



Specializing in FDA Regulatory Matters

EXPORTING GREEK FOODS TO THE UNITED STATES – 2020 & Beyond

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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.

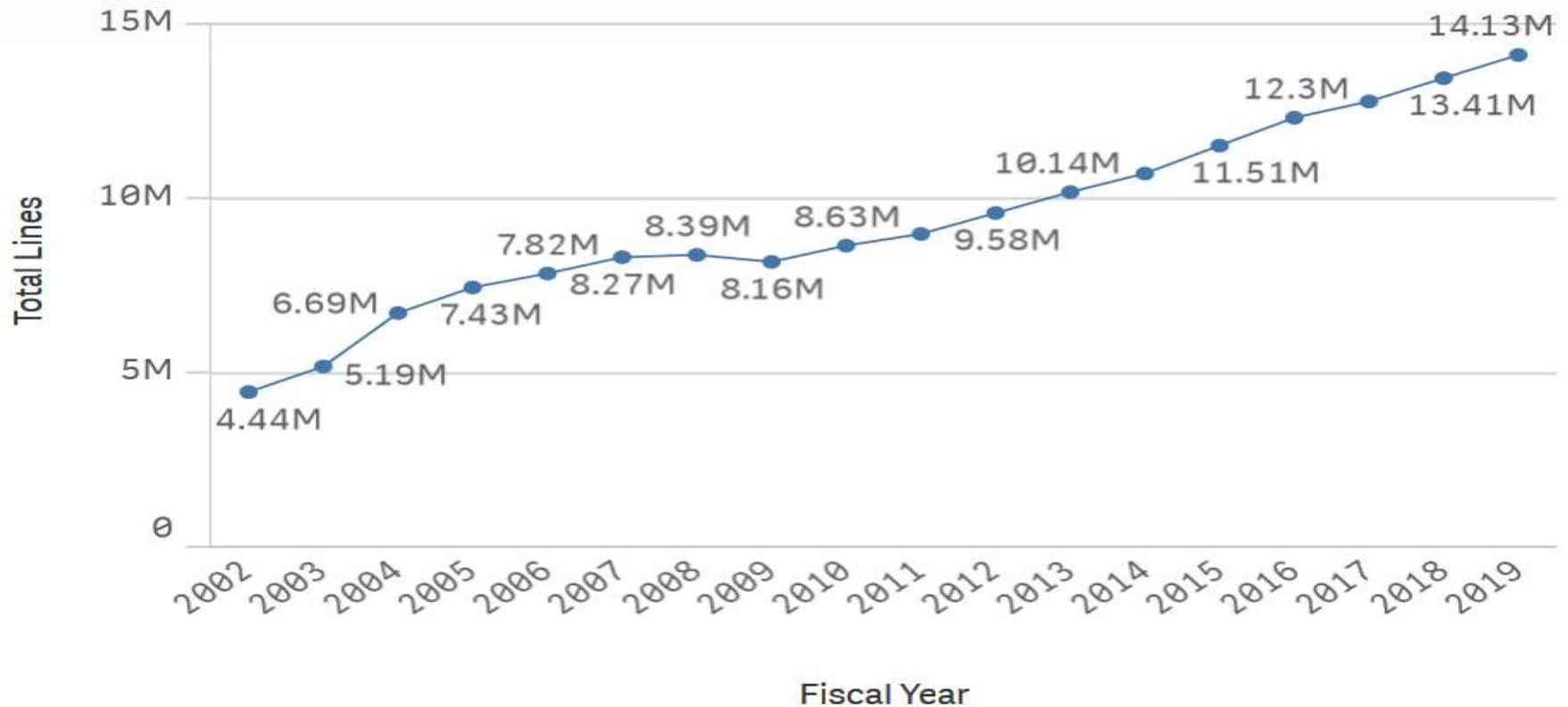
CERTIFIED LABORATORIES (CERTIFIED) specializes in all types of laboratory testing of imported foods to assist in passage through the US port of entry and for the release of imported foods place on hold by FDA or the US Customs & Border Protection



Total Food - Imports

Total Lines* of Products Imported by Fiscal Year

Fiscal Years: 2002 - 2019



*A line is a distinct product within a shipment. A single shipment may include multiple lines.

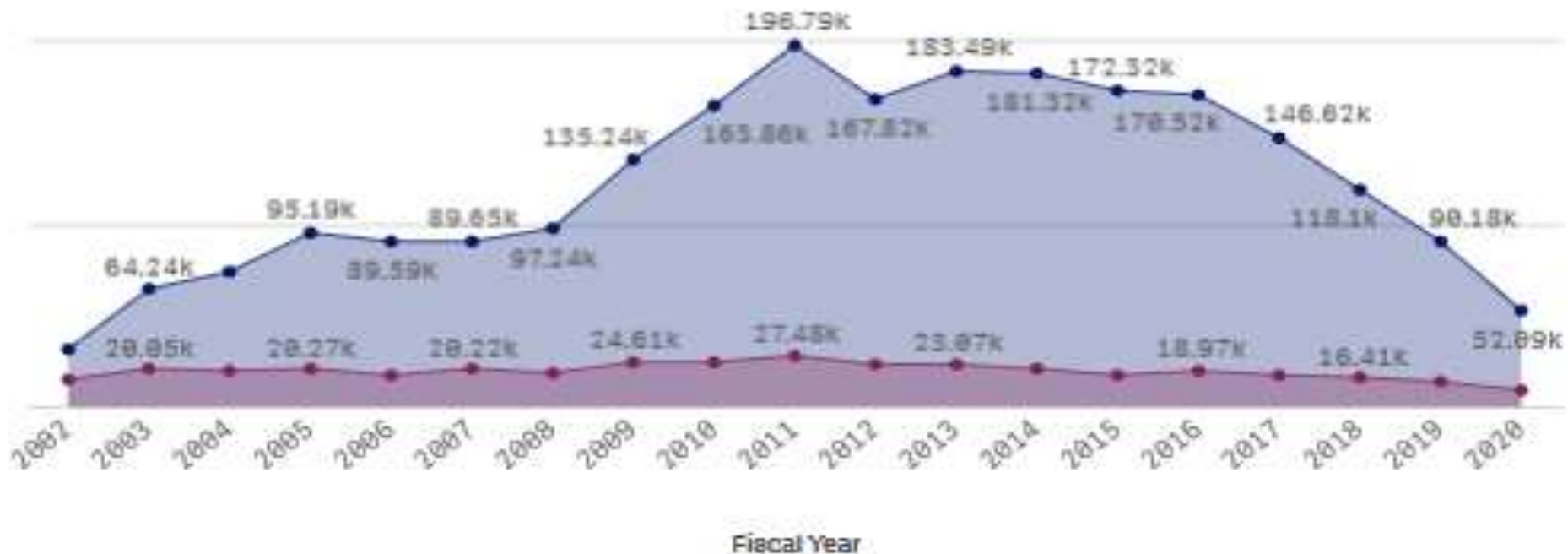
FDA Food Import Examinations

Examined and Sampled Line Totals by Fiscal Year

Fiscal Years: 2002 - 2020

Common Measures

Examined Lines Sampled Lines



TOTAL FOOD PRODUCT REFUSALS BY US GOVERNMENT FISCAL YEAR

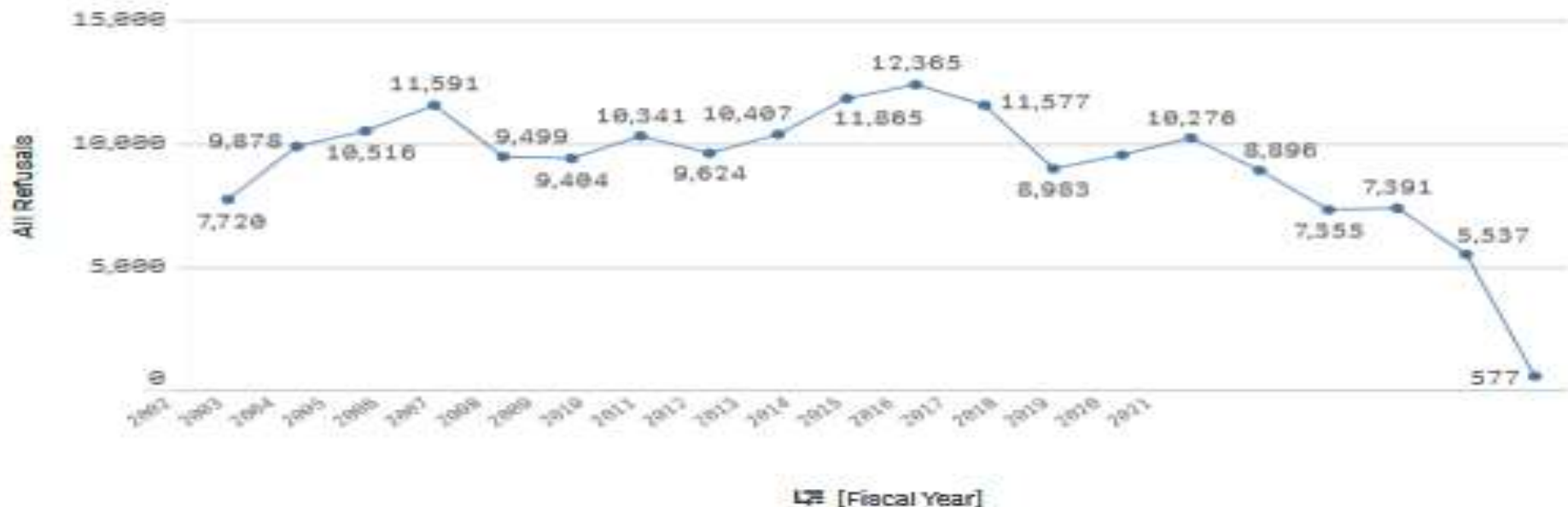
FY – 2020: 5,537

FY 2021 – 577 (6,924 if extrapolated)

Export

Refusals by Fiscal Year

Fiscal Years: 2002 - 2021

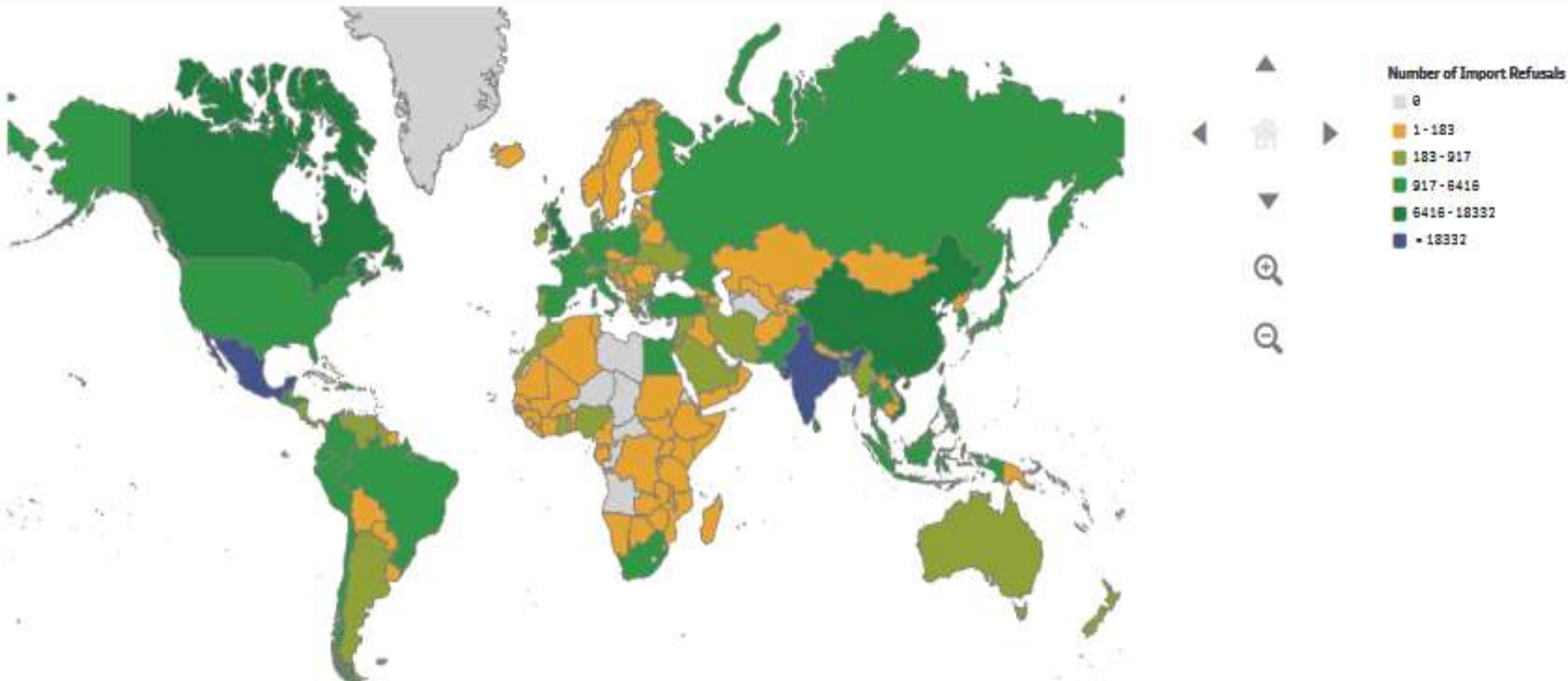


FDA Food Import Refusals by Country FY 2020

Human Foods - 183,322

Unique Shipment Lines Refused by Country

Total: 183,322



U.S. Ag Exports to Greece \$103M

Tree Nuts: \$32M

Soybeans: \$18.7M

Forest Products: \$7.1M

Distilled Spirits: \$5.7M

Seafood Products: \$4.8M

U.S. Ag Imports from Greece \$451.9M

Processed Fruits & Vegetables: \$224M

Seafood Products: \$51.9M

Vegetable Oils: \$50.6M

Cheese: \$31.6M

Cheese: \$31.6M

6 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 US FDA 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 Agent like EAS to register Greek food manufacturer and/or warehouse with FDA – simple

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 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



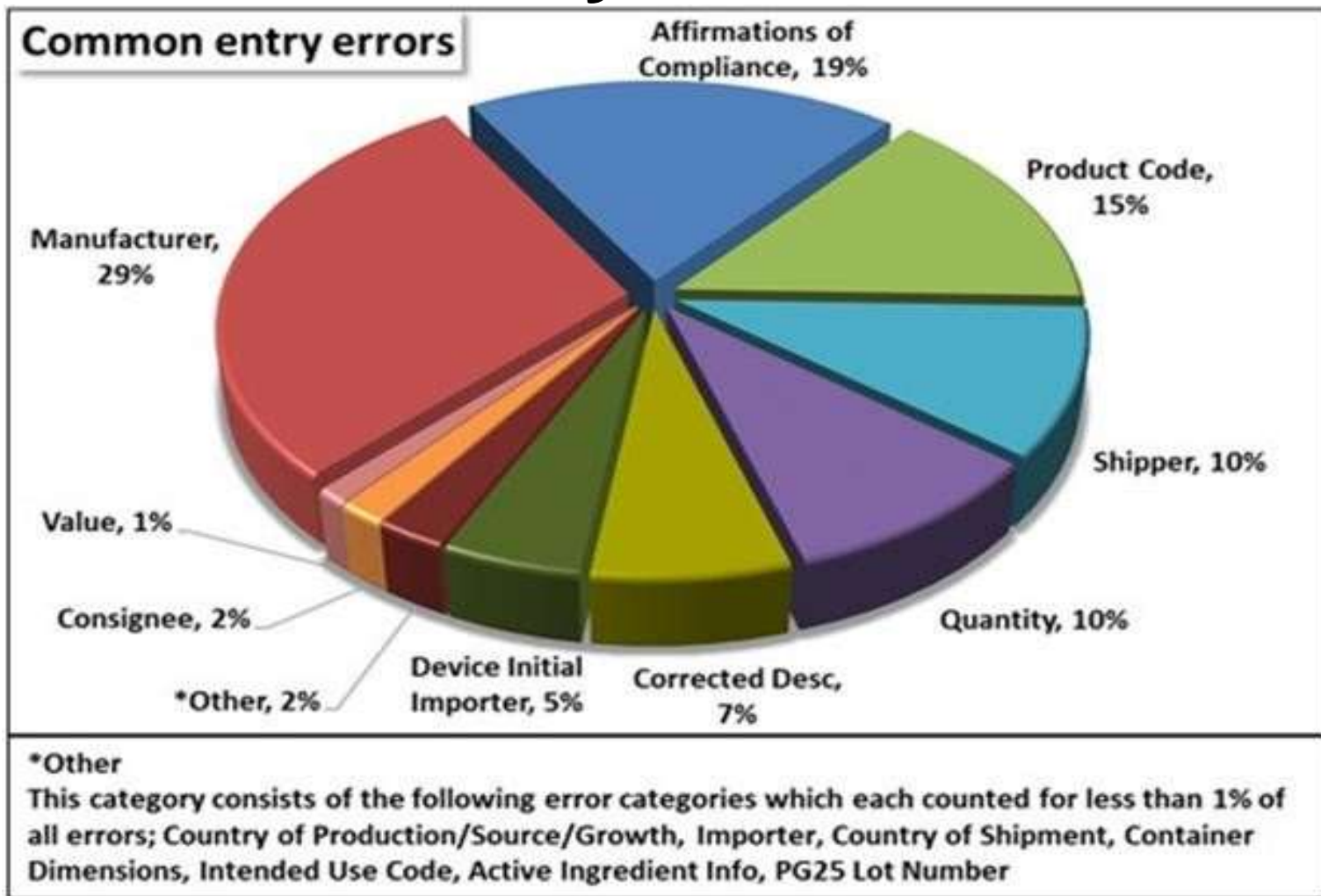
Hire a Consulting Firm Like EAS Consulting Group that can provide all of the services identified in Steps #1 - #6 and

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.

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.



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