U.S. FDA Import Alerts

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About Sarah Gurganus

Senior Regulatory Specialist

- Sarah Gurganus holds a Master of Science degree in Chemistry from Old Dominion University in Norfolk, Virginia and has experience in atmospheric and analytical research. Ms. Gurganus began her career with Registrar Corp reviewing the labeling and formulation of hundreds of products for FDA compliance. She now acts as head of Registrar Corp's Import Alerts department where she assists international companies to develop the petitions required for removal or exemption from detention under various FDA Import Alerts.

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Presentation Overview

- FDA Resource Management
- What is an Import Alert?
- Detention Without Physical Examination (DWPE)
- Format of Import Alerts
- Removal or Exemption from DWPE
- Registrar Corp's Solutions
- Questions & Answers

FDA's Solution to Handle Millions of Entries

FDA Resource Management

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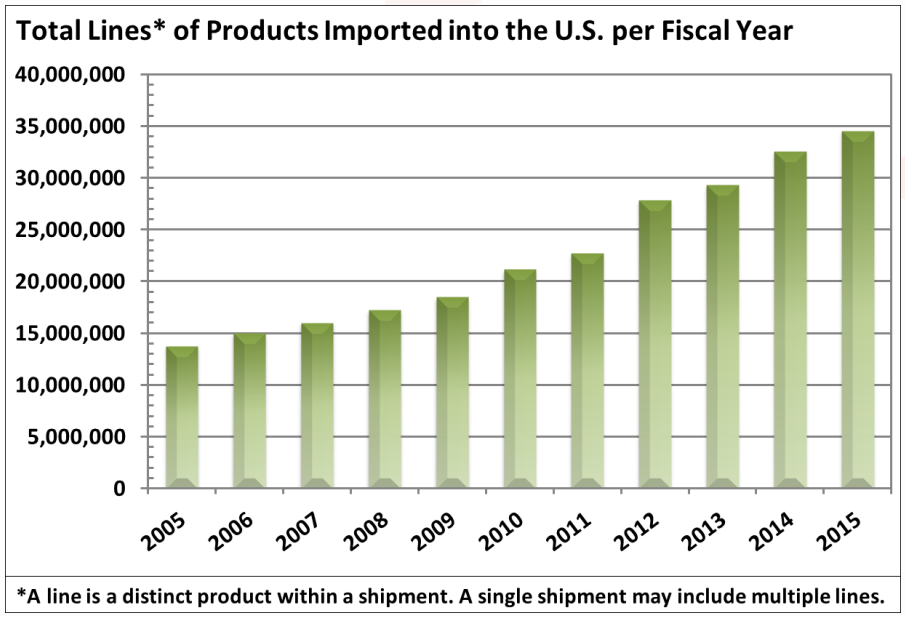
FDA Resource Management

- Nearly 35 million entries of FDA regulated products in FY 2015.
- Over 300 possible ports of entry.



http://www.fda.gov/ForIndustry/ImportProgram/default.htm

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FDA Resource Management

- In 2013, FDA was able to physically inspect only 1.9% of all food products entering the United States.

- FDA has developed systems that allow the agency to use the minimum amount of its limited resources to identify and detain products that are expected to be non-compliant.

FDA's Solution to Handle Millions of Entries

Import Alerts

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What is an Import Alert?

- Notice to all entry ports that certain products from specific areas or manufacturers may be violative.
- Created whenever FDA discovers a pattern of violation that creates a reason to believe that future shipments may be similarly violative.
- Instructs FDA compliance officers to detain these products.

More than 250 active Import Alerts

What is an Import Alert?

Types of Import Alerts

Types of Import Alerts

- Green List Import Alerts:
  - Subject to the alert unless you're on the Green List.

- Red List Import Alerts:
  - Only subject to the alert if you are on the Red List.

Green List Import Alerts

- Green List Import Alerts:
  - Inherently risky products from anywhere in the world.
    - 16-20: Puffer Fish (Tetrodotoxin)
  - Violations common or widespread in certain regions.
    - 16-07: Dried or Pickled Finfish from Thailand (Filth)
    - 99-29: Vegetable Protein products from China (melamine)

Red List Import Alerts

- Red List Import Alerts:
  - Based on the nature of the violation or history of the company.
    - 16-04: Misbranded Seafood
    - 45-02: Foods Containing Illegal and/or Undeclared Colors
    - 99-19: Food Products due to Salmonella

Import Alerts

Detention Without Physical Examination (DWPE)

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Detention Without Physical Examination (DWPE)

- Shipment will be detained without an inspector even looking at it.
- Works under the premise that the products *appear* violative based on a history of violation.
- NOT an *automatic refusal.*
  - The manufacturer or importer must present evidence to FDA that the product is NOT violative in order to get a shipment released from detention.
  - This process will repeat for ALL shipments for as long as the Import Alert is in effect.

Format of Import Alerts

Format of Import Alerts

- Available on the FDA website.
- All alerts follow the same format:
  - Identifying Information
  - Reason For Alert
  - Guidance
  - Product Description
  - Charge
  - [If country specific, the list of countries and products affected]
  - The appropriate list of facilities (red or green)

Format of Import Alerts

Import Alert # 16-124
Published Date: 09/12/2016
Type: DWPE
Import Alert Name:
"Detention Without Physical Examination Of Aquaculture Seafood Products Due To Unapproved Drugs"

Reason for Alert:
There has been an extensive commercialization and an increased consumption rate of aquaculture seafood products. As this industry grows, the use of unapproved new animal drugs and the misuse of approved new animal drugs in seafood raised through aquaculture also grows. The use of unapproved new animal drugs will have an impact on the safety of aquaculture products for consumers.

Guidance:
Districts may detain, without physical examination, the products from the firms identified in the attachmnet for this alert.

Contact the Division of Field Science at 301 796-6600 for questions or issues concerning science, science policy, analysis, preparation, or analytical methodology.

All requests for removal from detention without physical examination should be address to DIOP 301-796-0356.

Product Description:
Aquaculture seafood

Charge:
"The article is subject to refusal of admission pursuant to on 801(a)(3) in that it appears to be adulterated in that it or contains a new animal drug (or conversion product of) that is unsafe within the meaning of Section 512, which violation of Section 402(a)(2)(C)(ii)."

OASIS charge code - VETDRUGRES

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

Format of Import Alerts

CHILE

Comercial y Servicios Sur Austral, Ltda. — **Date Published : 08/10/2016**
Ruta 5 Sur 7 , Chamiza , Puerto Montt, Los Lagos CHILE

16 X - - 03 Salmon, all, Aquaculture Harvested Fishery/Seafood Products — Date Published: 08/10/2016
Desc:Salmon; Atlantic Coho- Farmed
Notes:Problem: Isoeugenol

CHINA

BEIHAI ANBANG SEAFOOD CO.,LTD — **Date Published : 09/09/2013**
INDUSTRIAL SECTION,CHINESE OVERSEAS , &DEVELOPMENT ZONE,BEIHAI,GUANGXI,CHINA , Beihai, Yanxizhuangzuzizhiqu CHINA

16 A - - 58 Tilapia — Date Published: 09/09/2013
Desc:Tilapia
Problems: MALACHITE GREEN;

16 X - - 06 Tilapia, Aquaculture Harvested Fishery/Seafood Products — Date Published: 09/09/2013
Desc:Tilapia
Problems: MALACHITE GREEN;

BEIHAI EVERGREEN AQUATIC PRODUCT SCI.&TECH. CO.,LTD. — **Date Published : 03/04/2016**
MIDDLE STATION, HEPU COUNTY,BEIHAI CITY , Beihai, Yanxizhuangzuzizhiqu CHINA

16 A - - 58 Tilapia — Date Published: 03/04/2016
Desc:Tilapia
Problems: SULFADIAZINE;

16 X - - 06 Tilapia, Aquaculture Harvested Fishery/Seafood Products — Date Published: 03/04/2016
Desc:Tilapia
Problems: SULFADIAZINE;

Import Alert Petitions

Removal or Exemption from DWPE

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Removal or Exemption from DWPE

What do you do if you find yourself or your supplier subject to DWPE?

PETITION!

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Removal or Exemption from DWPE

- A firm will remain subject to DWPE unless it provides evidence to FDA that it is no longer at risk.

- Evidence is provided in the form of a petition sent to Division of Import Operations (DIO) to request removal.
  - May be 100+ pages in length.
  - Requires extensive documentary evidence.

Import Alert Petitions

Petition Requirements

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Petition Requirements

- **Corrective Actions:** Documentary evidence that the problem has been corrected or prevented.
  - Corrective actions will vary depending upon the circumstances:
    - HACCP plan revisions
    - Change of suppliers
    - Label revisions
    - Lab analyses of every lot
    - Etc.

Petition Requirements

- **Shipments:** A series of non-violative shipments to verify that the corrective or preventive actions are sufficient.
  - Minimum of 5-12 routine commercial shipments spaced over a reasonable period of time.
  - Submission of shipping documents.
    - US Customs Form 3461 or 7501
    - Commercial Invoice
    - Packing List
    - Bill of Lading

Import Alert Petitions

FDA Review of Petitions

FDA Review of Petitions

- Division of Import Operations (DIO) reviews petitions in the order received.
  - Review periods can take several months.
  - FDA may request additional documentation or shipments during the course of the review.

FDA Review of Petitions

- If the petition is approved:
  - FDA will issue an approval letter to the submitter and notify all FDA district offices of the change in status.
  - Entries will no longer be subject to DWPE, but will remain subject to routine inspections.

- If the petition is denied:
  - FDA will issue a denial letter to the submitter including an explanation of the reason for denial.
  - Once any deficiencies have been corrected, a new petition may be submitted to FDA for further review.
  - No "penalty" for a denied petition.

DWPE Petition Assistance

- Assist the company to identify the cause of placement on Import Alert.
- Assist in the determination and implementation of certain types of corrective actions.
  - Label reviews, HACCP reviews, FCE/SID filing, registration, color batch certification, etc.
- Assist with FDA communications for each detained shipment after implementation of corrective actions.
- Develop petition for removal from DWPE and submit to FDA.
  - Provide an administrative review of documents regarding corrective actions and cleared shipments.
- Address FDA's questions during the review period.

Questions & Answers