Mastering FDA Compliance: Strategies for Navigating Enforcement and Import Regulations

JENNIFER DIAZ

Board Certified International Trade Attorney and President,
Diaz Trade Law

jen@diaztradelaw.com

305-456-3830

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.

DIAZ TRADE LAW

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.

DIAZ TRADE LAW

PRIZE TIME

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

DIAZ
TRADE LAW

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)

FDA

DIAZ TRADE LAW

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

DIAZ
TRADE LAW

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

DIAZ
TRADE LAW

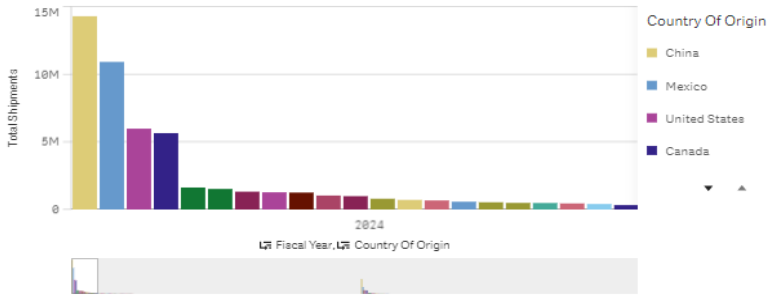
FY YEAR 2024-2025 – PRODUCTS IMPORTED INTO THE U.S. BY COUNTRY

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

Export

Total Shipments by Country of Origin Grouped by Fiscal Period

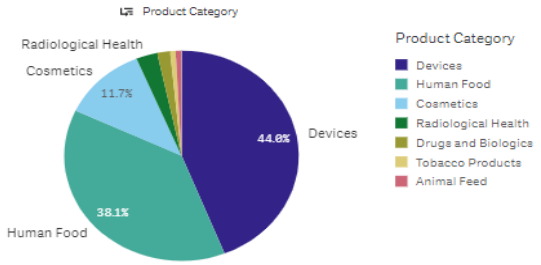
Countries: 226 of 240 | Fiscal Year: 2024, 2025



Export

Percentage of Shipments by Product Category

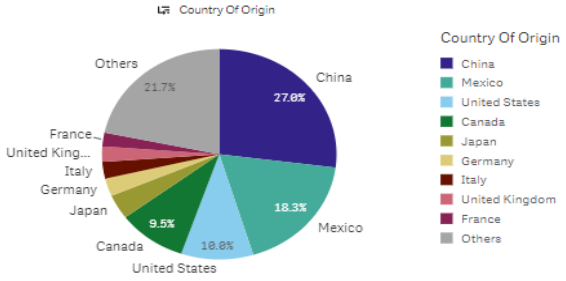
Countries: 226 of 240 | Fiscal Year: 2024, 2025



Export

Percentage of Shipments by Top 10 Countries of Origin

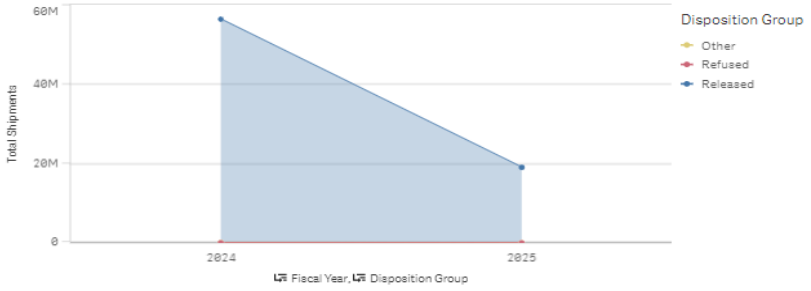
Countries: 226 of 240 | Fiscal Year: 2024, 2025



Export

Total Shipments by Final Disposition Grouped by Fiscal Period

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



DIAZ TRADE LAW

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

DIAZ TRADE LAW

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

DIAZ TRADE LAW

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

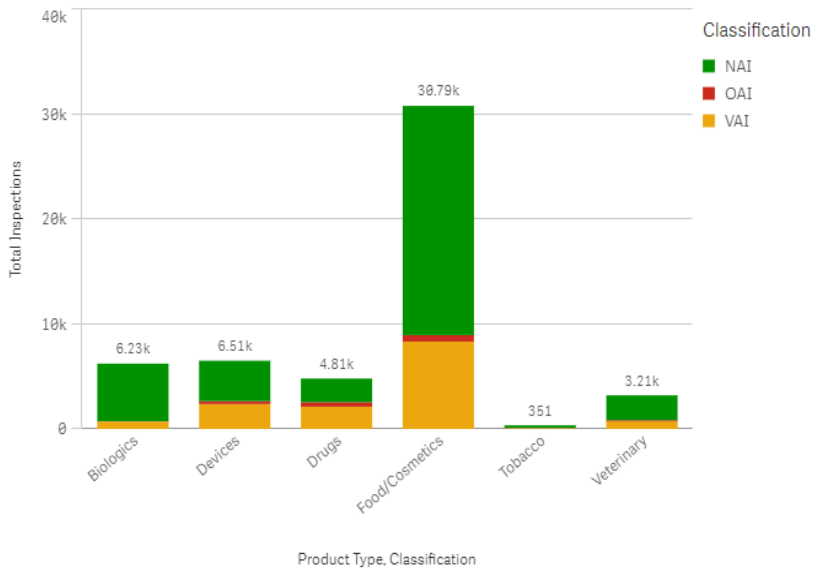
DIAZ
TRADE LAW

2022-2025 Inspection Findings

Export

Inspections Classification by Product Type

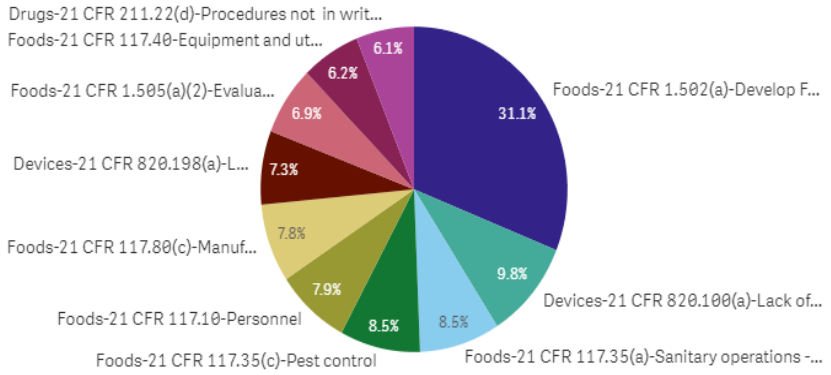
Fiscal Years: 2022, 2023, 2024, 2025



Export

Top 10 Citations

Fiscal Years: 2022, 2023, 2024, 2025



DIAZ TRADE LAW

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

DIAZ TRADE LAW

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)

DIAZ TRADE LAW

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

DIAZ TRADE LAW

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

DIAZ TRADE LAW

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

DIAZ TRADE LAW

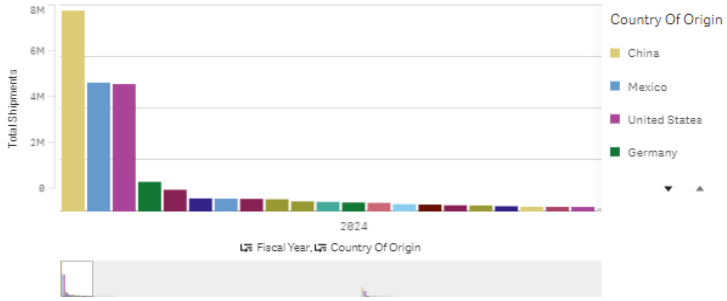
FY YEAR 2024-2025 – DEVICES IMPORTED INTO THE U.S. STATISTICS

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

Export

Total Shipments by Country of Origin Grouped by Fiscal Period

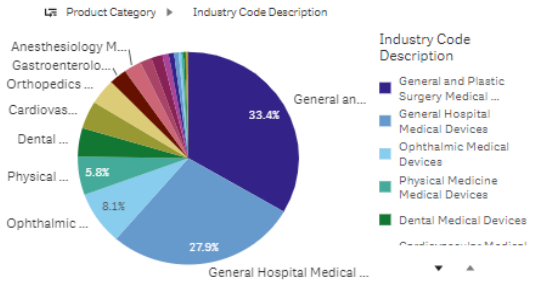
Countries: 195 of 240 | Fiscal Year: 2024, 2025



Export

Percentage of Shipments by Product Industry

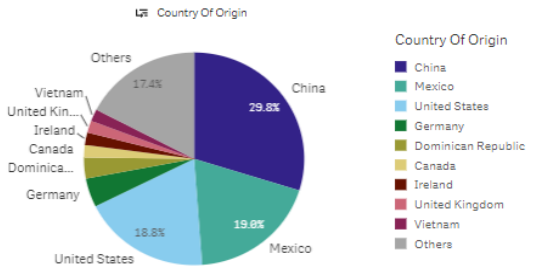
Product Category: Devices | Countries: 195 of 240 | Fiscal Year: 2024, 2025



Export

Percentage of Shipments by Top 10 Countries of Origin

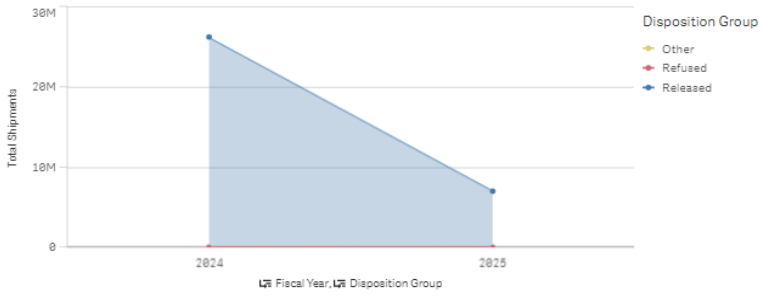
Countries: 195 of 240 | Fiscal Year: 2024, 2025



Export

Total Shipments by Final Disposition Grouped by Fiscal Period

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



DIAZ TRADE LAW

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)

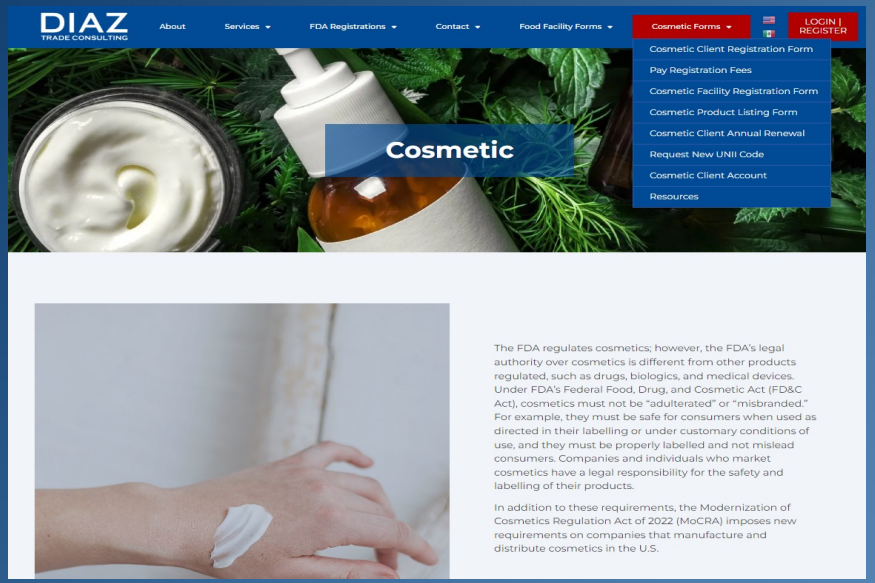
Common labeling violations include:

- **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

DIAZ TRADE LAW

CHECKLIST + NEW MoCRA REQUIREMENTS

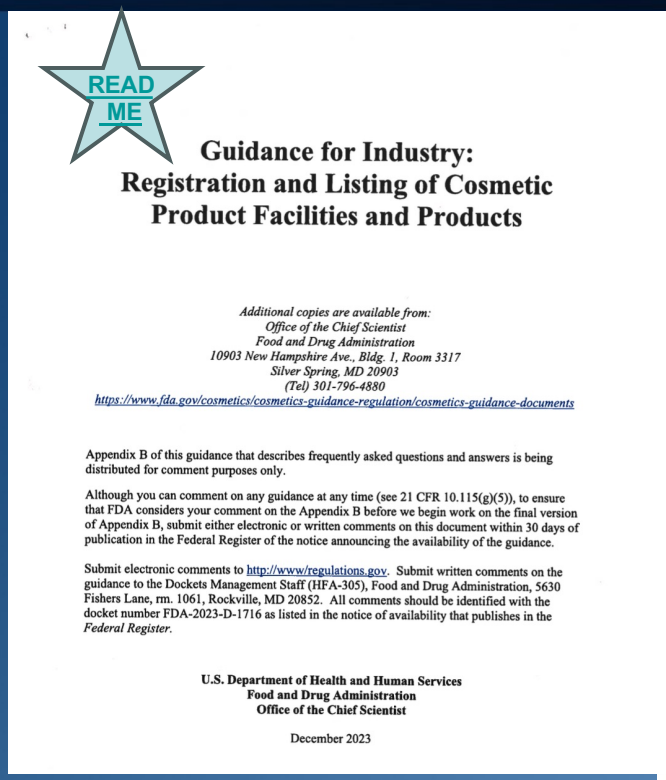
- Ensure your product meets the FDA's definition of a cosmetic: intended for cleansing, beautifying, promoting attractiveness, or altering appearance.
- Verify that all **ingredients** are safe and permissible for use in cosmetics.
- Ensure any **color additives** are FDA-approved for cosmetic use.
- 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



DIAZ TRADE LAW

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.



DIAZ TRADE LAW

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

DIAZ
TRADE LAW

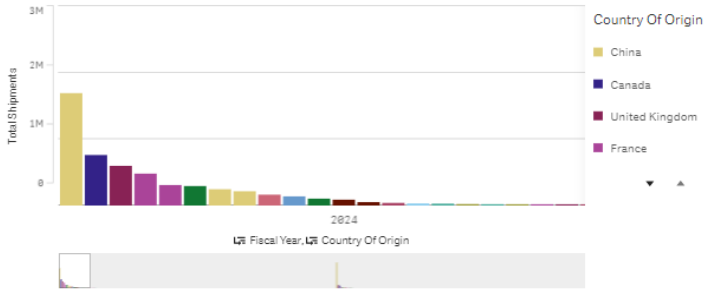
FY YEAR 2024-2025 – COSMETICS IMPORTED INTO THE U.S. STATISTICS

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

Export

Total Shipments by Country of Origin Grouped by Fiscal Period

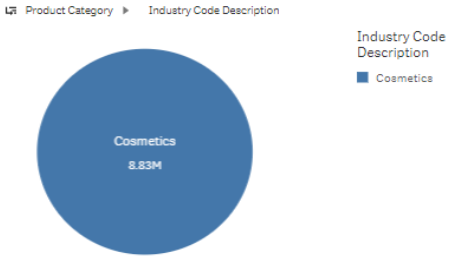
Countries: 187 of 240 | Fiscal Year: 2024, 2025



Export

Percentage of Shipments by Product Industry

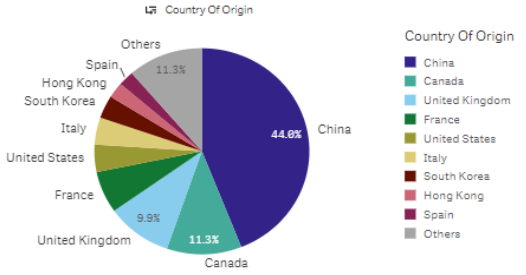
Product Category: Cosmetics | Countries: 187 of 240 | Fiscal Year: 2024, 2025



Export

Percentage of Shipments by Top 10 Countries of Origin

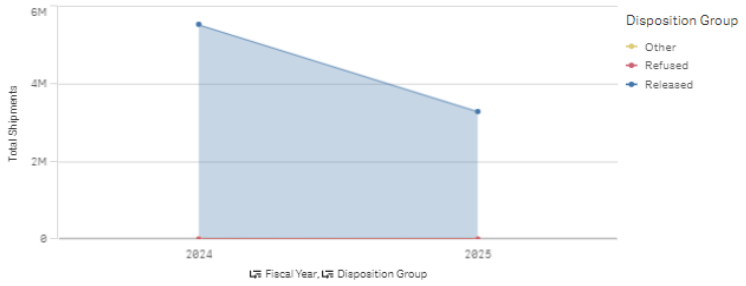
Countries: 187 of 240 | Fiscal Year: 2024, 2025



Export

Total Shipments by Final Disposition Grouped by Fiscal Period

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



DIAZ TRADE LAW

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

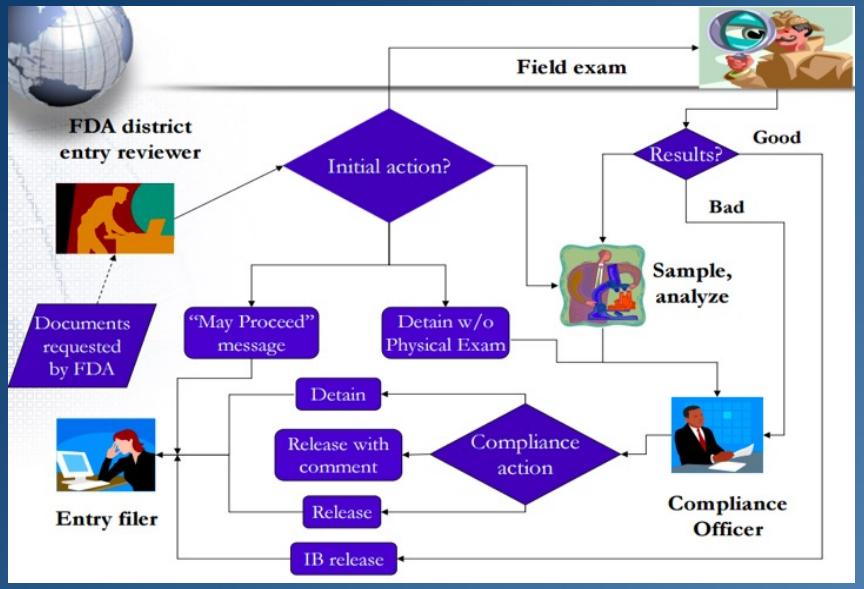
•Product labeling is not compliant (FDA does not pre-approve dietary supplement labeling, it is up to importers to

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

DIAZ TRADE LAW

TYPICAL FDA/CBP ENFORCEMENT ACTIONS

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



DIAZ TRADE LAW

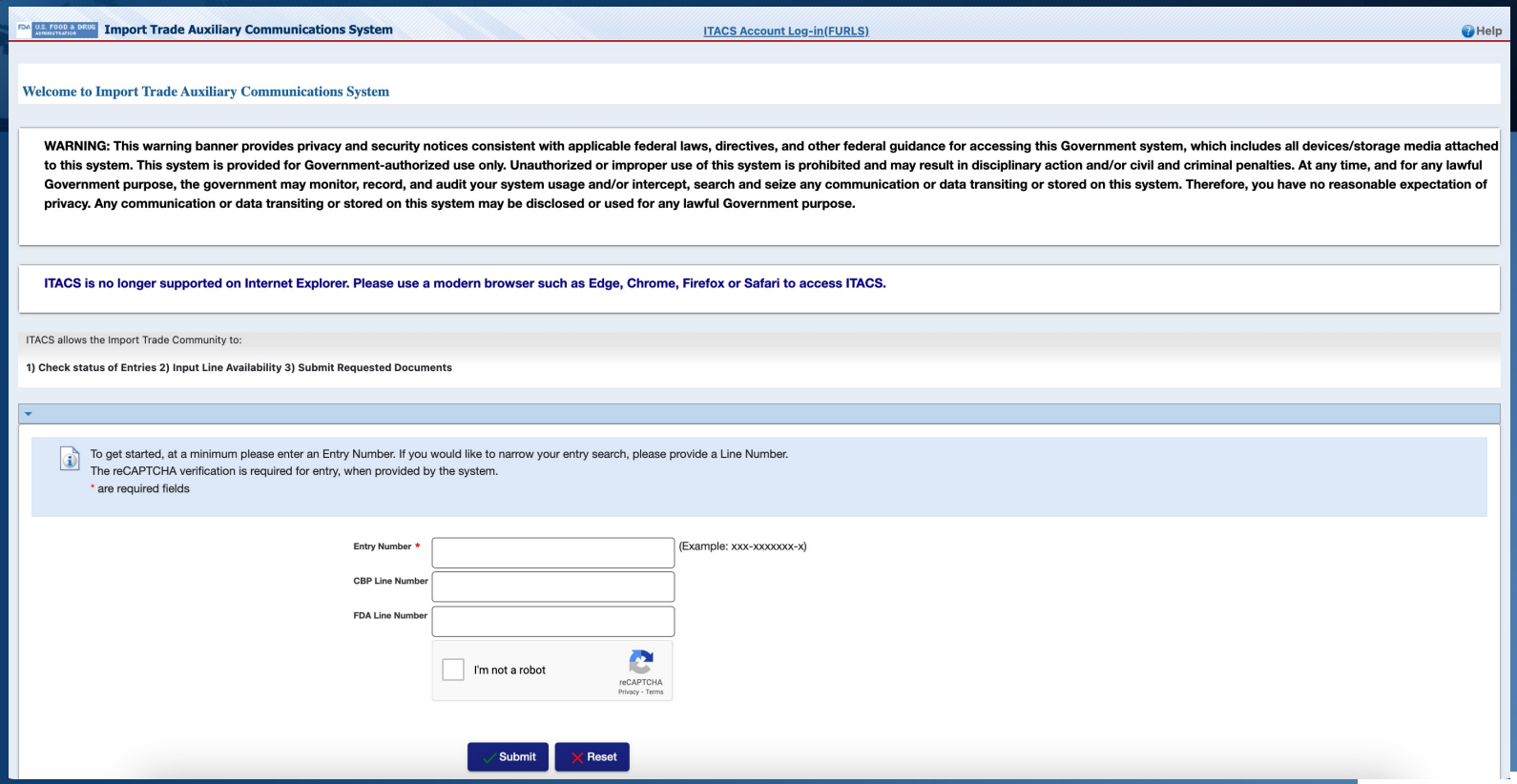
PRIZE TIME

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

- True or False?

DIAZ
TRADE LAW

ITACS

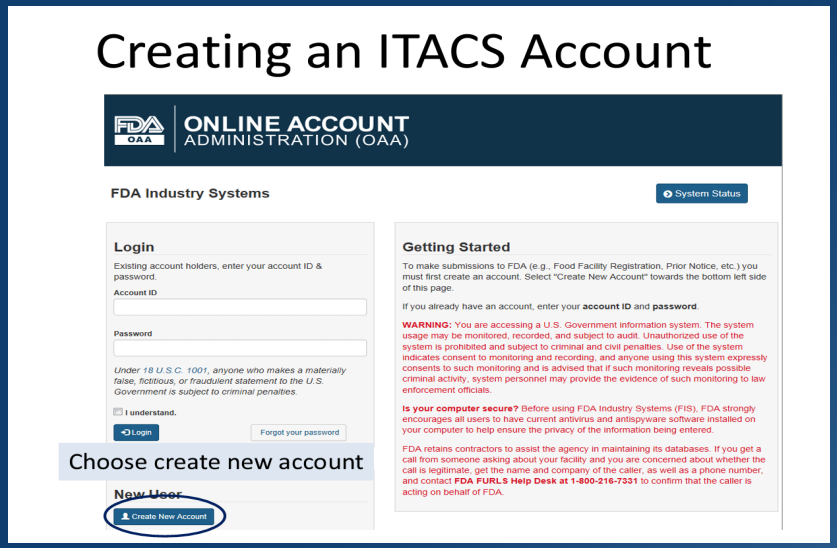


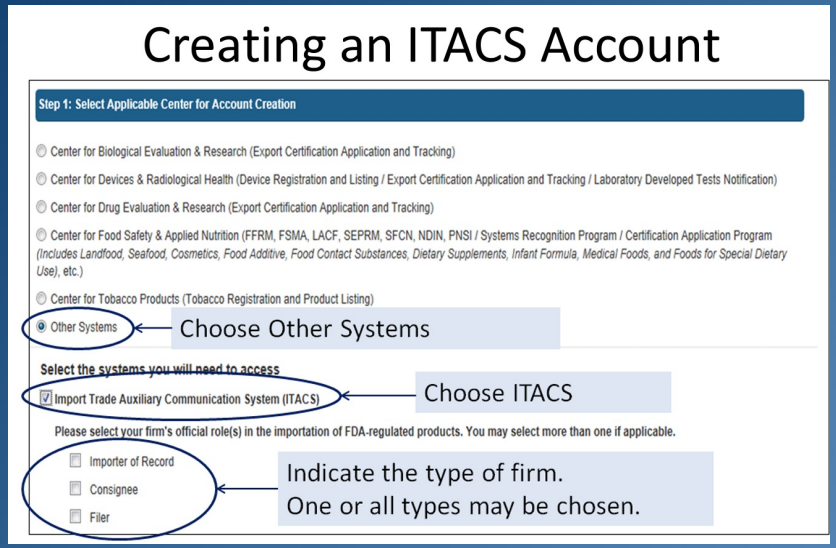
Import Trade Auxiliary Communications System

DIAZ TRADE LAW

HOW TO CREATE YOUR ITACS ACCOUNT

- Step by Step Instructions:





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

DIAZ TRADE LAW

PRIZE TIME

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

– True or False?

DIAZ
TRADE LAW

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

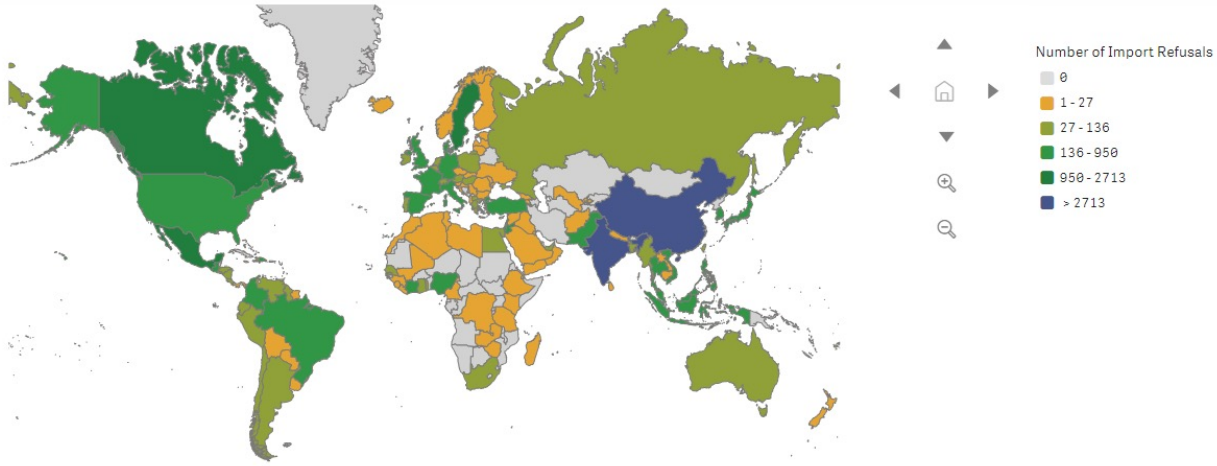
DIAZ
TRADE LAW

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

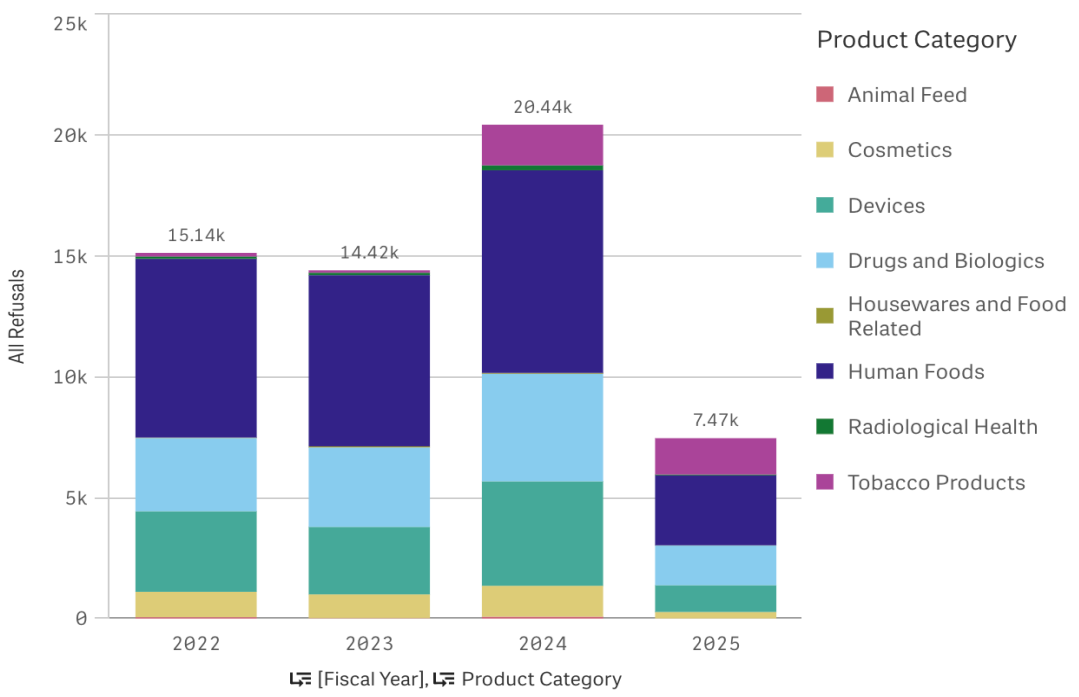
Total: 27,130



DIAZ TRADE LAW

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,

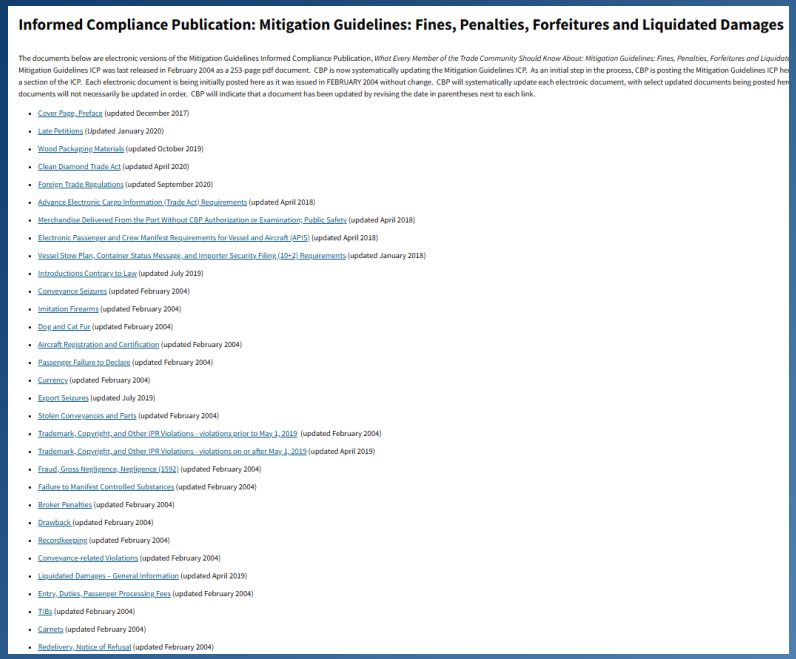
SAMANTHA J GAROFALO
Digitally signed by SAMANTHA J GAROFALO
Date: 2024.09.12 10:52:16 -04'00'

(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?

DIAZ
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

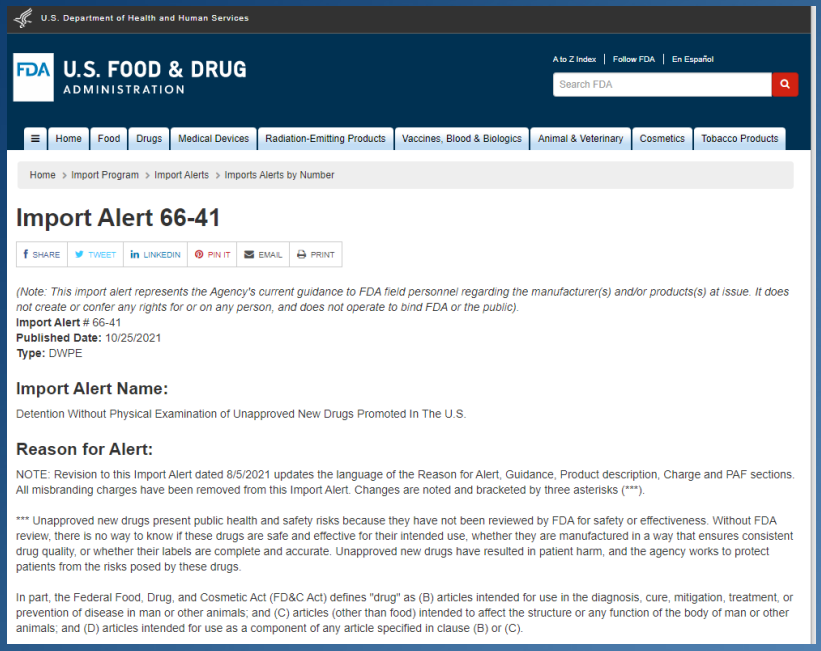
SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

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).

DIAZ TRADE LAW

DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE)

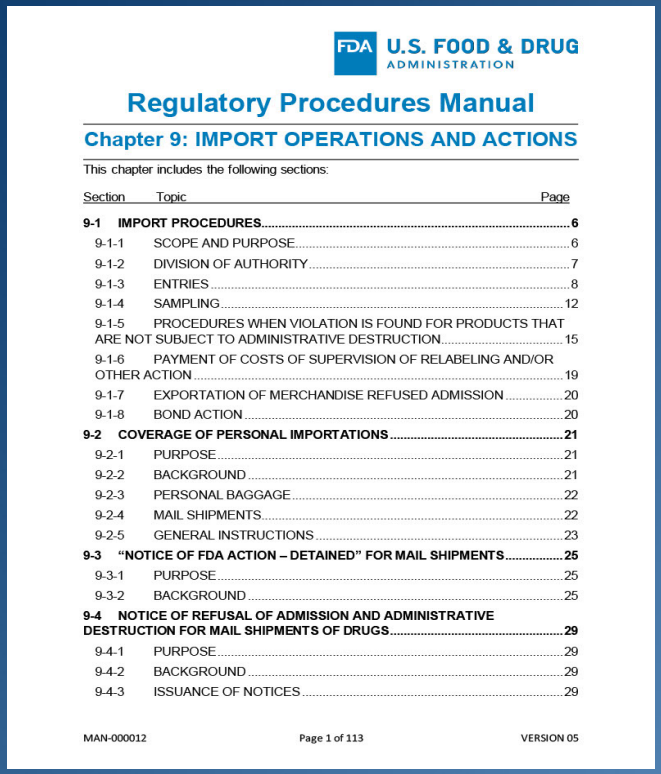
- Detention without physical examination, is appropriate when there exists **a**
  - **history of the importation of violative products**,
  - or **products that may appear violative**,
  - or when **other information indicates that future entries may appear violative**.

- 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:

DIAZ TRADE LAW

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.

DIAZ TRADE LAW

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?

DIAZ
TRADE LAW

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%

DIAZ TRADE LAW

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

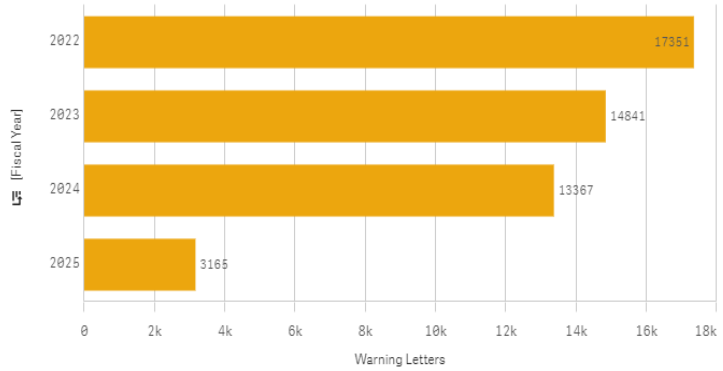
FY 2022-2025 WARNING LETTER STATISTICS

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

Export

Warning Letters by Fiscal Year

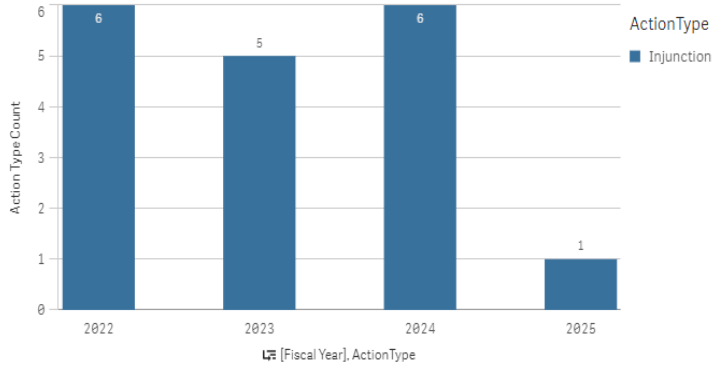
Fiscal Years: 2022, 2023, 2024, 2025



Export

Injunctions and Seizures by Fiscal Year

Fiscal Years: 2022, 2023, 2024, 2025



DIAZ TRADE LAW

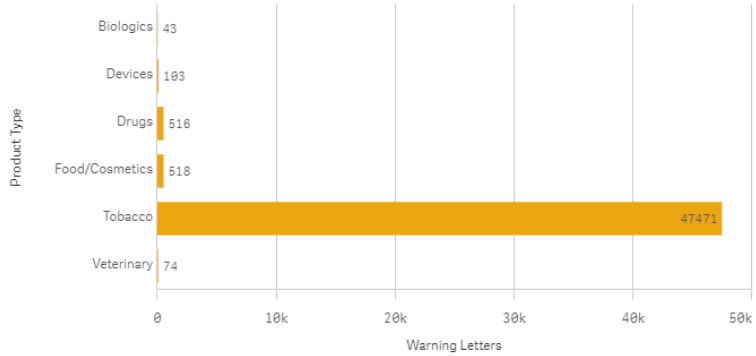
MOST WARNING LETTERS ISSUED FOR TOBACCO!

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.

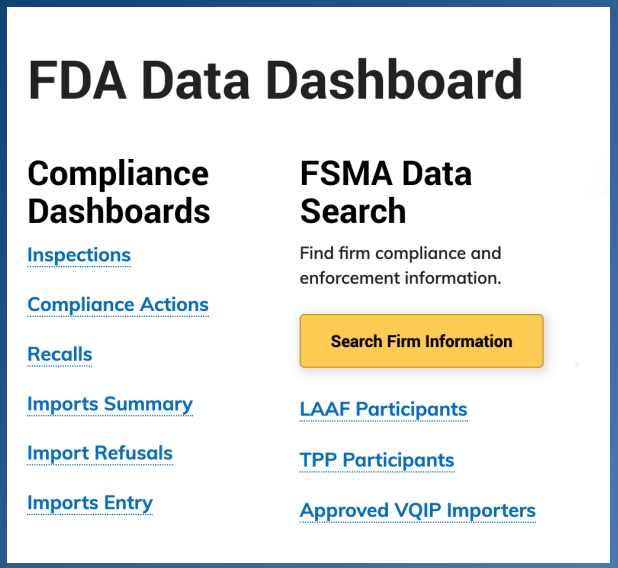
* Cases associated with multiple product types will be counted once for each product type. In those situations, the values for All Actions by product type may differ from All Actions by compliance action type.

DIAZ TRADE LAW

HOW TO USE FDA'S DATABASES TO PERFORM DUE DILIGENCE

- **What is the compliance history of the manufacturer, importer, and device?**

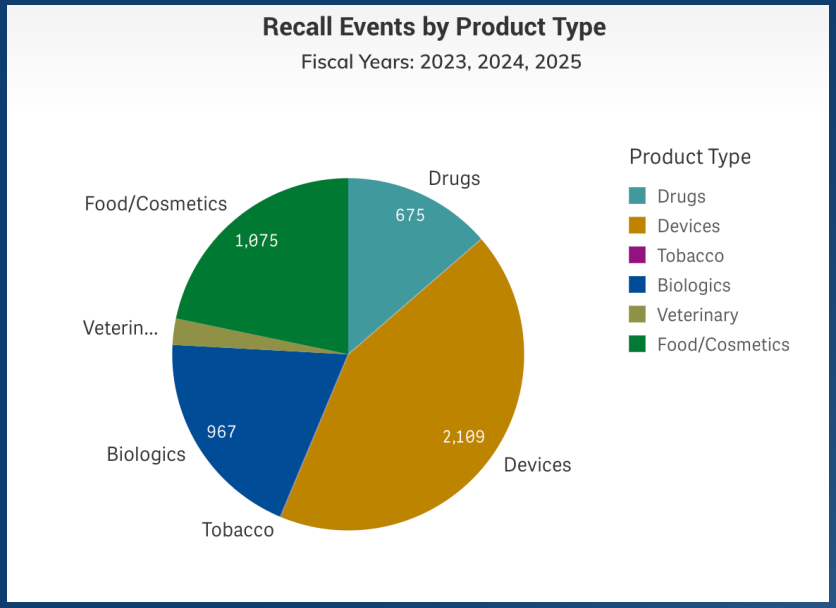
- FDA Data Dashboard (datadashboard.fda.gov)
  - Previous Inspections
  - Recalls
  - Warning Letters
  - Import Alerts
  - Refusals

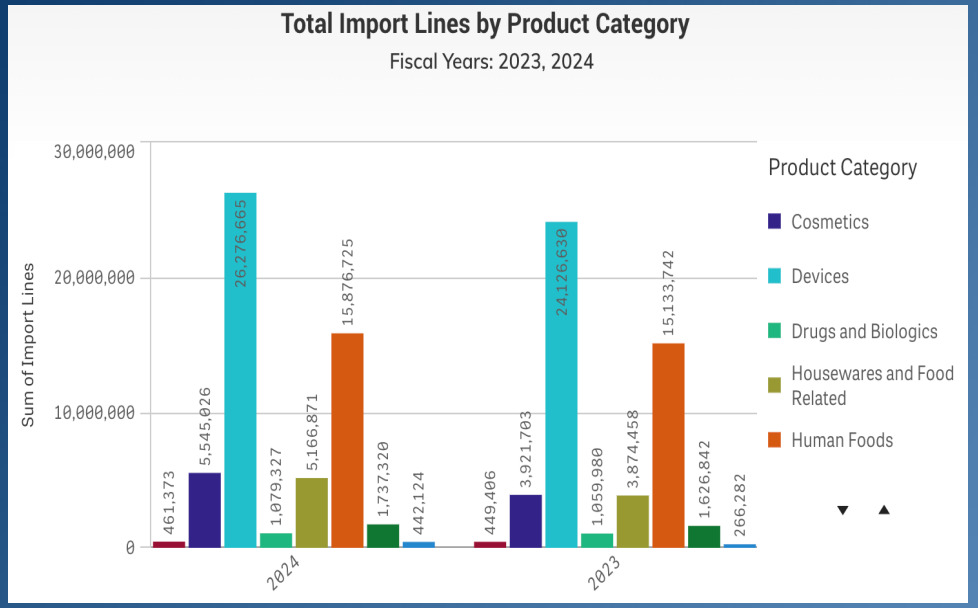


https://datadashboard.fda.gov/ora/index.htm

DIAZ TRADE LAW

MORE STATS!





DIAZ TRADE LAW

PRIZE TIME

Which product category had the highest number of recall events?

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

DIAZ
TRADE LAW

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

DIAZ TRADE LAW

DIAZ
TRADE LAW

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

TOP TIPS WHEN IMPORTING FOOD TO ENSURE COMPLIANCE

SCAN ME!

DIAZ
TRADE LAW

DIAZ
TRADE LAW

TOP TIPS* WHEN IMPORTING MEDICAL DEVICES TO ENSURE COMPLIANCE

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

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

ADDITIONAL RESOURCES FOR IMPORTING:

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

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

TOP TIPS WHEN IMPORTING MEDICAL DEVICES TO ENSURE COMPLIANCE

SCAN ME!

DIAZ
TRADE LAW

BLOG
DiazTradeLaw.com

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

DIAZ TRADE LAW

Diaz Trade Law Monthly Newsletter – Sign Up!

SUBSCRIBE

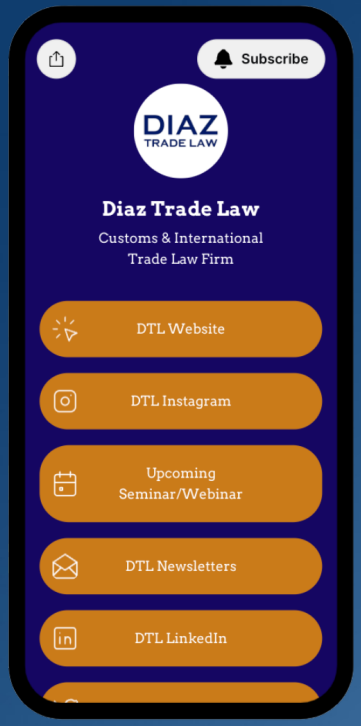
SCAN ME

DIAZ
TRADE LAW

KEEP IN TOUCH!

CONNECT WITH ME ON LINKEDIN!

SCAN ME



SCAN TO ACCESS
Diaz Trade Law's
Linktree

DIAZ TRADE LAW

Mastering FDA Compliance: Strategies for Navigating Enforcement and Import Regulations

JENNIFER DIAZ

Board Certified International Trade Attorney and President,
Diaz Trade Law

jen@diaztradelaw.com

305-456-3830