



Specializing in FDA Regulatory Matters

SIMPLE STEPS TO EXPORT GREEK FOOD TO THE UNITED STATES

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Who we are



EAS Consulting Group, LLC (EAS) specializes in Food and Drug Administration (FDA) regulatory matters. Our prime focus is to assist [domestic and foreign pharmaceutical](#), [medical device](#), [tobacco](#), [food](#), [dietary supplement](#), [cosmetic](#) and [biologics](#) firms comply with applicable laws and regulations. EAS is staffed with former FDA compliance and inspection officials and industry executives and is assisted by an extensive network of independent consultants with many years of FDA and industry experience.

Mission Statement

Our mission is to provide quality regulatory advice and service and to represent the best interests of our clients in an ethical, timely, and cost-efficient manner.

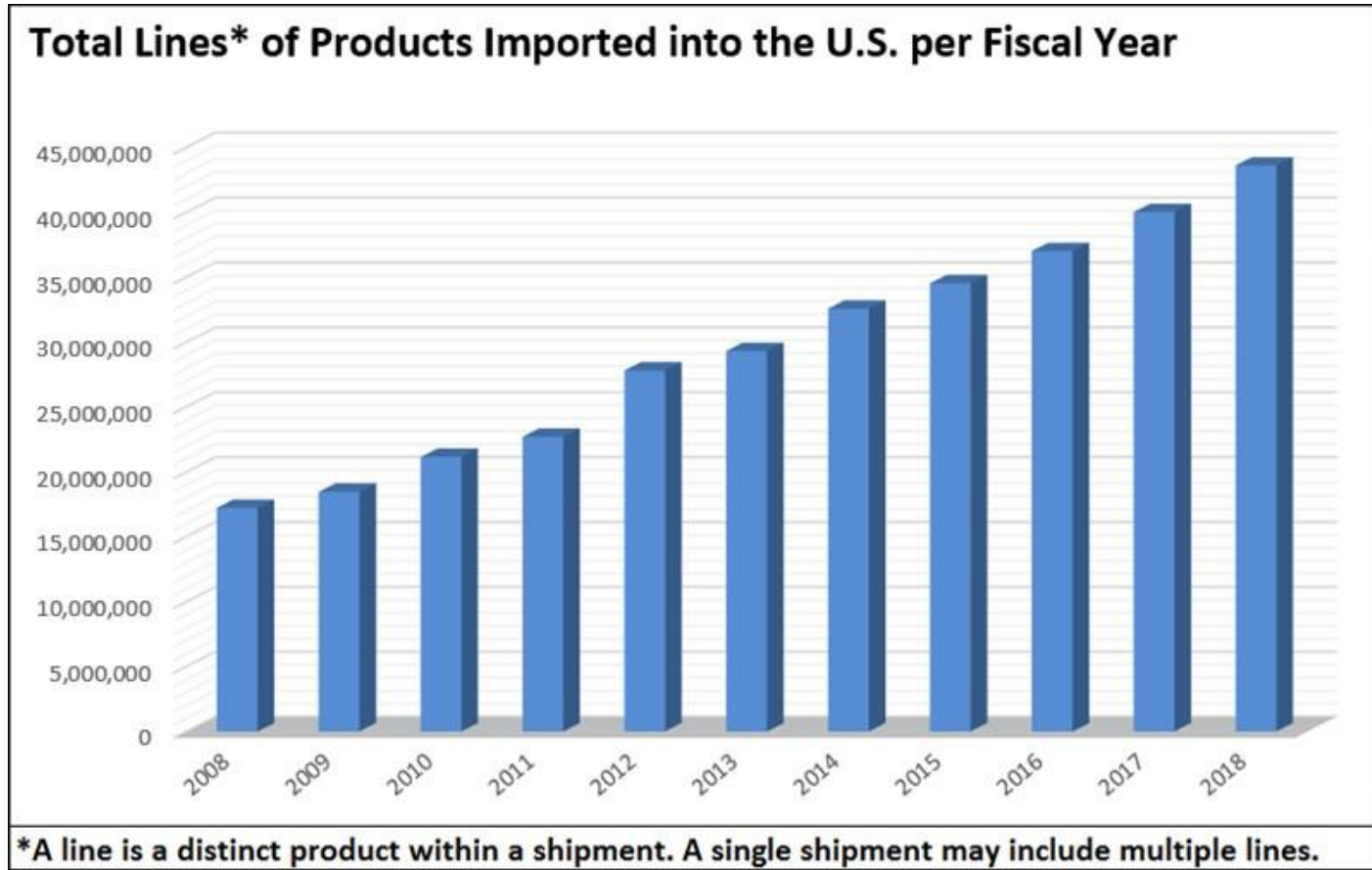


- 1960** - Arthur A. Checchi, a former FDA Associate Commissioner, founded the firm
- 1985** - Anthony Celeste, former FDA Director of Regional Operations takes over and renames the company “AAC Consulting Group”
- 1994** - Edward A. Steele retires from FDA after 30 years becomes AAC Vice President
- 2001** - AAC was acquired by Kendle International and Edward A. Steele, named President of AAC
- 2006** - Edward A. Steele, acquired the Food, Dietary Supplement, and Cosmetic consulting divisions and started EAS Consulting Group LLC
- 2012** - Edward A. Steele added new partners Dean Cirotta as President and Brett Steele as CFO. Expands Pharmaceutical, Medical Device, and Tobacco services
- Present** - EAS Consulting Group successfully supports all FDA regulated industries with 12 staff members and over 150 independent Advisors and Consultants

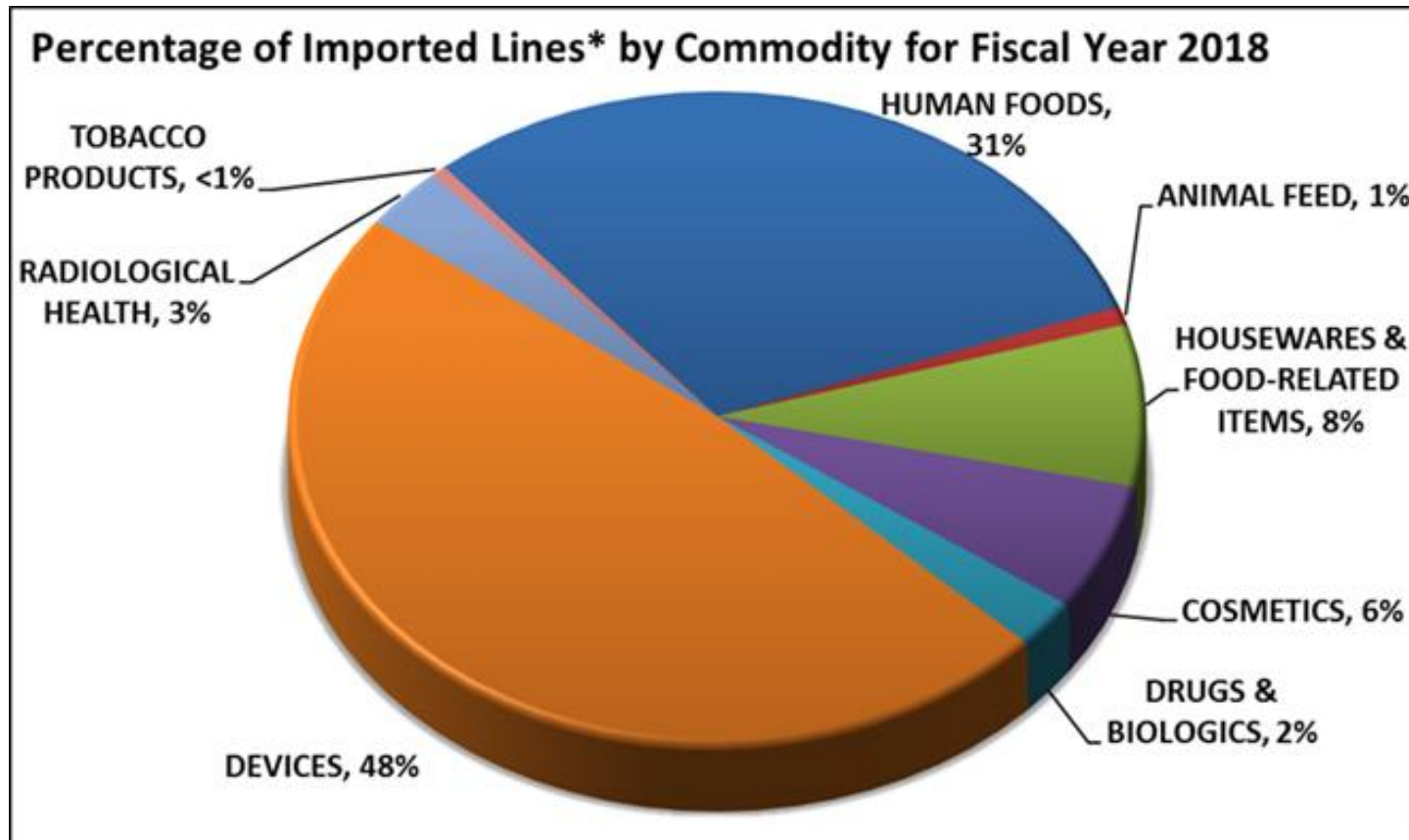
Foreign & Domestic Inspections



FDA Imported Products Into U.S.



Imported Products by Commodity



Food Bill Aims to Improve Safety

Research shows that the number of foodborne illness cases has increased in the United States, with more than 48 million cases in 2007. The CDC estimates that foodborne illness costs the economy \$15.5 billion annually. The bill aims to improve food safety by requiring the FDA to conduct more frequent inspections of food processing facilities, to require the FDA to issue more frequent recalls of contaminated food, and to require the FDA to issue more frequent warnings to consumers about food safety risks.



Food Safety Modernization Act (FSMA)

PL 111-353, 124 Stat. 3885



- Enacted January 4, 2011
- Sweeping new enforcement authority for FDA
- Self-enacting provisions and FDA deadlines on issuing regulations
- Lack of targeted funding
- FDA Structure for Enforcement

Eight (8) Foundation FSMA Rules

- 1. Human Food preventive controls**
- 2. Animal Feed preventative controls**
- 3. Produce rules – will set standards for farm growing practices**
- 4. Foreign Supplier Verification Proposed Rule**
- 5. Third Party Accreditation and Certification of Foreign Suppliers.**
- 6. Safe Food Transport – Inside the US only**
- 7. Intentional Adulteration & Food Defense**
- 8. Private Laboratory Accreditation & Certification (New)**

Importer and Supplier Responsibilities

- The first major compliance for importers is to verify that their foreign suppliers of food for human and animal consumption meet applicable FDA safety standards.
- Importers of FDA-regulated goods are responsible for ensuring that such imports are in compliance with FDA laws and regulations.
 - Before shipping into the U.S., importers should be aware of whether or not their product is listed on an import alert.

7 Simple Steps for Export of Food to USA



1. Identify a “Foreign Supplier Verification Program (FSVP)” Importer
2. Hire private US Customs Agent
3. Arrange for private FSMA-based audit/assessment of Greek food manufacturer
4. Ensure Greek food label meets US food labeling requirements
5. Hire consulting firm like EAS to serve as the FSVP Importer’s “Qualified Individual”
6. Hire US FSMA Agent to register Greek food manufacturer and/or warehouse with FDA – simple
7. Hire a Competent Consulting Firm Like EAS & Start Exporting

Exporting Greek Food to the USA – Step 1



Criteria for FSVP “Importer”

- **Office must be physically located in the USA & staffed**
- **No requirement to register FSVP “Importer’s” office with FDA**
- **Must obtain a Dunn & Bradstreet number (DUNs)**
- **FSVP Importer’s Office address, contact person name, contact person’s contact information and the specific types of Greek foods to be imported must be supplied to the private US Customs agent**

Exporting Greek Food to the USA – Step 2



Hire a Private US Customs Agent

- Will file all “trade” paperwork via the US Customs & Border Protection “ACE” electronic database for each shipment of Greek food imported into the USA
- Information submitted to “ACE” includes:
 - FSVP Importer Information
 - Type and amount of the imported Greek food
 - 24-hour prior notification
 - Correct Customs classification for imported Greek food

Exporting Greek Food to the USA – Step 3



Arrange for FSMA-based private audit/assessment of the Greek food manufacturer

- **Must comply with the FSMA “Preventive Controls for Human Foods (PCHF)” regulation**
- **Audit/Assessment will cover:**
 - **Written HACCP-like Preventive Controls food safety program**
 - **Review of the food manufacturing operations**
 - **Review of operational records**

Exporting Greek Food to the USA – Step 4



Ensure Greek food label meets US food labeling requirements

- **All label information must be in English – labels with both Greek and English languages discouraged**
- **All food ingredients must be evaluated to ensure they are allowed in foods in exported to the USA**
- **The nutritional “facts” panel format required by the US FDA is changing on January 1, 2020 and must be corrected no later than July 1, 2020**
- **The name of the food and any “claims” need to be closely evaluated to ensure compliance with US FDA requirements**

Exporting Greek Food to the USA – Step 5



Hire consulting firm like EAS to serve as the FSVP Importer's "Qualified Individual"

- **FSVP Qualified Individual must have knowledge and experience in food safety and the PCHF and FSVP regulations**
- **Short-Term – most Greek exporters will qualify as “Very Small Importers” and only need a attestation letter filed at the FSVP Importer’s office in the USA that the average annual value of the imported Greek food is less than \$1 million per year over the previous 3 years**
- **Long Term – once the average annual value of the imported Greek food exceeds \$1 million per year over the previous 3 years, then a full written food safety and risk assessment program must be developed by the FSVP Qualified Individual and filed at the FSVP Importer’s office in the USA**

Exporting Greek Food to the USA – Step 6



Hire US FSMA Agent to register Greek food manufacturer and/or food warehouse with FDA

- **US FSMA Agent must be located in the US**
- **Takes approximately 1 hour to complete the FDA FSMA registration for one Greek food exporter if the Greek exporter has provided the US FSMA Agent with the necessary information**
- **US FSMA Agent will handle all registration and FDA questions about the imported food for the Greek exporter**
- **US FSMA Agent needs to re-register the Greek food exporter every 2 years**
- **Any food exported to the US will be placed on hold or rejected if there is no FSMA registration**
- **FDA can withdraw a FSMA registration if there are serious food safety concerns about the imported Greek food – this prevents any further imports for that food from that Greek food manufacturer**

Exporting Greek Food to the USA – Step 7



Hire a Consulting Firm Like EAS Consulting Group that can provide all of the services identified in Steps #1 - #7 and

Start Exporting

Refused Entry – 801(a)

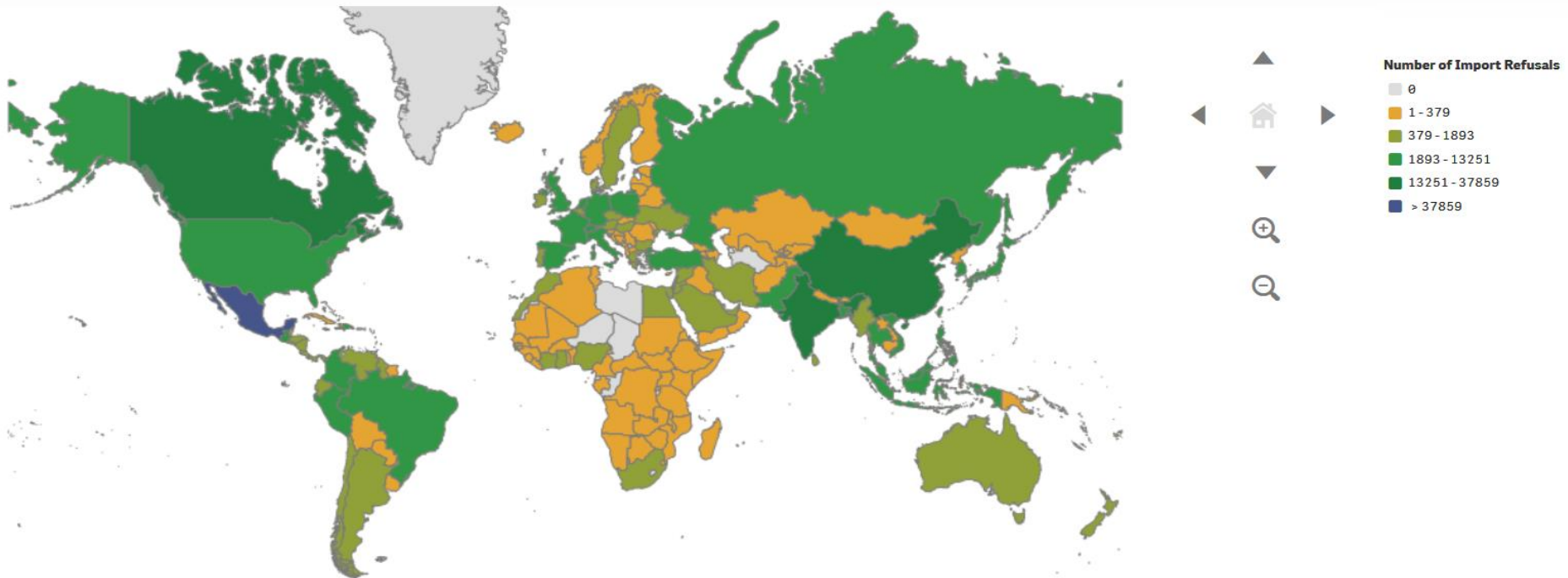
- FDA-regulated products are refused entry if they appear to be or have been found to be:
 - adulterated, meaning the product is contaminated, is not safe, unapproved, or does not otherwise meet applicable standards,
 - misbranded, meaning the labels contain false or misleading information, or the product is not registered and listed, if required,
 - forbidden or restricted for sale.
 - Products that do not comply with U.S. requirements may be refused admission. Refused products must be destroyed or exported from the United States within 90 days.

Total FDA Product Entry Refusals - 2002 - 2019

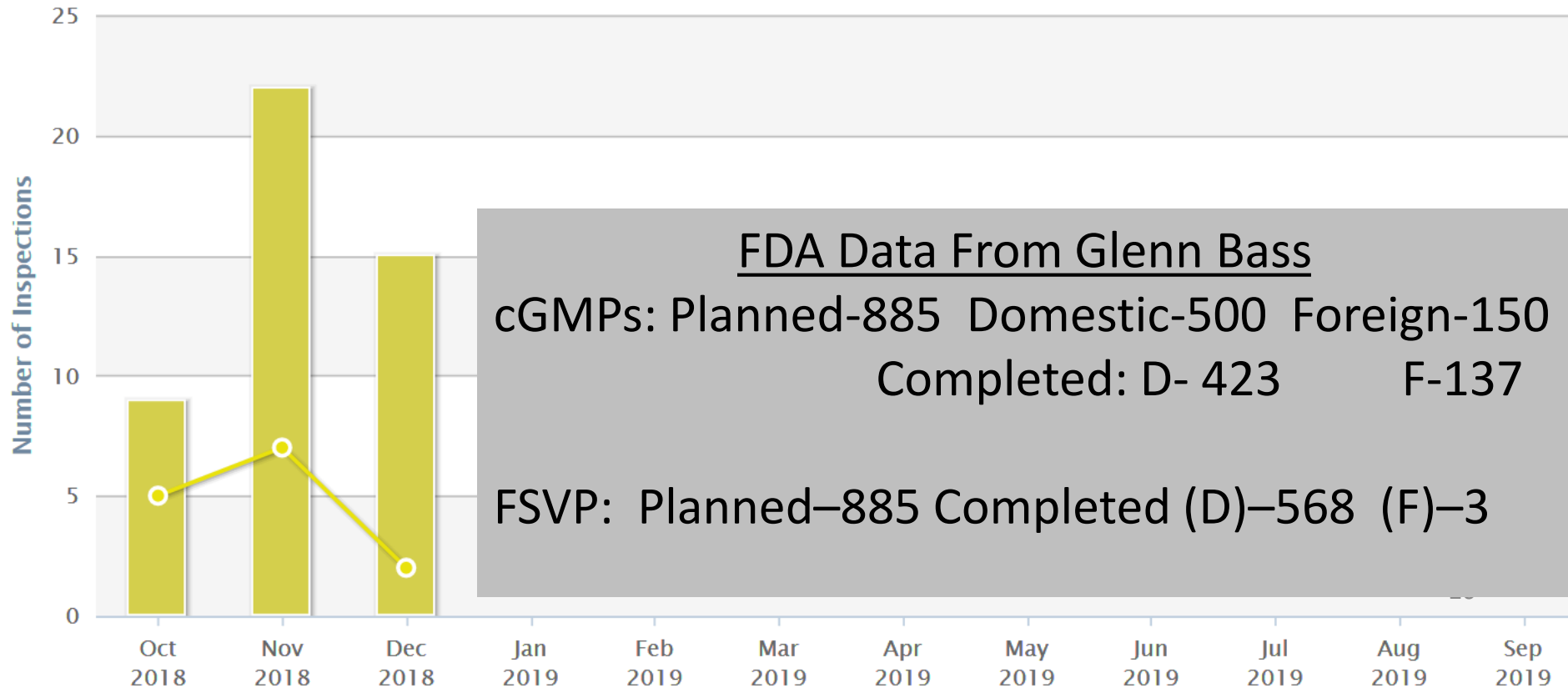
Animal Feed: 2,316 **Cosmetics: 21,230** **Devices: 114,286**
Drugs and Biologics: 56,850 **Housewares & Food Related: 1,948**
Human Foods: 175,777 (46%) **Radiological Health: 5,823**
Tobacco Products: 359

Unique Shipment Lines Refused by Country

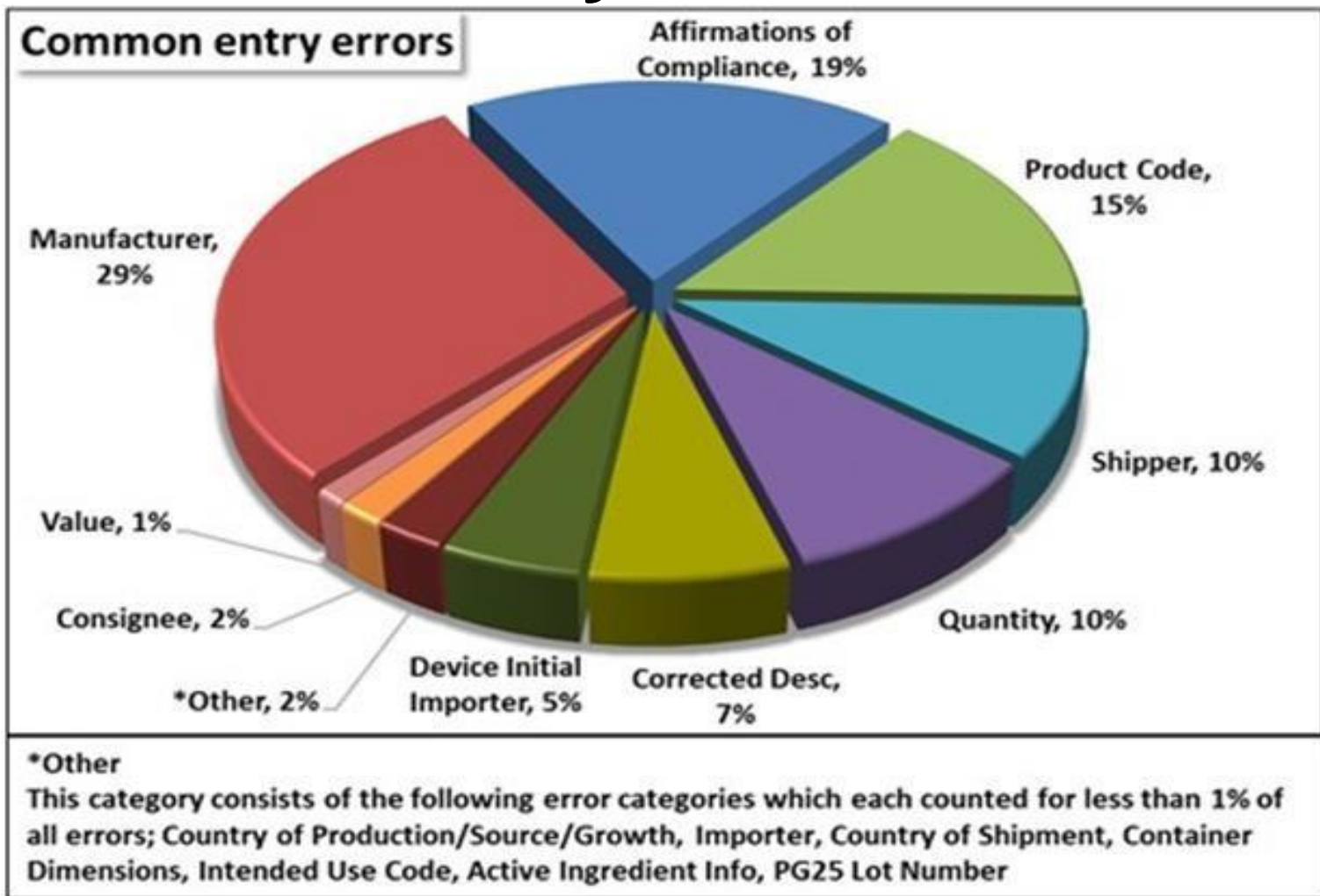
Total: 378,589



FDA Foreign Human Food Inspections FY 2019



Admissibility Common Entry Errors



What is the FDA Red, Green & Yellow list?



Type of List

Description

Red List

Firms, products and/or countries are subject to Detention without Physical Examination (DWPE) under an import alert.

Green List

Firms, products and/or countries that have met criteria for exemption from Detention without Physical Examination (DWPE) under an import alert.

Yellow List

Firms, products and/or countries subject to intensified surveillance; or firms that may have satisfied GMP issues but where the nature of violations may warrant further field examinations of individual entries and/or additional analyses.

***Thank
You***

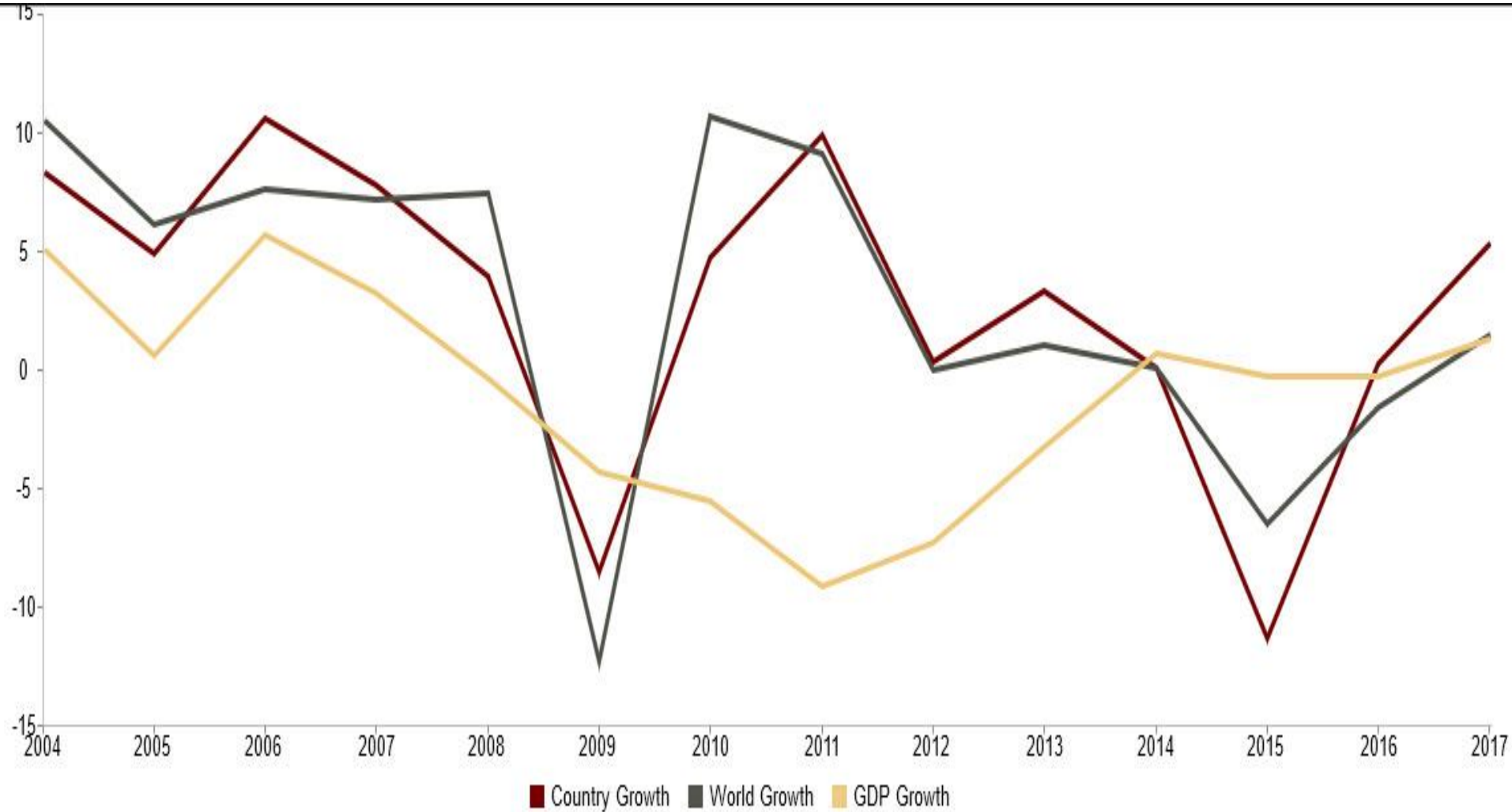


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Greece Country Growth vs World vs GDP Growth





2019 : U.S. trade in goods with Greece

NOTE: All figures are in millions of U.S. dollars on a nominal basis, not seasonally adjusted unless otherwise specified. Details may not equal totals due to rounding. Table reflects only those months for which there was trade.

Month	Exports	Imports	Balance
January 2019	90.6	138.8	-48.2
February 2019	113.6	92.1	21.5
March 2019	94.1	117.0	-22.9
April 2019	120.9	119.3	1.6
May 2019	101.6	122.3	-20.6
June 2019	151.6	154.6	-2.9
July 2019	139.4	190.3	-50.9
August 2019	84.9	119.8	-35.0
TOTAL 2019	896.8	1,054.2	-157.4

2018 : U.S. trade in goods with Greece

NOTE: All figures are in millions of U.S. dollars on a nominal basis, not seasonally adjusted unless otherwise specified. Details may not equal totals due to rounding. Table reflects only those months for which there was trade.

Month	Exports	Imports	Balance
January 2018	58.2	120.2	-62.0
February 2018	56.8	93.3	-36.5
March 2018	78.0	121.7	-43.7
April 2018	88.5	127.2	-38.7
May 2018	78.6	141.2	-62.6
June 2018	69.8	121.0	-51.1
July 2018	67.7	171.7	-104.0
August 2018	123.2	143.3	-20.1
September 2018	85.5	136.9	-51.4
October 2018	160.4	149.3	11.1
November 2018	94.3	147.4	-53.1
December 2018	123.2	132.6	-9.5
TOTAL 2018	1,084.1	1,605.8	-521.6

2017 : U.S. trade in goods with Greece

NOTE: All figures are in millions of U.S. dollars on a nominal basis, not seasonally adjusted unless otherwise specified. Details may not equal totals due to rounding. Table reflects only those months for which there was trade.

Month	Exports	Imports	Balance
January 2017	155.2	88.4	66.9
February 2017	37.1	100.3	-63.2
March 2017	53.0	99.6	-46.6
April 2017	63.1	95.3	-32.2
May 2017	68.2	110.9	-42.7
June 2017	51.9	115.3	-63.4
July 2017	59.4	107.4	-48.0
August 2017	57.2	114.8	-57.7
September 2017	70.4	112.3	-41.8
October 2017	170.8	110.8	60.0
November 2017	71.7	109.4	-37.7
December 2017	96.3	92.6	3.7
TOTAL 2017	954.2	1,257.1	-302.8