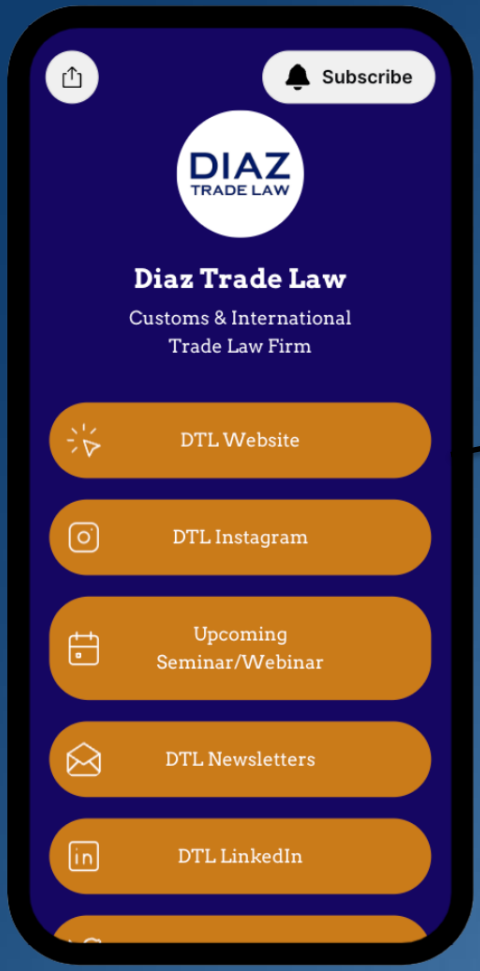
Keep in Touch!

Connect with me on LinkedIn!

SCAN ME



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Best Practice to Navigate FDA Enforcement Actions

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