# Mastering FDA Compliance: Strategies for Navigating Enforcement and Import Regulations


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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

- Top Rationale for FDA Enforcement for Food, Medical Devices, Cosmetics
- The Procedure and Requirements for Importing Food, Cosmetic and Medical Device Products
- The Primary Enforcement Actions Used By the FDA and How To Successfully Navigate FDA Enforcement Actions.
  - How To Use ITACS When Communicating with the FDA.
  - Process To Be Removed From The FDA Import Alert (Also Known as The FDA Red Or Blacklist)
  - Actions To Take When Your Company Receives an FDA Enforcement Action
- How To Use FDA's Databases to Perform Due Diligence.

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# PRIZE TIME

- Which of the following is NOT regulated by the FDA?
  A. Sunglasses
  B. Sunscreen
  C. Bed sheets
  D. Lip gloss
  E. Cigars


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# WHAT DOES FDA REGULATE?

- Human Foods (except most meat and poultry)
- Animal Foods
- Cosmetics
- Drugs (human and animal)
- Biologics
- Medical Devices (sunglasses)
- Electronic products that emit radiation
- Tobacco (Newest)


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# FDA'S MISSION

- FDA is charged with protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation emitting products; and regulating tobacco products.

Martin Makary, of Virginia,
to be Commissioner of
Food and Drugs

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# PRIZE TIME

- In FY2024, which product category saw the largest number of imports into the United States?
  A. Devices
  B. Food
  C. Cosmetics
  D. Tobacco
  E. Drugs


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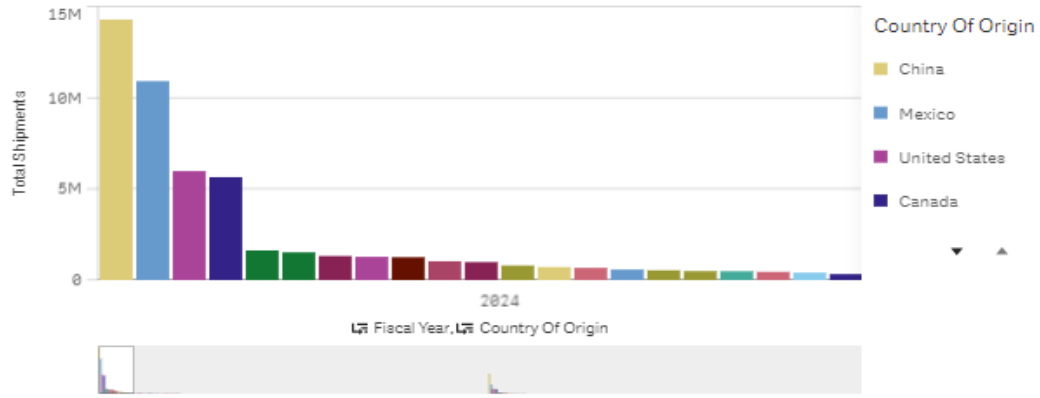
# FY YEAR 2024-2025 – PRODUCTS IMPORTED INTO THE U.S. BY COUNTRY

| Record Count | Starting Fiscal Year | Ending Fiscal Year |
|---|---|---|
| 75,675,046 | 2024 | 2025 |

Export

## Total Shipments by Country of Origin Grouped by Fiscal Period

Countries: 226 of 240 | Fiscal Year: 2024, 2025

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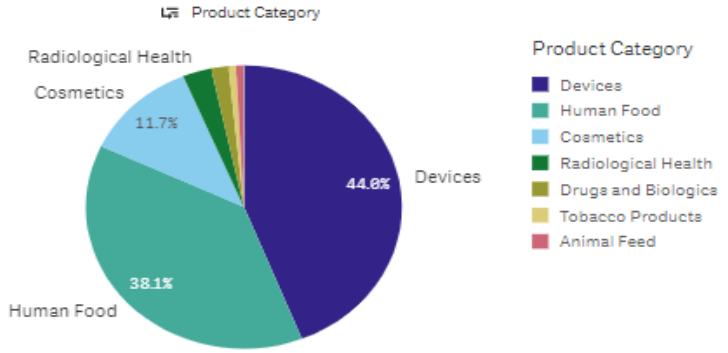
## Percentage of Shipments by Product Category

Countries: 226 of 240 | Fiscal Year: 2024, 2025

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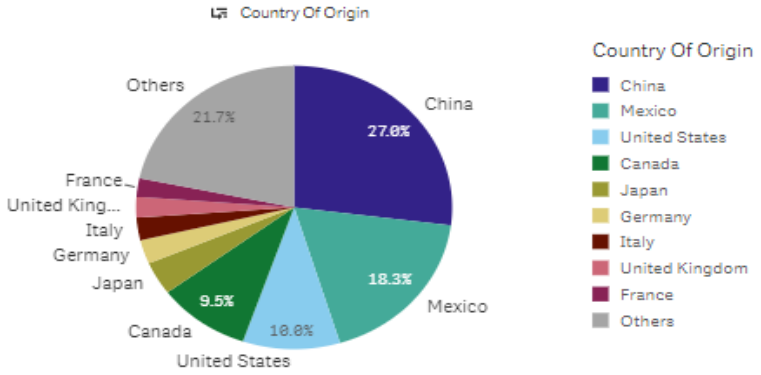
## Percentage of Shipments by Top 10 Countries of Origin

Countries: 226 of 240 | Fiscal Year: 2024, 2025

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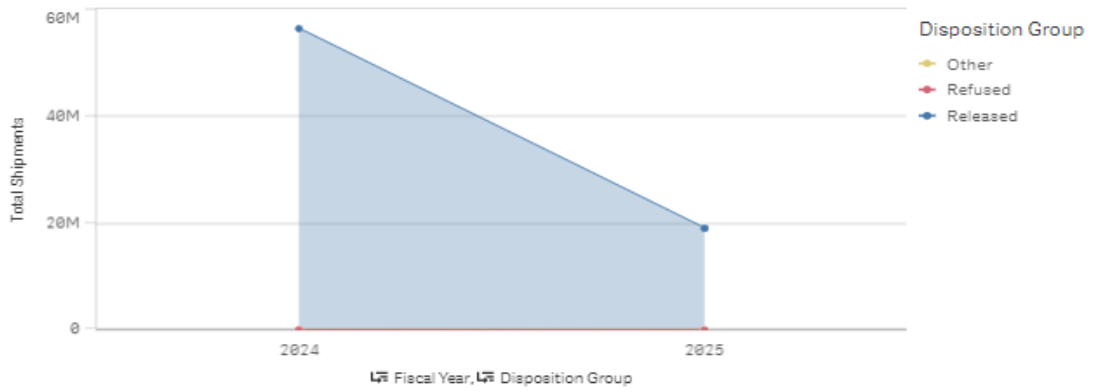
## Total Shipments by Final Disposition Grouped by Fiscal Period

Countries: 226 of 240 | Fiscal Year: 2024, 2025

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# TOP RATIONALES FOR DETENTION OF FOOD

- Manufacturer (processor, packer or person holding food product) is not registered with the FDA pursuant to the Bioterrorism Act. (You can Register with the FDA here: www.FDA-USA.com)
- Low Acid Canned Foods (LACF) are imported without establishment registration (FCE #) or scheduled process (SID #)
- The products are subject to an Import Alert
- Product labeling is not compliant (FDA does not pre-approve food labeling, it is up to importers to ensure it is compliant before importing)

**Common labeling violations include:**

- Failure to list allergens
- Failure to declare ingredients
- Failure to include a proper "Nutrition Facts" label (incorrect formats for Nutrition Facts labeling is also common) required by 21 C.F.R. 101.9
- Color additives are not declared correctly (or at all) on the label or not certified
- Food additives are unsafe or not declared on the label

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# What Is Required To Import A Food Into the U.S.?

1. FDA BTA Registration (FDA-USA.com)
2. Provide advanced notice to the FDA that a food is being imported (i.e. Prior Notice)
3. Current good manufacturing practices
4. Food Safety Modernization Act (FSMA) – Including Foreign Supplier Verification Program (FSVP)
5. Food labeling
6. Recordkeeping & Reporting

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# PRIZE TIME

- The top Inspection finding of the FDA (from FY22-25) was which of the following:
  A. No FSVP In place
  B. Lack of GMP's
  C. No written processes
  D. Not operating under sanitary operations


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# 2022-2025 Inspection Findings

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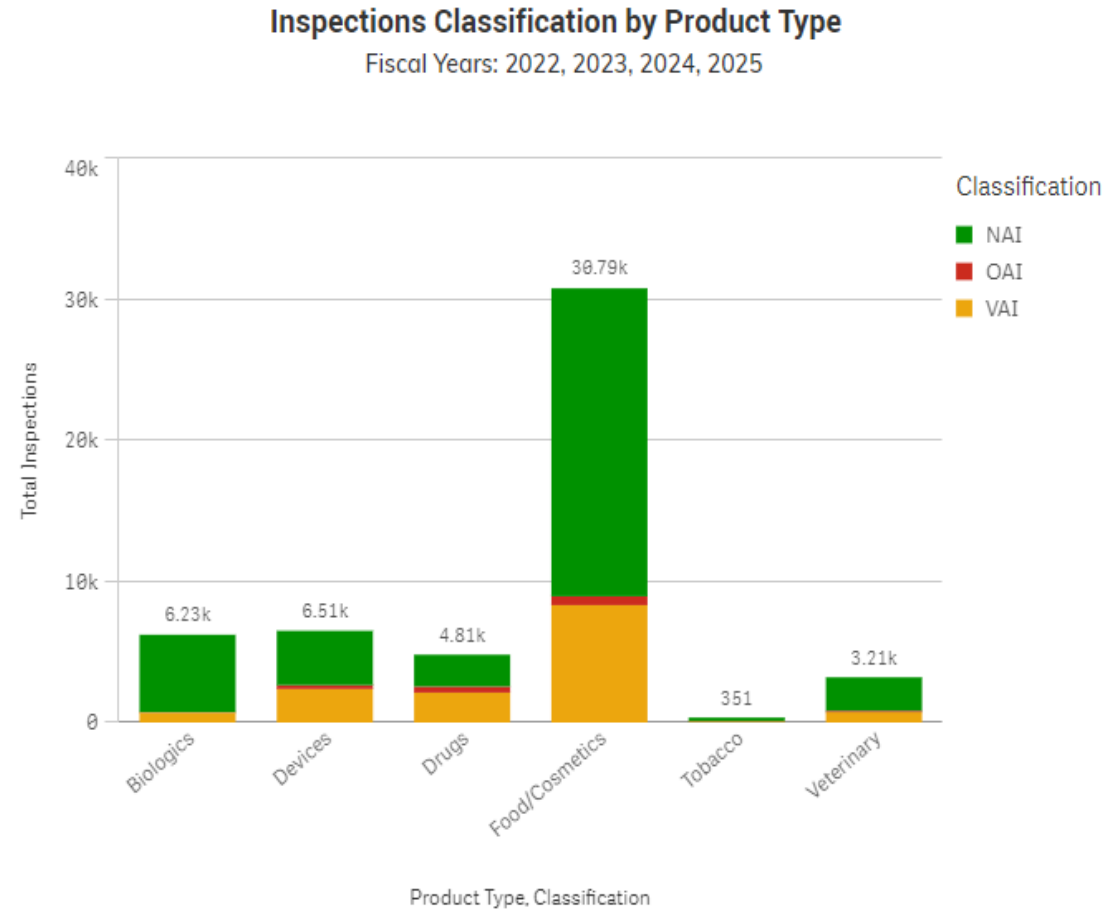


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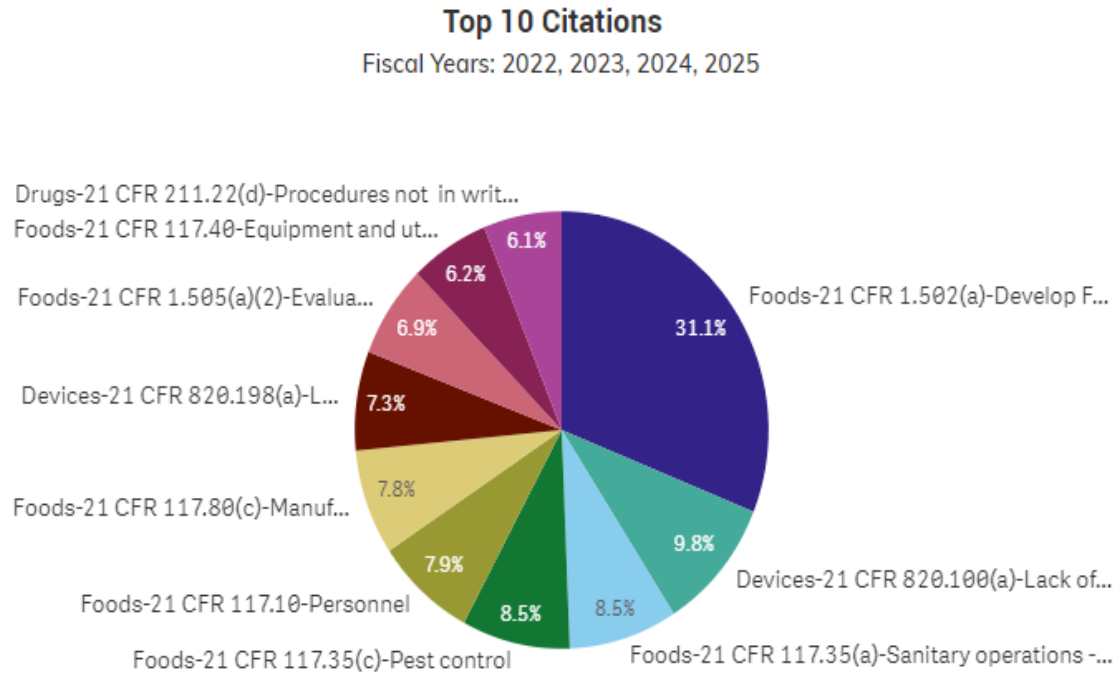


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# FSMA – FSVP Tip!

- Ensure you and your manufacture comply with FDA Food Safety Modernization Act (FSMA) standards and you have a Foreign Supplier Verification Program (FSVP) in place.
  - Preventative Controls for Human Food
  - Preventative Controls for Animal Feed
  - Produce Safety
  - Foreign Supplier Verification Program
  - 3rd Party Accreditation and Certification
  - Sanitary Transportation
  - Food Defense



https://www.fda.gov/media/94281/download

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# TOP RATIONALES FOR DETENTION OF DRUGS

1. Label is not in English
2. Label does not contain adequate directions for use
3. Active Pharmaceutical Ingredients (API) is not properly labeled or listed
4. Drug contains a "new" chemical or a different dosage making the product a "new drug"
5. Product labeling is not compliant (FDA does not pre-approve drug labeling, it is up to importers to assure it is compliant before importing)

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# CHECKLIST TO IMPORT OTC DRUGS

- **Regulatory Compliance**: Ensure the product meets an FDA OTC monograph (OTC MONOGRAPHS @ FDA | FDA) or has an approved NDA/ANDA.
- **Facility Registration**: Register the foreign manufacturing facility with the FDA and designate a U.S. agent.
- **Proper Labeling**: Labels must meet FDA standards, include required information, and **be in English.**
- **Follow cGMP Standards**: Manufacture in compliance with FDA's Good Manufacturing Practices.
- **Customs Filing**: Ensure the broker submits accurate FDA Product Codes and Affirmation of Compliance codes to CBP/FDA via ACE.

| OTC Monograph ID | Published Date | OTC Monograph Title | Therapeutic Conditions |
|---|---|---|---|
| M001 | 10/14/2022 | Antacid Products for Over-the-Counter Human Use | Antacid |
| M002 | 09/20/2021 | Antiflatulent Products for OTC Human Use | Antiflatulent |
| M003 | 05/02/2023 | First Aid Antiseptic Drug Products for Over-the-Counter Human Use | N/A |
| M004 | 05/02/2023 | First Aid Antibiotic Drug Products for Over-the-Counter Human Use | Antimicrobial/Antibacterial |
| M005 | 12/16/2021 | Topical Antifungal Drug Products for Over-the-Counter Human Use | Antifungal |
| M006 | 11/23/2021 | Topical Acne Drug Products for Over-the-Counter Human Use | Acne |
| M007 | 05/02/2023 | Laxative Drug Products for Over-the-Counter Human Use | Laxative |
| M008 | 04/04/2022 | Antidiarrheal Drug Products for Over-the-Counter Human Use | Antidiarrheal |
| M009 | 11/23/2021 | Antiemetic Drug Products for Over-the-Counter Human Use | Antiemetic |
| M010 | 09/20/2021 | Nighttime Sleep Aid Drug Products for OTC Human Use | Nighttime Sleep-Aid |
| M011 | 10/14/2022 | Stimulant Drug Products for Over-the-Counter Human Use | Stimulant |
| M012 | 10/14/2022 | Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use | Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic |
| M013 | 10/14/2022 | Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use | Internal Analgesic |
| M014 | 09/20/2021 | Topical Otic Drug Products for OTC Human Use | Otic |
| M015 | 10/01/2021 | Anorectal Drug Products for Over-the-Counter Human Use | Anorectal |
| M016 | 09/24/2021 | Skin Protectant Drug Products for Over-the-Counter Human Use | Skin Protectant |
| M017 | 05/02/2023 | External Analgesic Drug Products for Over-the-Counter Human Use | External Analgesic |
| M018 | 04/04/2022 | Ophthalmic Drug Products for Over-the-Counter Human Use | Ophthalmic |
| M019 | 11/23/2021 | Antiperspirant Drug Products for Over-the-Counter Human Use | Antiperspirant |
| M020 | 09/24/2021 | Sunscreen Drug Products for Over-the-Counter Human Use | Sunscreen |
| M021 | 05/02/2023 | Anticaries Drug Products for Over-the-Counter Human Use | Anticaries |
| M022 | 10/14/2022 | Oral Healthcare Drug Products for Over-the-Counter Human Use | Oral Healthcare |
| M023 | 10/14/2022 | Poison Treatment Drug Products for Over-the-Counter Human Use | Poison Treatment |
| M024 | 12/16/2021 | Anthelmintic Drug Products for Over-the-Counter Human Use | Anthelmintic |
| M025 | 12/16/2021 | Cholecystokinetic Drug Products for Over-the-Counter Human Use | Cholecystokinetic |
| M026 | 11/23/2021 | Deodorant Drug Products for Internal Use for Over-the-Counter Human Use | Internal Deodorant |
| M027 | 12/16/2021 | Orally Administered Menstrual Drug Products for Over-the-Counter Human Use | Menstrual |
| M028 | 10/01/2021 | Wart Remover Drug Products for Over-the-Counter Human Use | Wart Remover |
| M029 | 10/01/2021 | Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use | Ingrown Toenail |
| M030 | 09/20/2021 | Corn and Callus Remover Drug Products for OTC Human Use | Corn and Callus Remover |
| M031 | 10/01/2021 | Pediculicide Drug Products for Over-the-Counter Human Use | Pediculicide |
| M032 | 12/16/2021 | Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use | N/A |
| NM900 | 09/21/2021 | Non-Monograph Conditions NM900: Drug Products Containing Certain Active Ingredients Offered Over-the-Counter for Certain Uses | N/A |

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# TOP RATIONALES FOR DETENTION OF MEDICAL DEVICES

- The **manufacturer/exporter** 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 ensure it is compliant before importing)

**Common labeling violations include:**

- Label is not in English
- Label is false or misleading

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# CHECKLIST TO IMPORT DEVICES

- **Classify the Device**: Identify if it's Class I, II, or III to determine regulatory requirements.
- **Premarket Requirements**: Ensure compliance with 510(k), PMA, or exemption rules based on the device class.
- **Register and List**: Register your facility (fee for FY25 is $9,280!) with the FDA and list your device(s).
- **Labeling**: Meet FDA labeling standards, including intended use and warnings.
- **Quality Standards**: Follow FDA Quality System Regulations (QSR).
- **Import Documentation**: Provide required info to CBP and FDA, including Affirmation of Compliance codes.
- **U.S. Agent**: Designate an agent for FDA communications if you're a foreign facility.

## Who Must Register, List and Pay the Fee

### 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 |

Who Must Register, List and Pay the Fee | FDA

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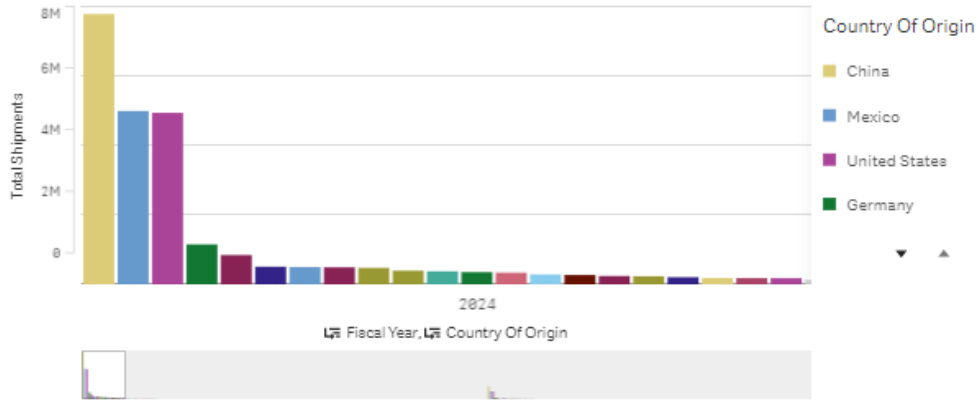
# FY YEAR 2024-2025 – DEVICES IMPORTED INTO THE U.S. STATISTICS

| Record Count | Starting Fiscal Year | Ending Fiscal Year |
|---|---|---|
| 33,298,716 | 2024 | 2025 |

Export

### Total Shipments by Country of Origin Grouped by Fiscal Period

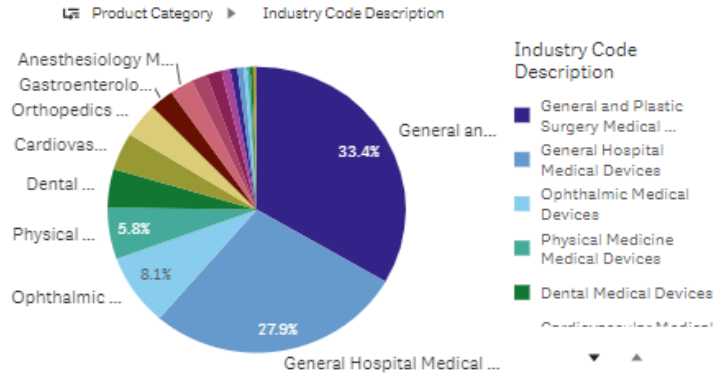
Countries: 195 of 240 | Fiscal Year: 2024, 2025




Export

### Percentage of Shipments by Product Industry

Product Category: Devices | Countries: 195 of 240 | Fiscal Year: 2024, 2025

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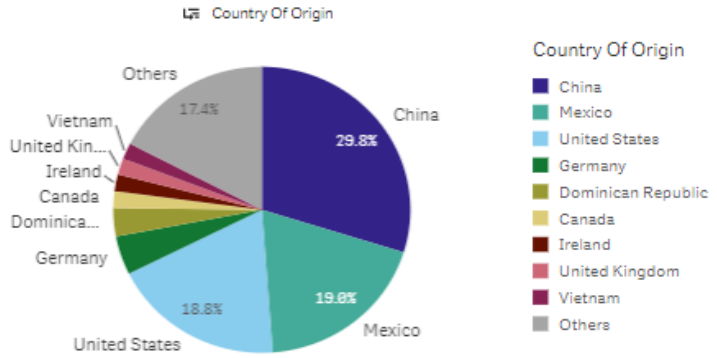
### Percentage of Shipments by Top 10 Countries of Origin

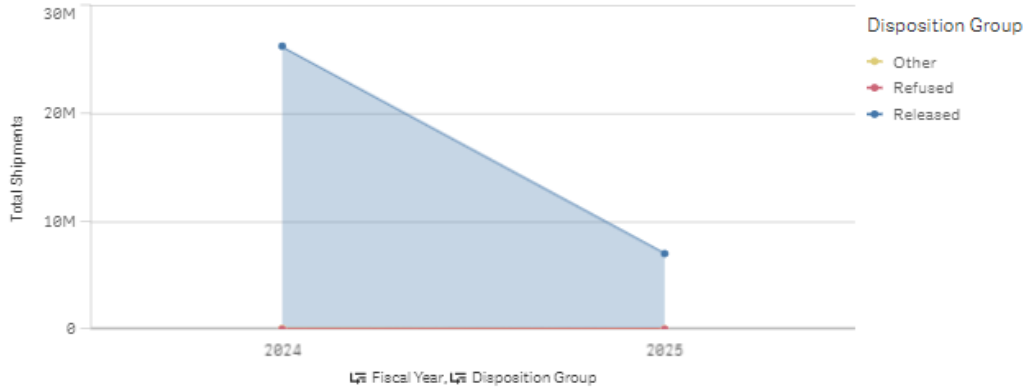
Countries: 195 of 240 | Fiscal Year: 2024, 2025




Export

### Total Shipments by Final Disposition Grouped by Fiscal Period

Countries: 195 of 240 | Fiscal Year: 2024, 2025

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# TOP RATIONALES FOR DETENTION OF COSMETICS

- Ensure cosmetic is not subject to an Import Alert (for example IA 66-41 for cosmetics labeled with drug claims)
- The cosmetics are contaminated and unsafe to use
- The cosmetics are manufactured under unsanitary conditions
- The cosmetics contain a non-permitted color additive
- Product labeling is not compliant (FDA does not pre-approve cosmetic labeling, it is up to importers to assure it is compliant before importing)

## Common labeling violations include:

- **Cosmetic contains a "drug" claim**
- Label is not in English
- Labeling is missing ingredients
- Label lacks warnings and adequate directions for use
- Missing the net quantity of contents

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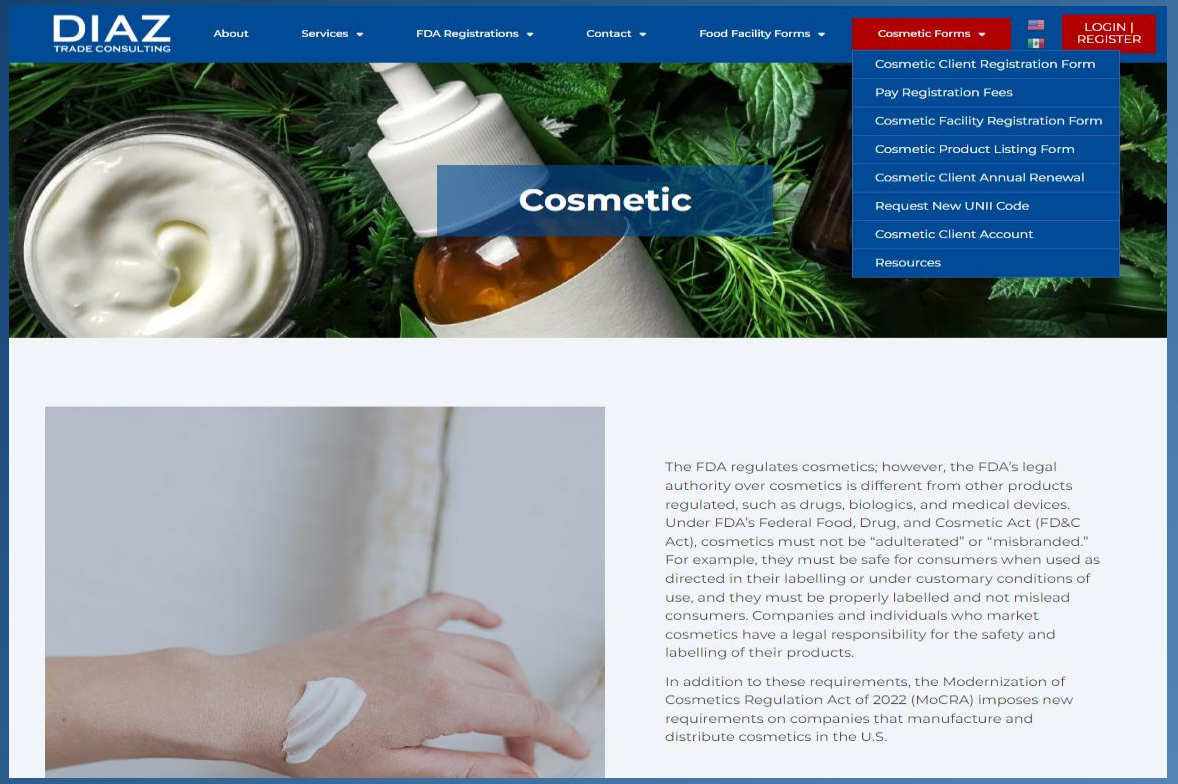
# CHECKLIST + NEW MoCRA REQUIREMENTS

- Ensure your product meets the FDA's definition of a cosmetic: intended for cleansing, beautifying, promoting attractiveness, or altering appearance.
- Verify that all **ingredients** are safe and permissible for use in cosmetics.
- Ensure any **color additives** are FDA-approved for cosmetic use.
- Ensure **labeling** is compliant (no drug claims!)
- Adhere to **GMP** to ensure product quality and safety.
- **Confirm compliance with new MoCRA requirements**
  - FDA registration for cosmetics facilities
  - Product listings for each cosmetic product
  - Adverse event reporting
  - Safety substantiation
  - Compliance with Good Manufacturing Practices (GMPs)
  - Fragrance allergen labeling
  - New records access and mandatory recall authority

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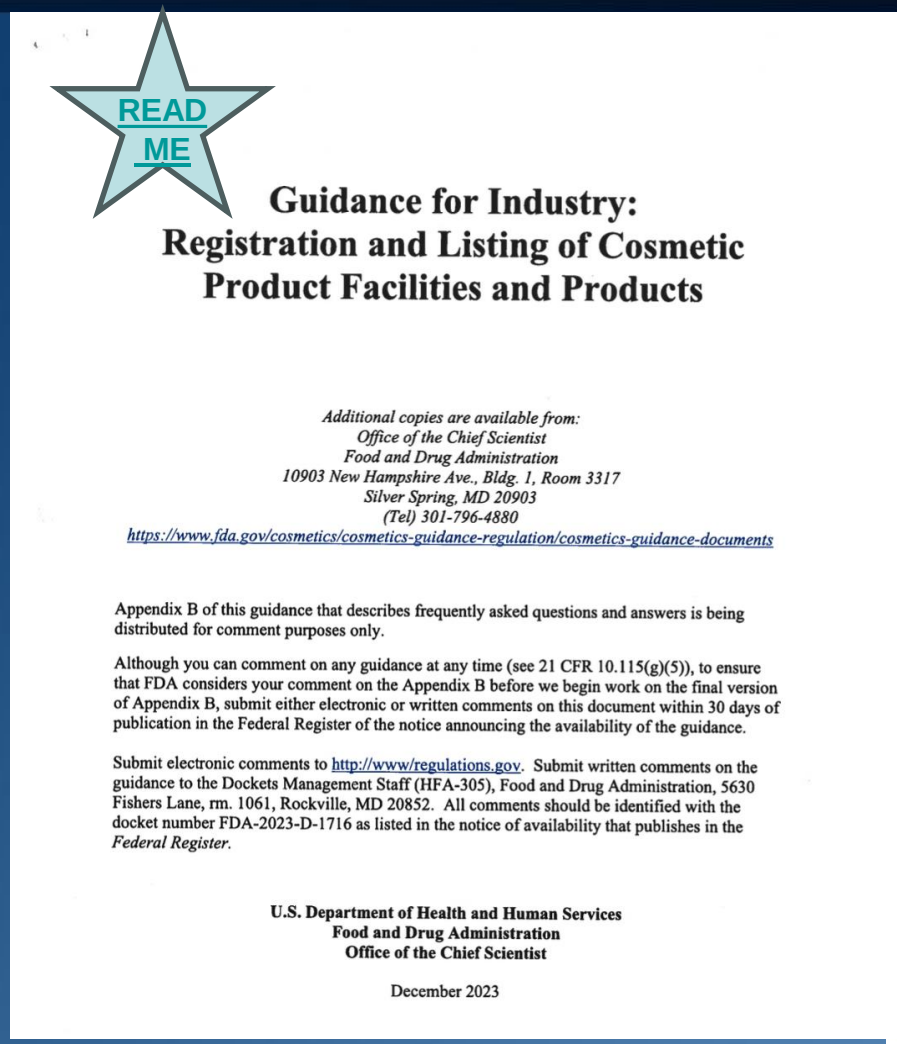
# FDA REGISTRATION FOR COSMETICS FACILITIES

- Now mandatory!
  - The end of VCRP (voluntary cosmetic registration program – as of March 27, 2023)

- Who must register?
  - Manufacturers and processors must register their facilities with FDA and renew their registration every two years.

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# PRIZE TIME

In FY2024, which country was the top source for cosmetics imported into the United States?

A. Canada
B. United Kingdom
C. United States
D. China


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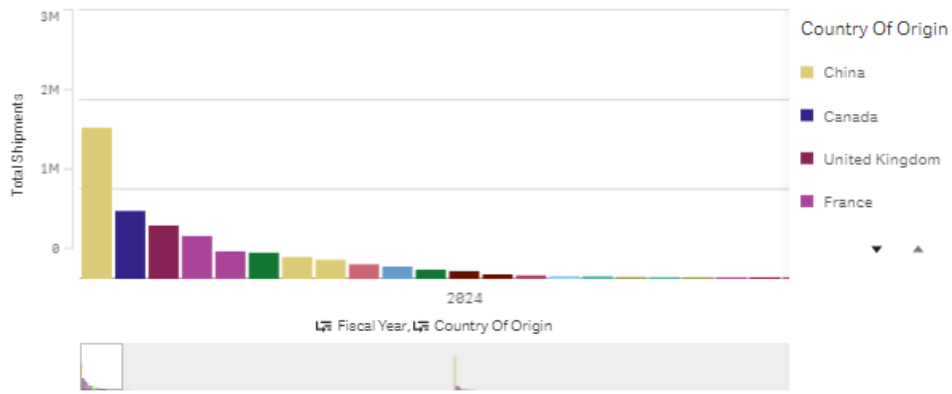
# FY YEAR 2024-2025 – COSMETICS IMPORTED INTO THE U.S. STATISTICS

| Record Count | Starting Fiscal Year | Ending Fiscal Year |
|---|---|---|
| 8,825,091 | 2024 | 2025 |

Export

**Total Shipments by Country of Origin Grouped by Fiscal Period**

Countries: 187 of 240 | Fiscal Year: 2024, 2025

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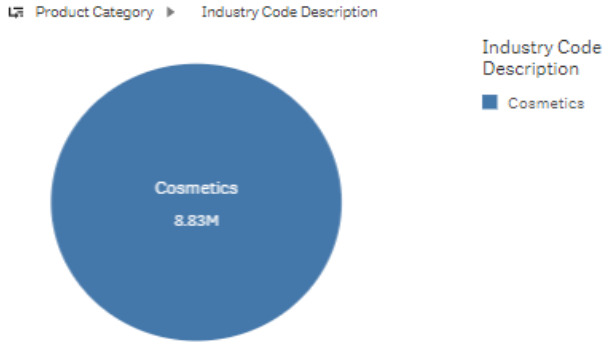
**Percentage of Shipments by Product Industry**

Product Category: Cosmetics | Countries: 187 of 240 | Fiscal Year: 2024, 2025

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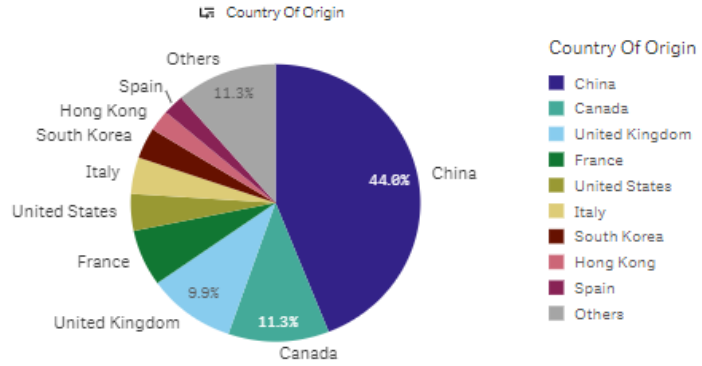
**Percentage of Shipments by Top 10 Countries of Origin**

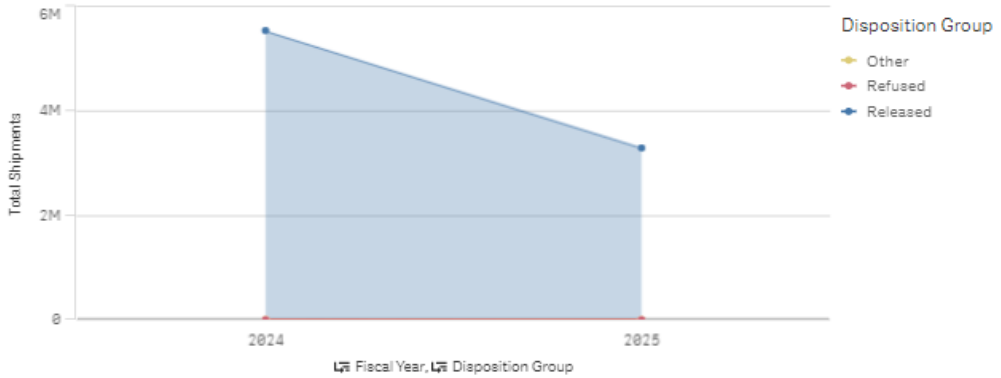
Countries: 187 of 240 | Fiscal Year: 2024, 2025




Export

**Total Shipments by Final Disposition Grouped by Fiscal Period**

Countries: 187 of 240 | Fiscal Year: 2024, 2025

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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.

***Food Products Top Rationales for Detention***

•Manufacturer (processor, packer or person holding food product) is not registered with the FDA pursuant to the Bioterrorism Act. (You can Register with the FDA here: www.FDA-USA.com)

•Low Acid Canned Foods (LACF) are imported without establishment registration (FCE #) or scheduled process (SID #)

•The products are subject to an Import Alert

•Product labeling is not compliant (FDA does not pre-approve food labeling, it is up to importers to assure it is compliant before importing)

•Common labeling violations include:

1.Label is not in English

2.Incorrect or missing statement of identity

3.Failure to list allergens

4.Failure to declare ingredients

5.Failure to include a proper "Nutrition Facts" label (incorrect formats for Nutrition Facts labeling is also common) required by 21 C.F.R. 101.9

6.Color additives are not declared correctly (or at all) on the label or not certified

7.Food additives are unsafe or not declared on the label

***Dietary Supplements Top Rationales for Detention***

•The products are subject to an Import Alert

•Product labeling is not compliant (FDA does not pre-approve dietary supplement labeling, it is up to importers to

[Summary of TOP Reasons for Detention of Goods - Customs & International Trade Law Firm (diaztradelaw.com)]

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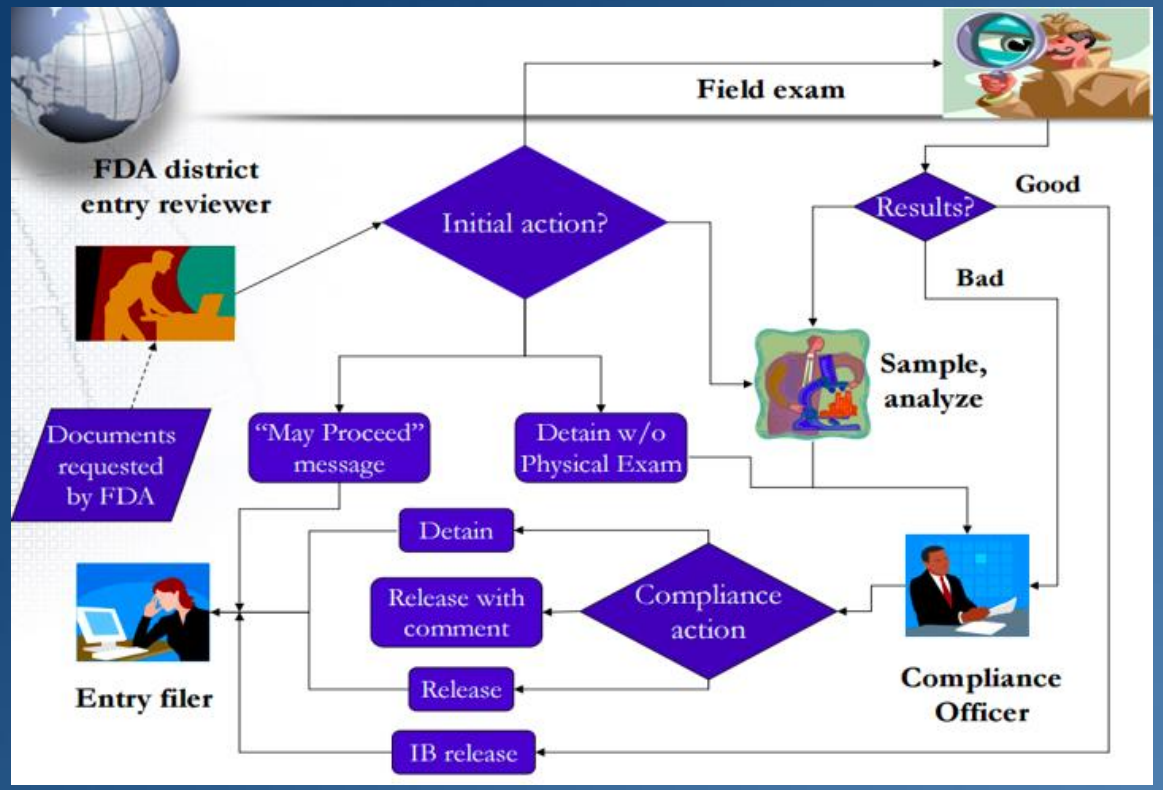
# TYPICAL FDA/CBP ENFORCEMENT ACTIONS

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

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# PRIZE TIME

ITACS is a terrific tool to check FDA's admissibility status and communicate with the FDA

- True or False?


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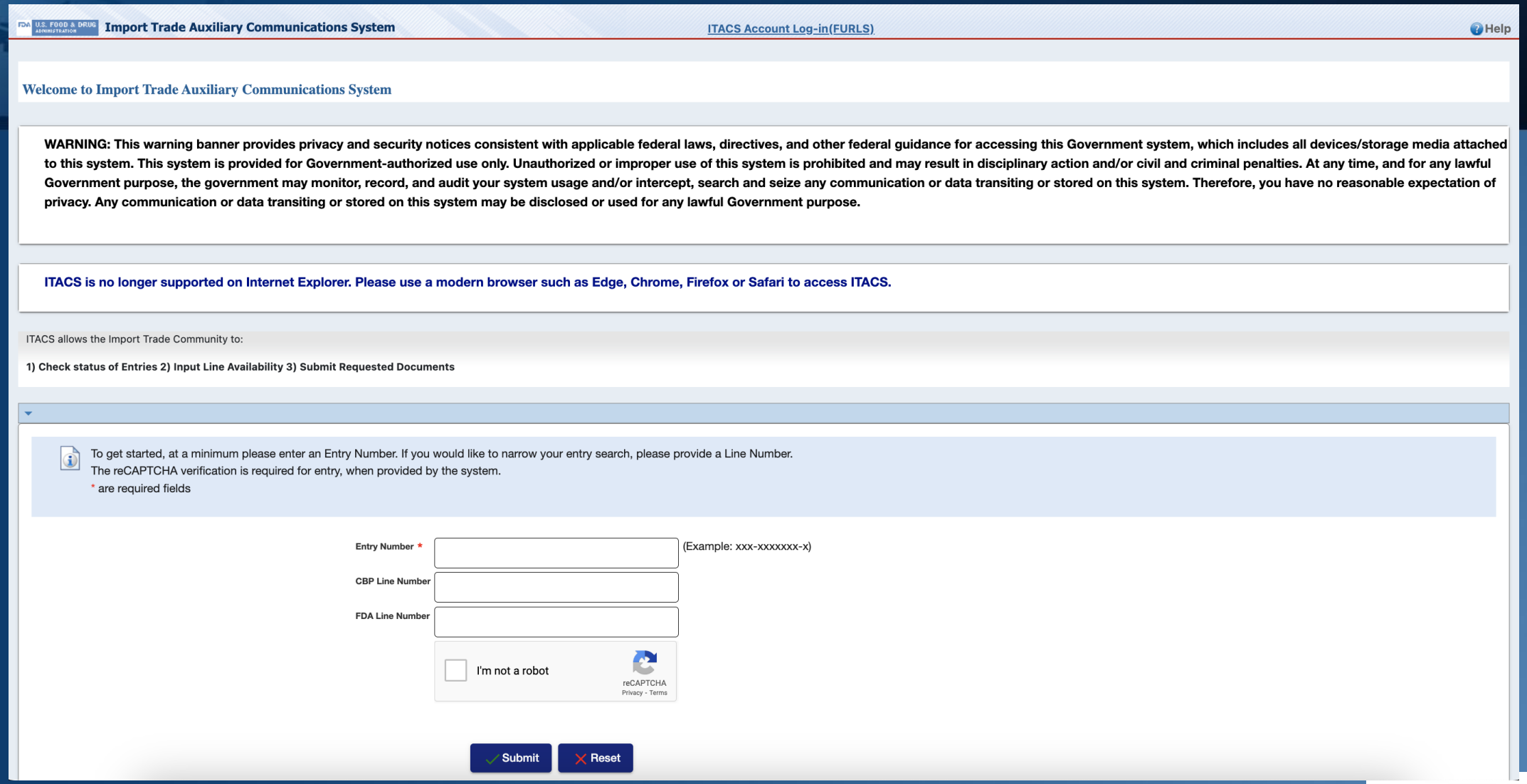
# ITACS




Import Trade Auxiliary Communications System

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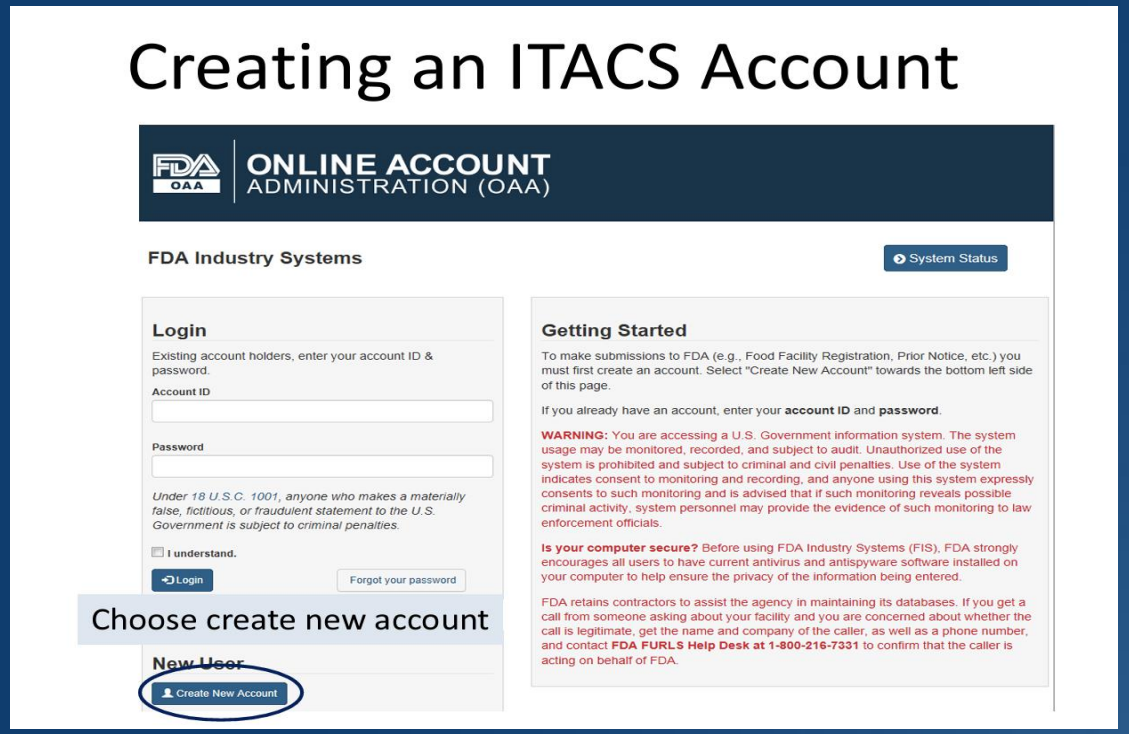
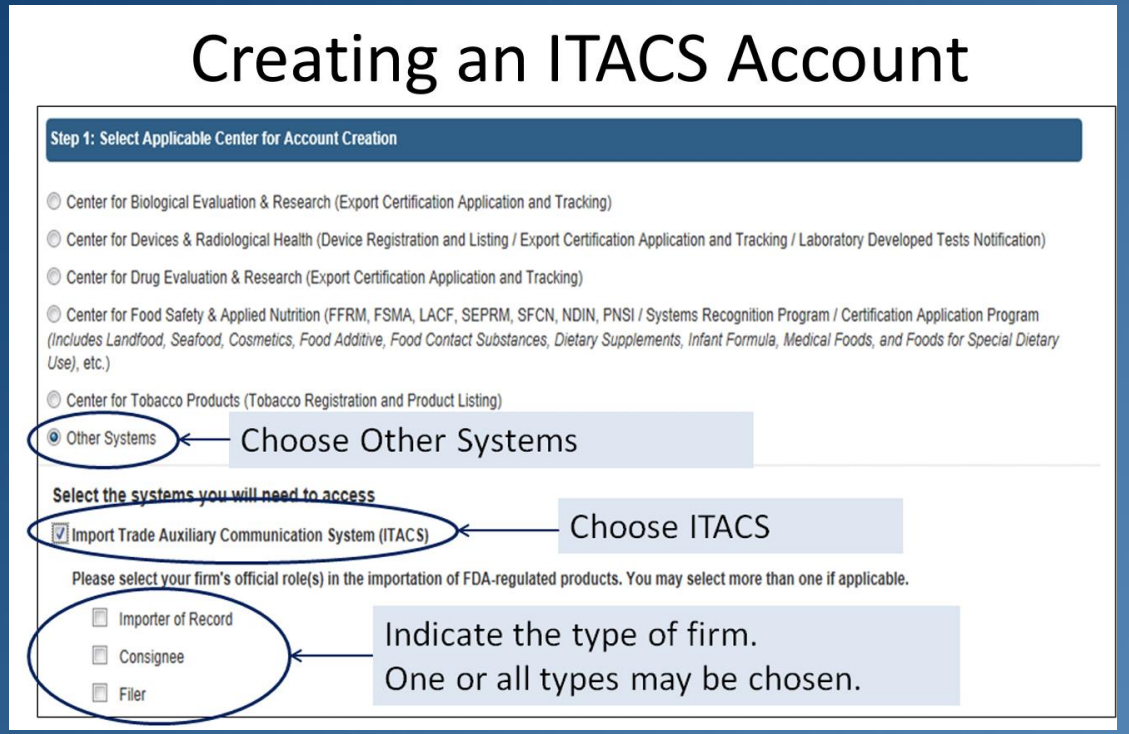
# HOW TO CREATE YOUR ITACS ACCOUNT

- Step by Step Instructions:




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

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# PRIZE TIME

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

– True or False?


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# NOTICE OF FDA ACTION #1

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

Entry Number:

Notice Number: 1

Importer:

Port of Entry: 5206, Miami Int'L Airport, FL
Arrival Date:
Filer of Record
Consignee:

**HOLD DESIGNATED**

**Documents Required and Notify FDA of Availability**
Summary of Current Status of Individual Lines

| Line ACS/ACE/FDA | Product Description | Quantity | Current Status |
|---|---|---|---|
| 11/1 | PKR TIL FRESH FIL 5-9OZ 1X10LB | 360 BX | Pending FDA Review |

* =Status change since the previous notice. Carefully read the sections which follow for important information regarding these lines. Please notify FDA and provide documentation, if you do not agree with the quantity listed in the Notice of Action.

@ = Consignee ID

**PRODUCTS NOT RELEASED BY FDA**

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

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

Please provide documentation concerning all products in this entry to the FDA. Include the USCBP Entry document (e.g. CF-3461 or CF-7501), bill of lading/airway bill, and commercial invoice for these products, annotated to show the USCBP/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include location and location identifiers, where applicable, for all lines in this entry.

DIAZ TRADE LAW

# PRIZE 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?


DIAZ TRADE LAW

# NOTICE OF FDA 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.
- 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.
- Request extension from the FDA NOW!

DIAZ TRADE LAW

# CONDITIONAL RELEASE

- 19 C.F.R. 141.113
- Food, drugs, devices, and cosmetics —
  - For purposes of determining the admissibility of any food, drug, device, or cosmetic, the release from CBP custody of any such product will be deemed conditional.
  - The conditional release period will terminate 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.

DIAZ TRADE LAW

# NOTICE OF REFUSAL

**HOLD DESIGNATED**

**Documents Required and Notify FDA of Availability**

Summary of Current Status of Individual Lines

| | | | | |
|---|---|---|---|---|
| * | 91/1 | ORANGE JUICE DRINK | 256 CS | Refuse |
| * | 91/2 | ORANGE JUICE DRINK | 64 CS | Refuse |
| * | 101/1 | ORANGE JUICE DRINK | 264 CS | Refuse |

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 Division 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.

DIAZ TRADE LAW

# 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."

DIAZ TRADE LAW

# REFUSAL

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

DIAZ TRADE LAW

# PRIZE 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. CBP/FP&F does not confer with FDA

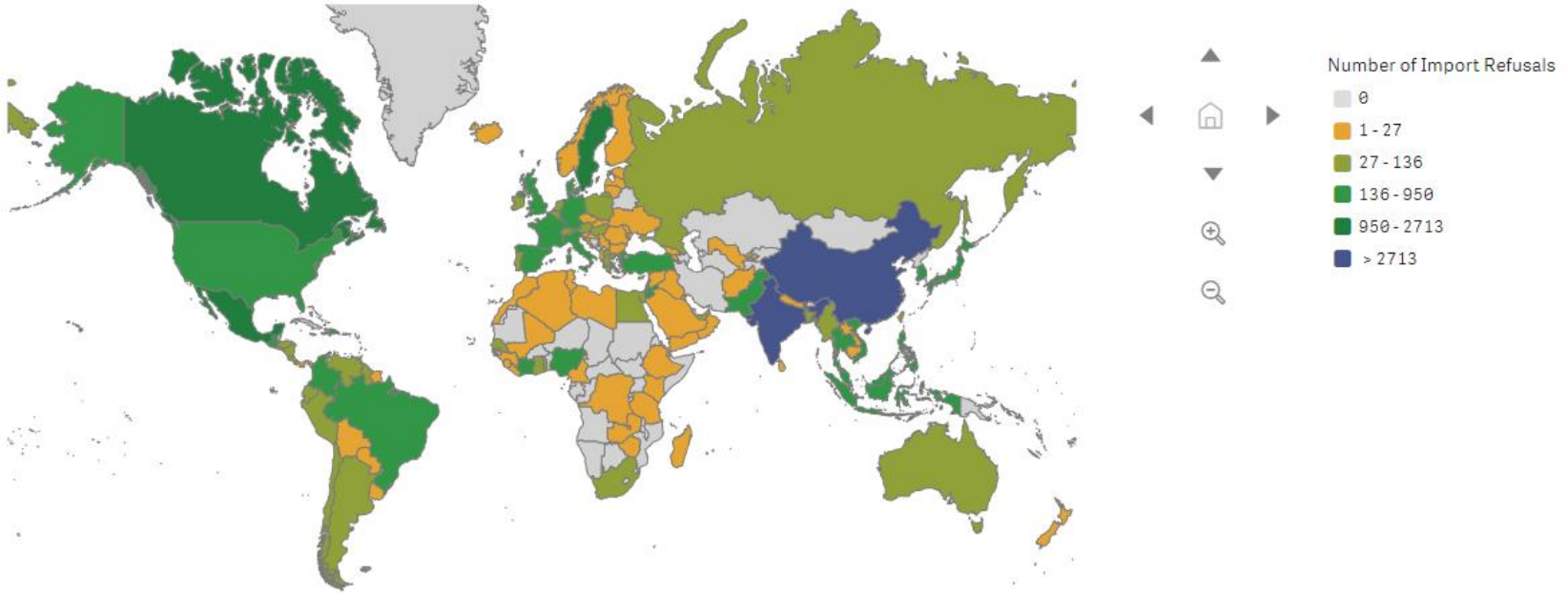

DIAZ TRADE LAW

# FY 2024-2025 REFUSAL STATISTICS

| Refusals by Product Category: | Animal Feed | Cosmetics | Devices | Drugs and Biologics | All Refusals |
|---|---|---|---|---|---|
| | 89 | 1,539 | 5,383 | 5,962 | 27,130 |
| | Housewares & Food Related | Human Foods | Radiological Health | Tobacco Products | |
| | 44 | 11,009 | 237 | 2,867 | |

**Unique Shipment Lines Refused by Country**

Total: 27,130

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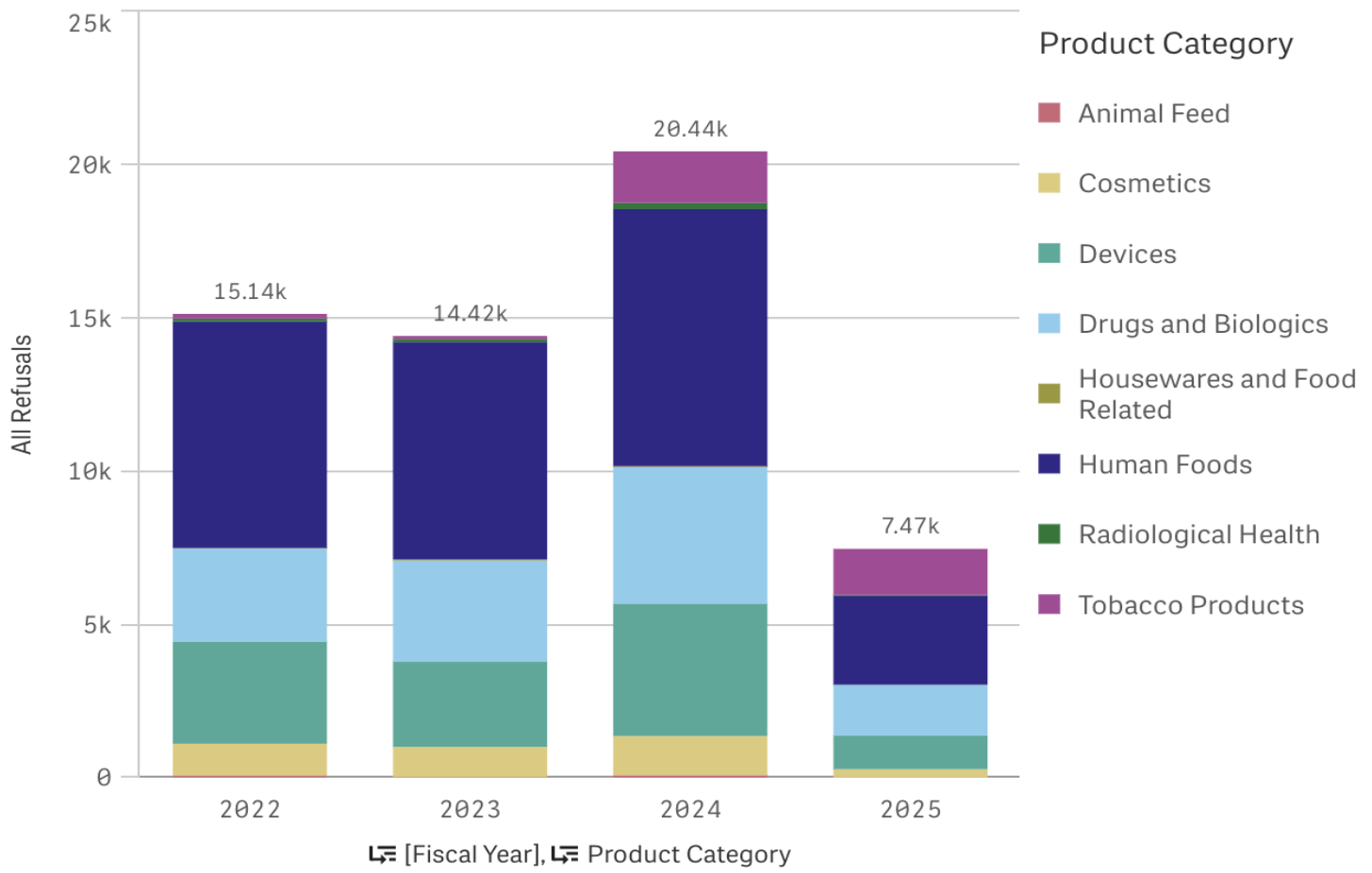
# Refusals by Product

Fiscal Years: 2022, 2023, 2024, 2025




**Refusals by Product Category:**

| Animal Feed | | Cosmetics | | Devices | | Drugs and Biologics |
|---|---|---|---|---|---|---|
| 169 | + | 3,580 | + | 11,560 | + | 12,413 |

| Housewares & Food Related | | Human Foods | | Radiological Health | | Tobacco Products |
|---|---|---|---|---|---|---|
| 105 | + | 25,767 | + | 431 | + | 3,438 |

All Refusals
57,463

DIAZ TRADE LAW

# LIQUIDATED DAMAGES

6601 NW 25th Street
Miami, FL 33122

U.S. Customs and Border Protection

**RE:**

Dear Sir/Madam:

This is regarding the above referenced claim incurred under the provisions of 19 CFR 142.12, 19 CFR 113.62(b) and 19 CFR 113.62(n)(1), in the assessed amount of $50,000.00

Upon further review of this case, it has been determined that cancellation is warranted. Accordingly, pursuant to *title 19, Code of Federal Regulations, section 172.11*, this claim is hereby cancelled, and this case is considered closed in our records.

Should you require additional information regarding this matter, please contact Samantha Garofalo or my staff at (305) 869-2891 or samantha.garofalo@cbp.dhs.gov.

Sincerely,

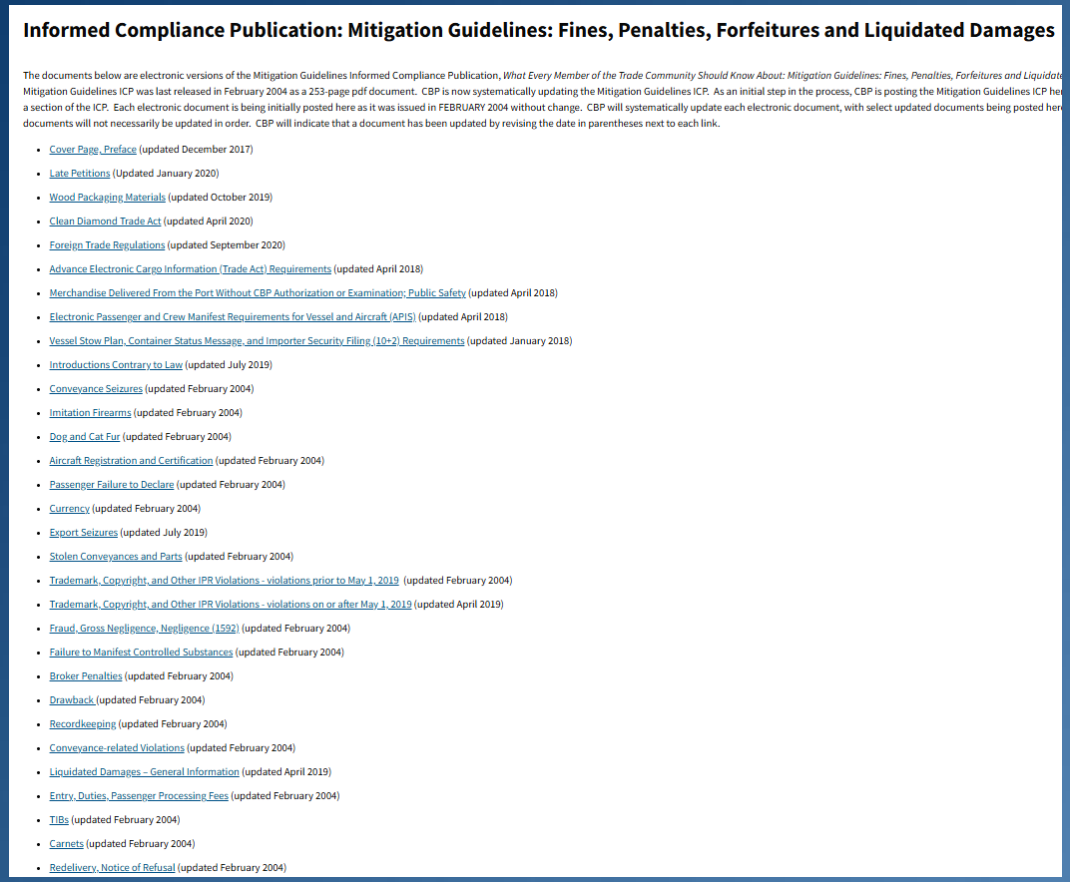
SAMANTHA J GAROFALO Digitally signed by SAMANTHA J GAROFALO Date: 2024.09.12 10:52:10 -04'00'

(for) Robert Del Toro
Director, Fines, Penalties and Forfeitures

DIAZ TRADE LAW

# FP&F PETITION PROCESS

- Claim from CBP
- **60 days** to respond
- FP&F Mitigation Guidelines / Mitigating Factors



**Informed Compliance Publication: Mitigation Guidelines: Fines, Penalties, Forfeitures and Liquidated Damages**

The documents below are electronic versions of the Mitigation Guidelines Informed Compliance Publication, *What Every Member of the Trade Community Should Know About: Mitigation Guidelines: Fines, Penalties, Forfeitures and Liquidate*
Mitigation Guidelines ICP was last released in February 2004 as a 253-page pdf document. CBP is now systematically updating the Mitigation Guidelines ICP. As an initial step in the process, CBP is posting the Mitigation Guidelines ICP he
a section of the ICP. Each electronic document is being initially posted here as it was issued in FEBRUARY 2004 without change. CBP will systematically update each electronic document, with select updated documents being posted her
documents will not necessarily be updated in order. CBP will indicate that a document has been updated by revising the date in parentheses next to each link.

- Cover Page, Preface (updated December 2017)
- Late Petitions (Updated January 2020)
- Wood Packaging Materials (updated October 2019)
- Clean Diamond Trade Act (updated April 2020)
- Foreign Trade Regulations (updated September 2020)
- Advance Electronic Cargo Information (Trade Act) Requirements (updated April 2018)
- Merchandise Delivered From the Port Without CBP Authorization or Examination; Public Safety (updated April 2018)
- Electronic Passenger and Crew Manifest Requirements for Vessel and Aircraft (APIS) (updated April 2018)
- Vessel Stow Plan, Container Status Message, and Importer Security Filing (10+2) Requirements (updated January 2018)
- Introductions Contrary to Law (updated July 2019)
- Conveyance Seizures (updated February 2004)
- Imitation Firearms (updated February 2004)
- Dog and Cat Fur (updated February 2004)
- Aircraft Registration and Certification (updated February 2004)
- Passenger Failure to Declare (updated February 2004)
- Currency (updated February 2004)
- Export Seizures (updated July 2019)
- Stolen Conveyances and Parts (updated February 2004)
- Trademark, Copyright, and Other IPR Violations - violations prior to May 1, 2019 (updated February 2004)
- Trademark, Copyright, and Other IPR Violations - violations on or after May 1, 2019 (updated April 2019)
- Fraud, Gross Negligence, Negligence (1592) (updated February 2004)
- Failure to Manifest Controlled Substances (updated February 2004)
- Broker Penalties (updated February 2004)
- Drawback (updated February 2004)
- Recordkeeping (updated February 2004)
- Conveyance-related Violations (updated February 2004)
- Liquidated Damages – General Information (updated April 2019)
- Entry, Duties, Passenger Processing Fees (updated February 2004)
- TIBs (updated February 2004)
- Carnets (updated February 2004)
- Redelivery, Notice of Refusal (updated February 2004)

DIAZ TRADE LAW

# PRIZE TIME

Once you are placed on an Import Alert it is impossible to be removed?

- True or False?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TRADE LAW

# IMPORT ALERTS

## Import Alert Industry Categories

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

| Industry Categories |
| --- |
| Foods |
| Color Additives |
| Conveyances |
| Cosmetics |
| Vitamins |
| Human Drug |
| Biologics |
| Animal Drug & Feeds |
| Medical Devices & Diagnostic Products |
| Rad Health |
| Miscellaneous |
| Tobacco Products |

## Import Alert Industry Group Medical Devices & Diagnostic Products

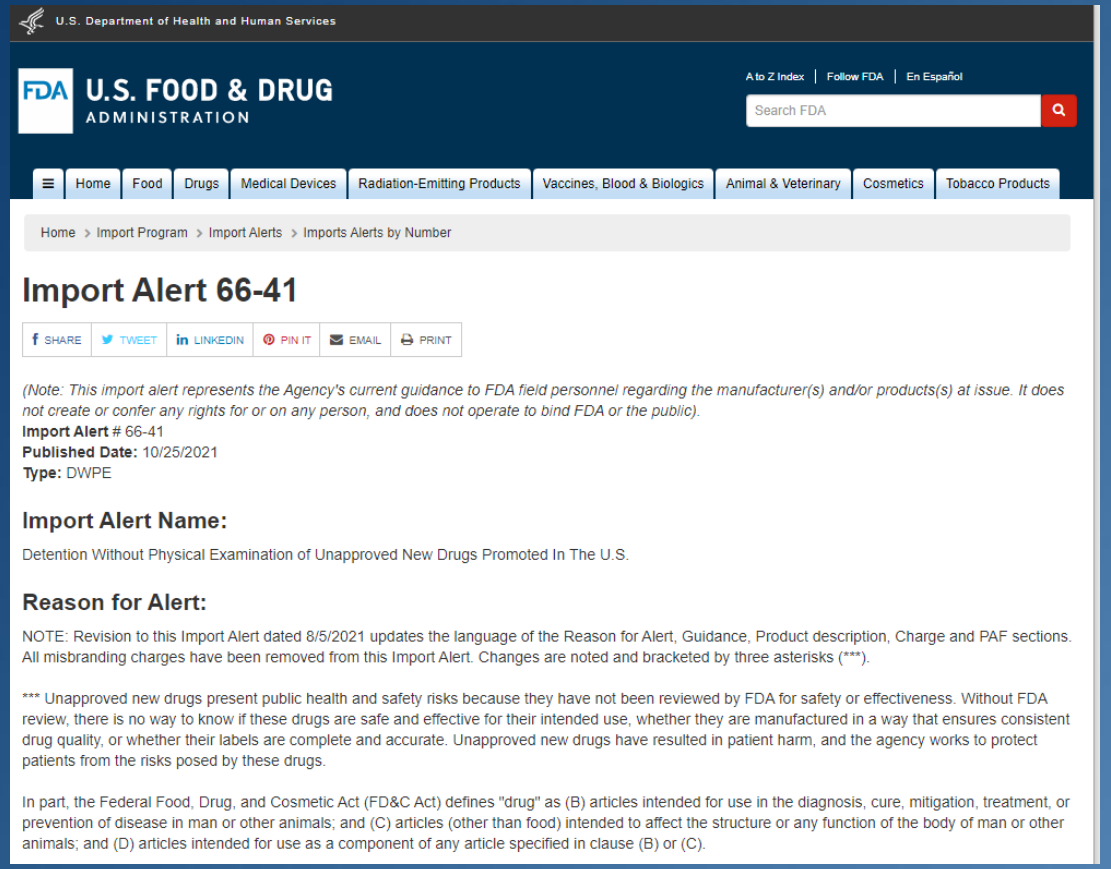
SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

| 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 |

DIAZ TRADE LAW

# IMPORT ALERT

- Import Alerts are listed by Country and Industry
  - Import Alert # 66-41
  - Type: DWPE (Detention Without Physical Examination)
  - Import Alert Name:
    - "Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S."



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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

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

## Import Alert 66-41

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

*(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** # 66-41
**Published Date:** 10/25/2021
**Type:** DWPE

### Import Alert Name:

Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.

### Reason for Alert:

NOTE: Revision to this Import Alert dated 8/5/2021 updates the language of the Reason for Alert, Guidance, Product description, Charge and PAF sections. All misbranding charges have been removed from this Import Alert. Changes are noted and bracketed by three asterisks (***).

*** Unapproved new drugs present public health and safety risks because they have not been reviewed by FDA for safety or effectiveness. Without FDA review, there is no way to know if these drugs are safe and effective for their intended use, whether they are manufactured in a way that ensures consistent drug quality, or whether their labels are complete and accurate. Unapproved new drugs have resulted in patient harm, and the agency works to protect patients from the risks posed by these drugs.

In part, the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines "drug" as (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (B) or (C).

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# DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE)

- Detention without physical examination, is appropriate when there exists **a**
  - **history of the importation of violative products**,
  - or **products that may appear violative**,
  - or when **other information indicates that future entries may appear violative**.

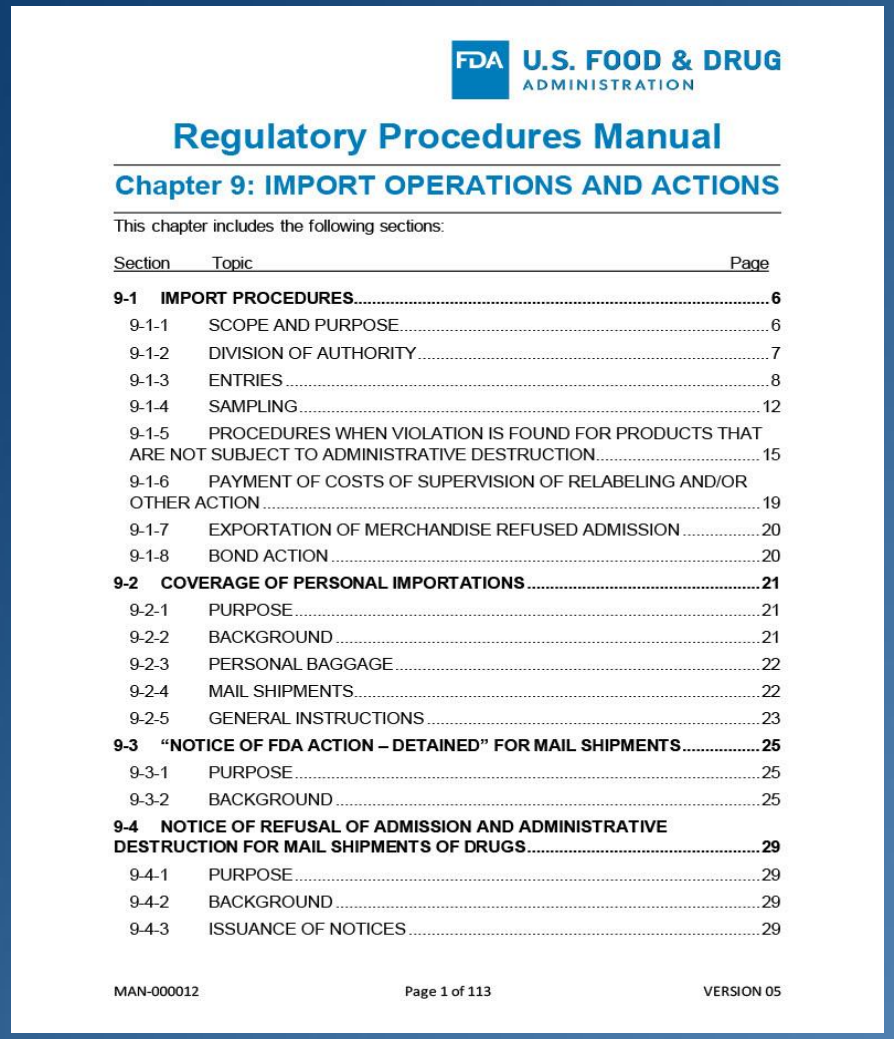
- Detention without physical examination properly places the responsibility for ensuring compliance with the law on the importer

DIAZ TRADE LAW

# 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

**Regulatory Procedures Manual**

**Chapter 9: IMPORT OPERATIONS AND ACTIONS**

This chapter includes the following sections:





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FDA U.S. FOOD & DRUG ADMINISTRATION

Office of Inspections and Investigations

November 8, 2024

Diaz Trade Law
12700 Biscayne Blvd, Suite 401
North Miami, FL, 33181

Via Email:

CASE #

This letter is in response to your request to remove Glucosoral Beverage Apple Artificially Flavored Oral Rehydration Drink (Manzana Solucion Electrolita Oral), Glucosoral Beverage Cherry Artificially Flavored Oral Rehydration Drink (Cereza Solucion Electrolita Oral), Glucosoral Beverage Coconut Artificially Flavored Oral Rehydration Drink (Coco Solucion Electrolita Oral), and Glucosoral Beverage Peach Artificially Flavored Oral Rehydration Drink (Melocoton Solucion Electrolita Oral) from , from Detention Without Physical Examination (DWPE) under Import Alert # 99-39, "Detention Without Physical Examination of Imported Food Products That Appear to Be Misbranded."

The information you provided, as well as FDA's national entry data, were reviewed. The data indicates that Glucosoral Beverage Apple Artificially Flavored Oral Rehydration Drink (Manzana Solucion Electrolita Oral), Glucosoral Beverage Cherry Artificially Flavored Oral Rehydration Drink (Cereza Solucion Electrolita Oral), Glucosoral Beverage Coconut Artificially Flavored Oral Rehydration Drink (Coco Solucion Electrolita Oral), and Glucosoral Beverage Peach Artificially Flavored Oral Rehydration Drink (Melocoton Solucion Electrolita Oral) from have met the criteria for removal from DWPE.

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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# PRIZE TIME

If a product is subject to an Import Alert, it may be detained at the U.S. border without physical examination

– True or False?


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# WARNING LETTERS

- The U.S. Food and Drug Administration (FDA) issues warning letters to notify companies or individuals of significant violations of federal regulations

| | Subject | # | % |
|---|---|---|---|
| 2024 | Family Smoking Prevention and Tobacco Control Act/Adulterated/Misbranded | 148 | 28% |
| | CGMP/Finished Pharmaceuticals/Adulterated | 83 | 16% |
| | Foreign Supplier Verification Program (FSVP) | 34 | 6% |
| | CGMP/QSR/Medical Devices/Adulterated | 17 | 3% |
| | Unapproved New Drugs/Misbranded | 16 | 3% |
| | Finished Pharmaceuticals/Unapproved New Drug/Misbranded | 14 | 3% |
| | CGMP/Food/Prepared, Packed or Held Under Insanitary Conditions/Adulterated | 13 | 2% |
| | Seafood HACCP/CGMP for Foods/Adulterated | 10 | 2% |
| | Investigational Device Exemptions (IDE)/Premarket Approval Application (PMA) Adulterated Device | 9 | 2% |

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# TOP TIPS WHEN RESPONDING TO A WARNING LETTER

- Respond On Time - 15 days! Be timely.
- 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.
- Focus On The Importance Of The Warning
- Write a thorough, proactive response
- Consult With Legal Counsel If Necessary
- Respond In Descending Order of Importance
- Take Responsibility
- Address Each Item Individually
- Identify Correct Causes Of Findings
- Develop Corrective Action Plans
- Set attainable goals!

DIAZ TRADE LAW

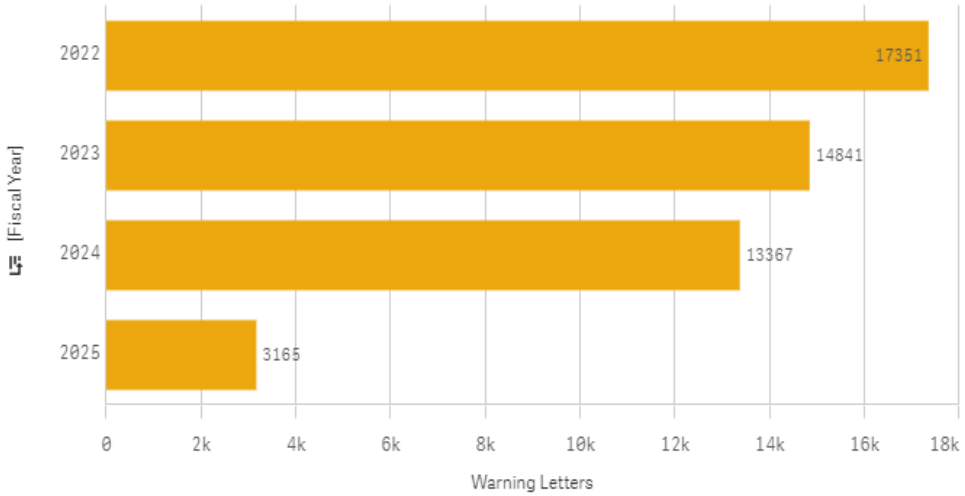
# FY 2022-2025 WARNING LETTER STATISTICS

| Compliance Actions: | Warning Letters | | Injunctions | | Seizures | All Actions |
|---|---|---|---|---|---|---|
| | 48,724 | + | 18 | + | 0 | 48,742 |

Export

**Warning Letters by Fiscal Year**

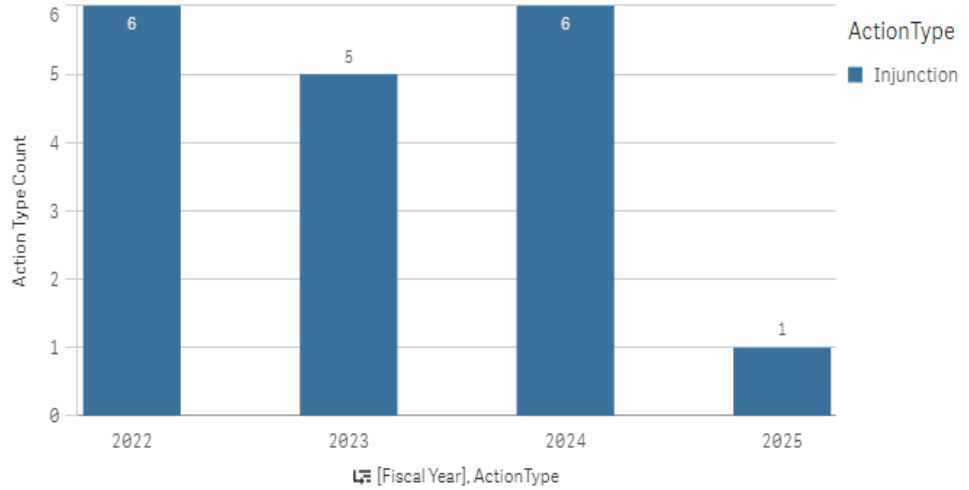
Fiscal Years: 2022, 2023, 2024, 2025




Export

**Injunctions and Seizures by Fiscal Year**

Fiscal Years: 2022, 2023, 2024, 2025

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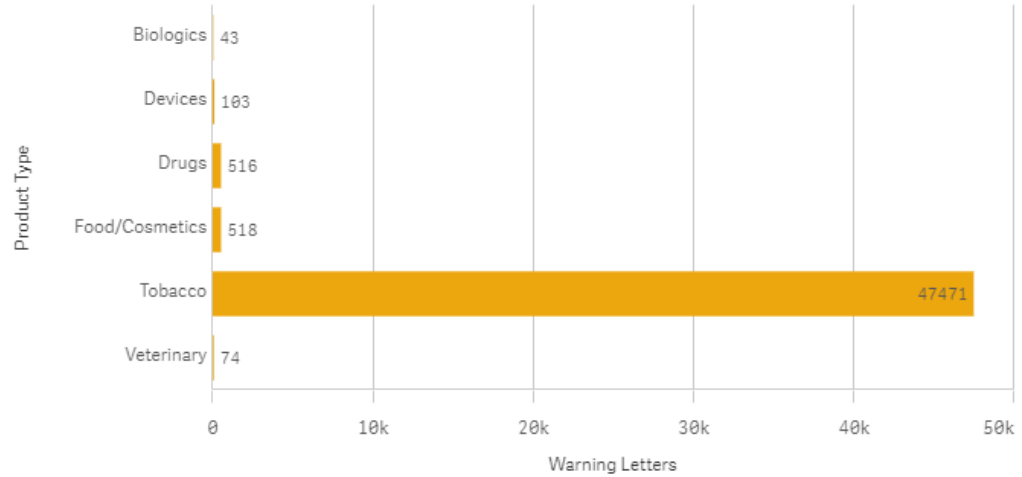
# MOST WARNING LETTERS ISSUED FOR TOBACCO!

| Actions by Product Type: | Biologics | | Devices | | Drugs | | Food / Cosmetics | | Tobacco | | Veterinary | All Actions * |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 43 | + | 103 | + | 516 | + | 518 | + | 47,471 | + | 74 | 48,725 |

Export

**Warning Letters by Product Type**

Fiscal Years: 2022, 2023, 2024, 2025




Export

**Injunctions and Seizures by Product Type**

Fiscal Years: 2022, 2023, 2024, 2025

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

* Cases associated with multiple product types will be counted once for each product type. In those situations, the values for All Actions by product type may differ from All Actions by compliance action type.

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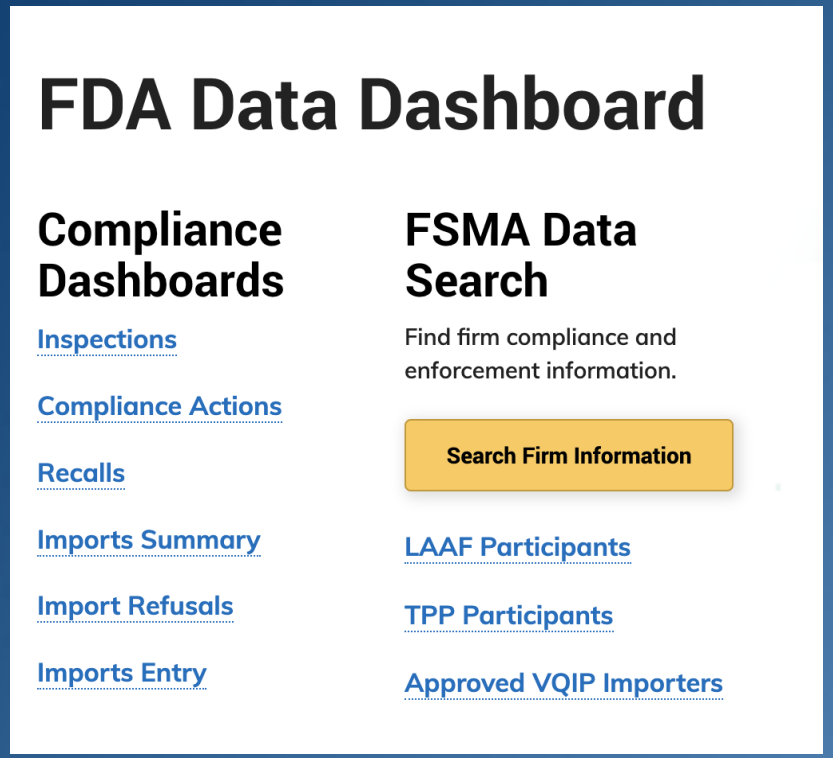
# HOW TO USE FDA'S DATABASES TO PERFORM DUE DILIGENCE

- **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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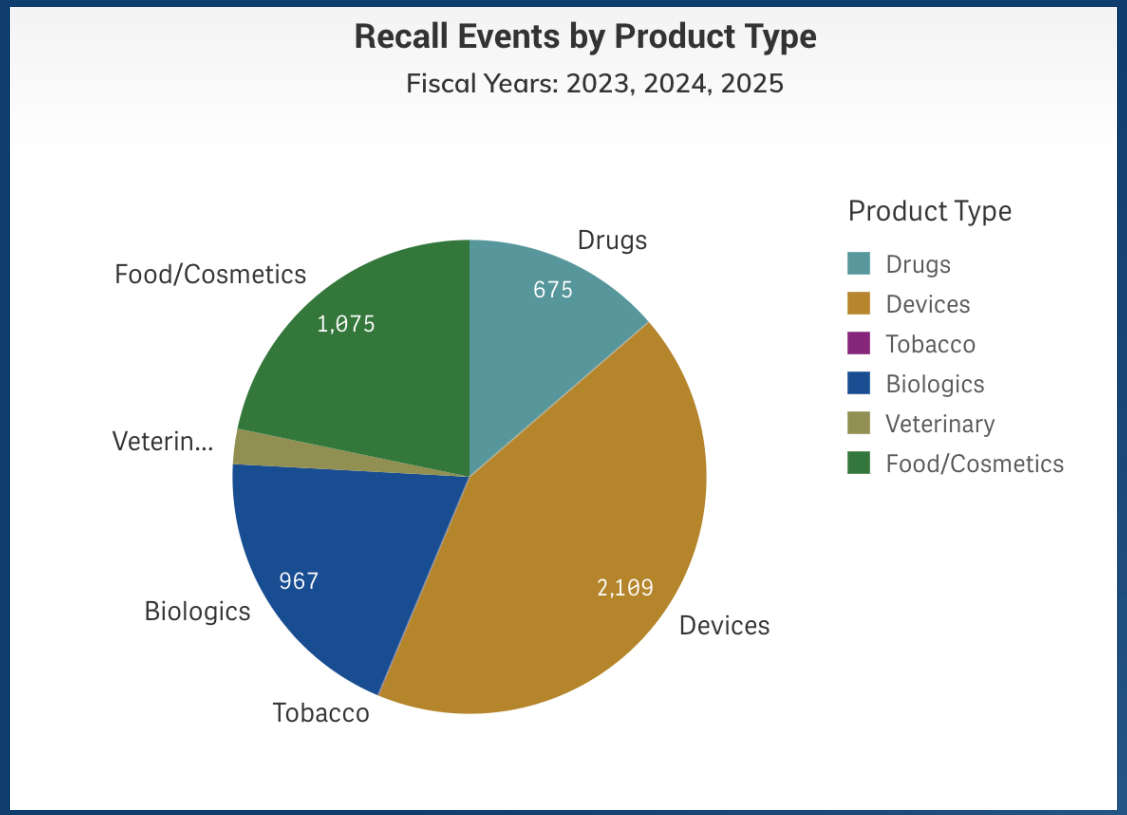
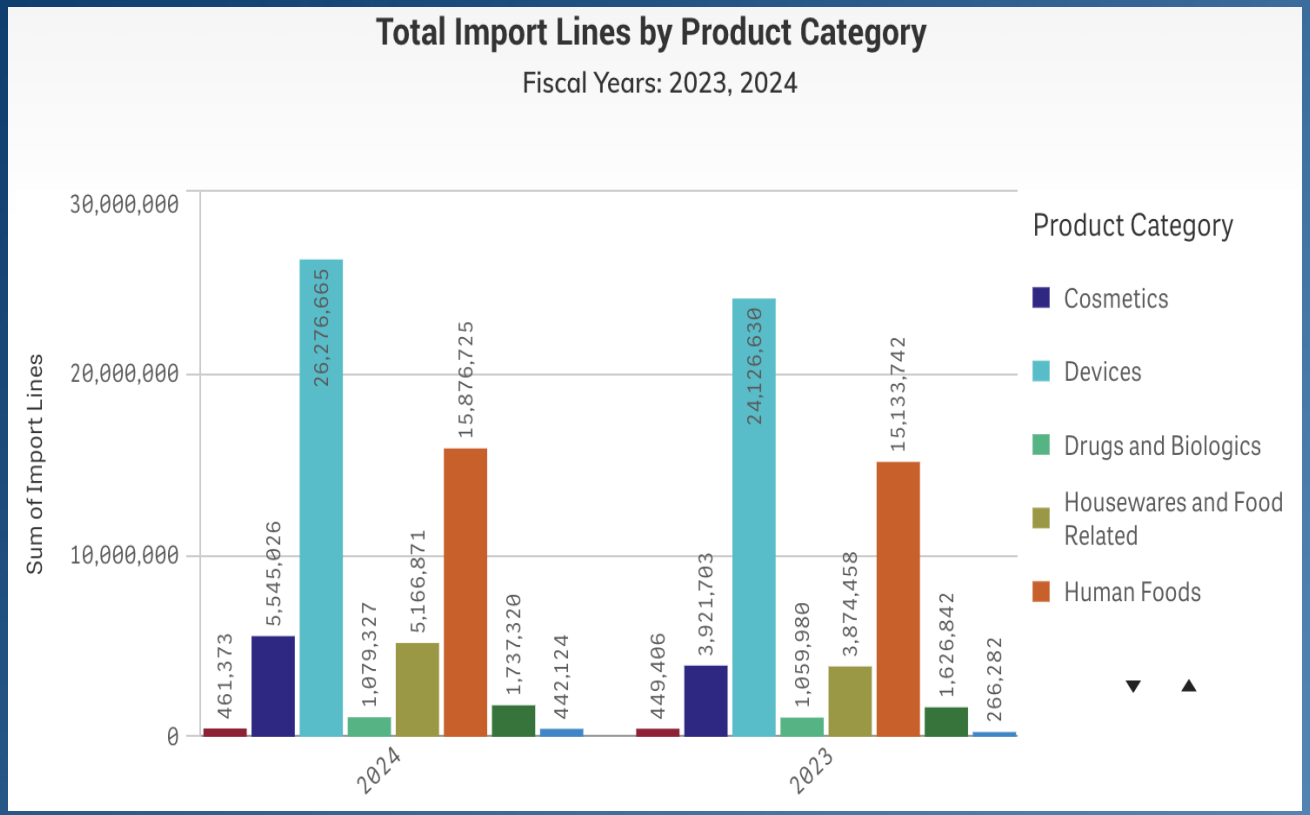
# MORE STATS!

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# PRIZE TIME

Which product category had the highest number of recall events?

A. Tobacco
B. Drugs
C. Devices
D. Food/Cosmetics


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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=8a54e8f088422of2018f4e388&id=27569bfof6
- FDA Data Dashboard - FDA Dashboards - Home
- Labeling Guide for Food - https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf
- Labeling Guide for Dietary Supplements - https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide
- ITACS Process - https://www.fda.gov/media/106771/download
- FDA Discusses TOP Reasons for Detention of Goods - https://diaztradelaw.com/fda-discusses-top-reasons-for-detention-of-goods-2/
- Import Alert: Detention without Physical Examination - https://www.fda.gov/industry/actions-enforcement/import-alerts
- Regulatory Procedures Manual - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual
- Am I Subject to FSVP? - https://www.fda.gov/media/94281/download
- FDA discusses TOP reasons for the detention of goods - https://diaztradelaw.com/fda-discusses-top-reasons-for-detention-of-goods-2/
- Part 101 – Food Labeling - https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101

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# TOP TIPS WHEN IMPORTING FOOD TO ENSURE COMPLIANCE

## SCAN ME!

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## TOP 10 TIPS* WHEN IMPORTING FOOD INTO THE U.S. TO ENSURE COMPLIANCE

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

1. Ensure your product complies with **FDA labeling** requirements (is in English, contains a compliant Principal Display Panel (PDP), Nutrition Facts and Informational Panel.
2. Ensure your Manufacturer's establishment is **registered with the FDA** and provides you with their Bioterrorism Act (BTA) Registration Number (if the manufacturer is foreign, ensure they have a U.S. agent www.diaztradeconsulting.com)
3. Perform **Due diligence**.
   a. Perform a meaningful risk analysis (trust but verify), review Warning Letters, Import Alerts, Inspections, and Recalls (use the FDA Data Dashboard).
4. Ensure you and your manufacture comply with FDA Food Safety Modernization Act (**FSMA**) standards and have a Foreign Supplier Verification Program (**FSVP**) in place.
   a. Preventative Controls for Human Food
   b. Preventative Controls for Animal Feed
   c. Produce Safety
   d. Foreign Supplier Verification Program
   e. 3rd Party Accreditation and Certification
   f. Sanitary Transportation
   g. Food Defense
5. Keep records proving you used **Reasonable Care. Review Importing into the U.S.: A Guide for Commercial Importers** (includes a reasonable care checklist).
6. Do you source products from many countries? Confirm you're using the correct **Country of Origin (COO)** and that your product is labeled with the valid COO.
7. Confirm you are using the correct **HTSUS & FDA Product Code**.
   a. Harmonized Tariff Schedule – **https://hts.usitc.gov/**
   **b. FDA product code builder**
8. Confirm you are using the correct **value** for your product; do you use related parties? Request a binding ruling from CBP.
9. Determine whether you should request a **binding ruling** from Customs.
   a. Customs Rulings Online - **http://rulings.cbp.gov/**
10. If you receive a Notice of FDA Action, be RESPONSIVE and request an extension if needed!

**ADDITIONAL RESOURCES FOR IMPORTING:**

- Basic Importing and Exporting
- CBP's Rulings and Legal Decisions
- Trade Data Online
- Stay in the Know! Sign Up For our Customs and Trade Blog

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



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# 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

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# TOP TIPS WHEN IMPORTING MEDICAL DEVICES TO ENSURE COMPLIANCE

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## A New Era in Cosmetics Regulation: The Modernization of Cosmetic Regulations Act

READ ME

In recent years, the cosmetics industry has experienced exponential growth, with new products being introduced almost daily. The average American consumer uses six to 12 cosmetics products daily. This growth has resulted in a need for more comprehensive regulation of cosmetic products to ensure consumer safety. The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is a new law that aims to modernize and strengthen cosmetic regulations in the United States.

## FDA's Proposed New National Drug Code – What You Need to Know

READ ME

The Food and Drug Administration (FDA) is proposing to amend their regulations governing the format of the National Drug Code (NDC). The NDC is a standard for uniquely identifying drug products marketed in the United States. The current standard has several acceptable formats. If the proposal is finalized, it will standardize the format of all NDCs.

## FDA Issues Draft Guidance for Registration and Listing of Cosmetic Product Facilities and Products

READ ME

On August 7, 2023, the U.S. Food and Drug Administration (FDA) issued draft guidance to assist cosmetics companies submitting cosmetic product listings and cosmetic product facility registrations to the agency. The agency characterized the guidance as playing a critical role in helping to ensure the safety of cosmetic products that many consumers use day-to-day.

## FDA Issues New Rules on Use of the Term "Healthy" on Food Labeling

READ ME

On December 19, 2024, the FDA announced a final rule to update the criteria that food must meet to qualify for use of the claim "healthy".

### New Requirements

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# Mastering FDA Compliance: Strategies for Navigating Enforcement and Import Regulations


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