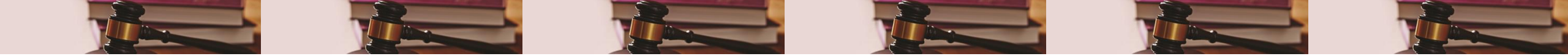


# Importing Products into the US and Navigating Import Alerts

**Desmond Brown**, Division of Food Defense Targeting, ORA, FDA
**Ted Poplawski**, Special Assistant, Division of Import Operations, ORA, FDA
**Angel Suarez**, Independent Consultant, EAS Consulting Group LLC
*Moderated by* **Robert Durkin**, Of Counsel, Arnall Golden Gregory LLP

FDLI

# Division of Food Defense Targeting (DFDT)

## Enforcement, Litigation, and Compliance Conference

Desmond Brown, DFDT Watch Commander

December 2019

# Presentation Objectives

- Review the Bioterrorism Act (BTA)
- Discuss the Prior Notice (PN) Regulations
- Look at PN Role in the Nation's Food Defense System

# Potential Consequences of a Bioterrorism Event

- Serious public health consequences or death
- Widespread public fear
- Negative economic consequences

# Food Comes From all Over the World

# Key Phases of the Bioterrorism Act

**FD&C Act** — **1938**

***Bioterrorism Act 2002**

**Sec. 305:** Facility Registration

**Sec. 307:** Prior Notice Requirement

**FSMA 2010**

**Sec.102:**

- Article refused by another country

# Food That Require PN Under the BTA

- ***Most*** **imported food for humans and animals: Including…**

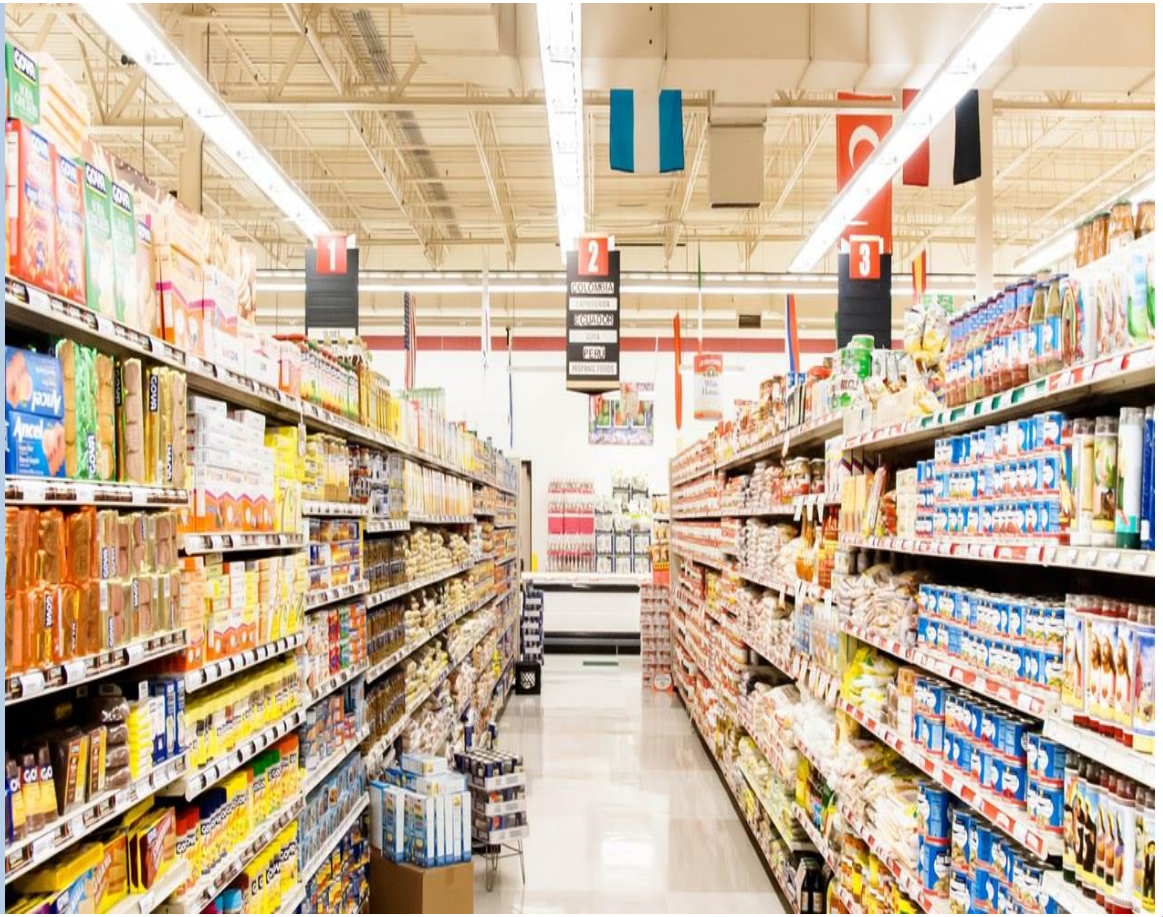
# Security Risk Drives PN Manual Reviews

- Direct intelligence
- Food manufactured in high-risk countries
- Food shipments linked with high-risk entities

# Most Frequent PN Violations

- **No valid FFR on file with FDA** (21 CFR 1.225
- **Inaccurate PN information** (21 CFR 1.283)
  (manufacture, manufacturer's address, multiple different products, product identity)
- **PN submissions for non-food items** (21 CFR 1.277)

# DFDT Protecting the U.S. Food Supply




FDLI

# The End

## Thank You

## Division of Food Defense Targeting

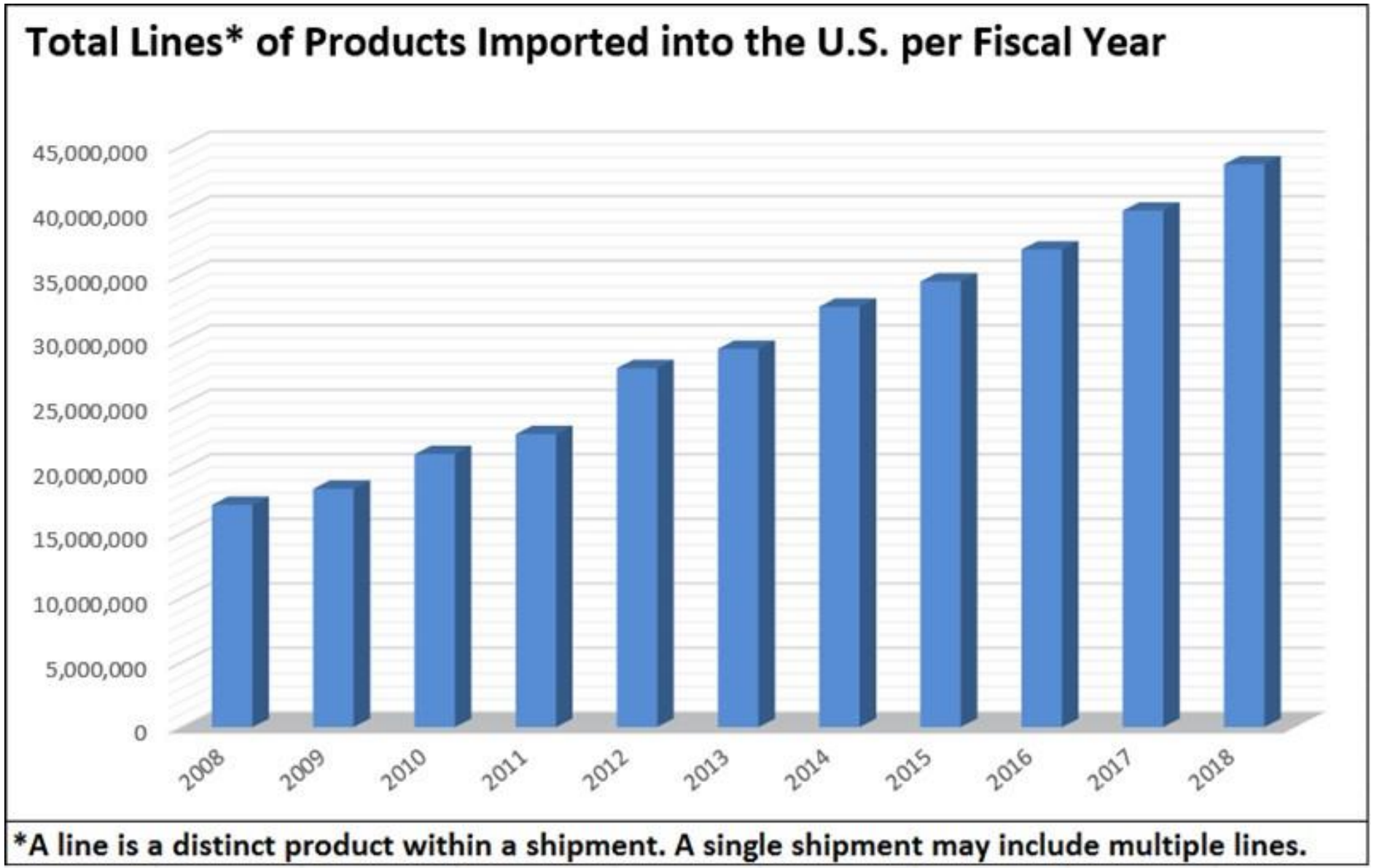
**866-521-2297**

**24/7/365**

# Importing Products into the US and Navigating Import Alerts

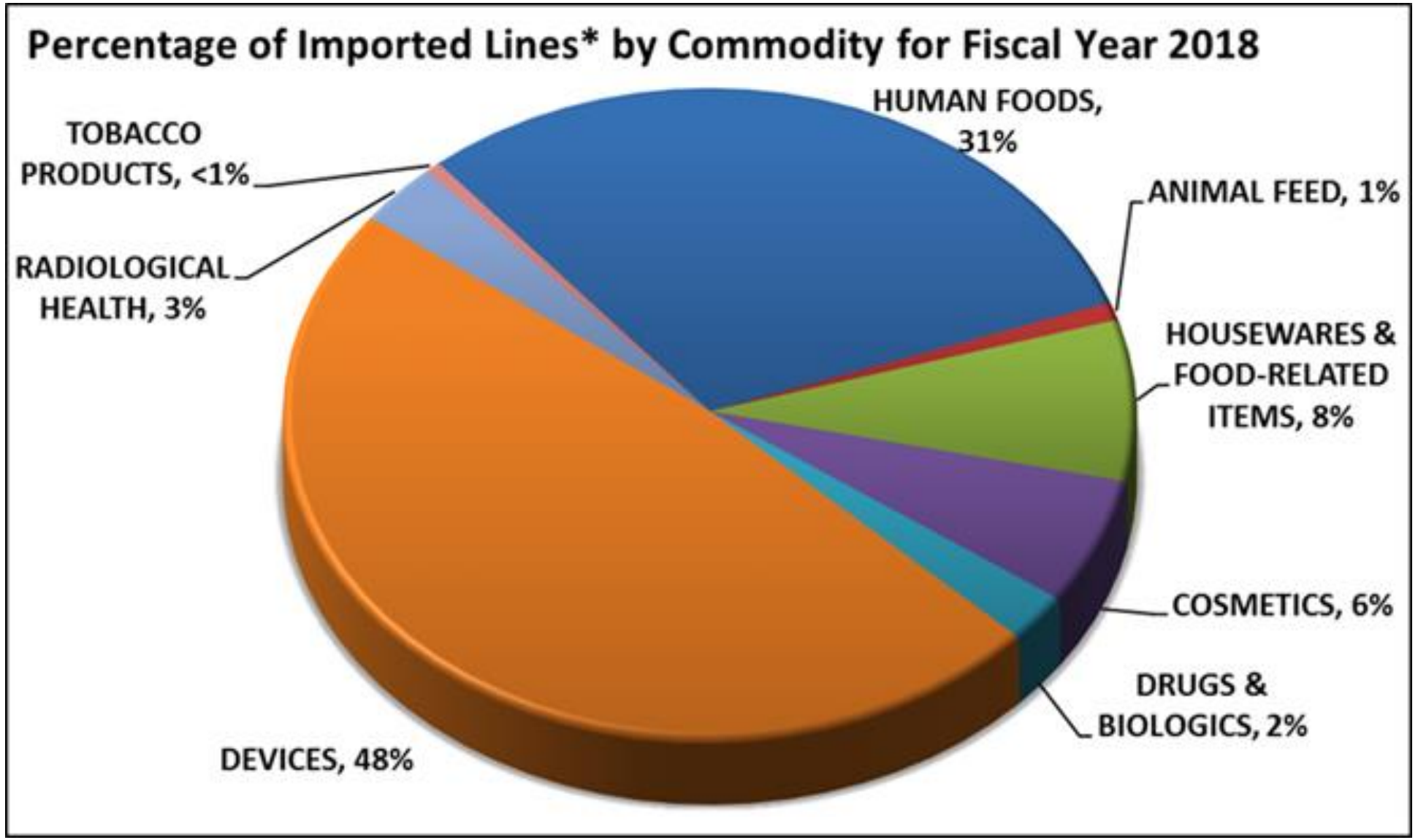
Angel M Suarez
EAS Independent Consultant
asuarez@easconsultinggroup.com

FDLI


Total Lines* of Products Imported into the U.S. per Fiscal Year
45,000,000
40,000,000
35,000,000
30,000,000
25,000,000
20,000,000
15,000,000
10,000,000
5,000,000
0
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
*A line is a distinct product within a shipment. A single shipment may include multiple lines.

FDLI

# Imported Products by Commodity



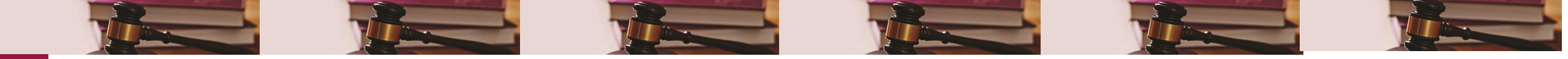

FDLI

# Imports - FSMA

**FSMA** unprecedented authority to better ensure that imported products meet U.S. standards and are safe for U.S. consumers. New authorities include:

- **Importer accountability**
- **Third Party Certification**
- **Certification for high risk foods**
- **Voluntary qualified importer program**
- **Authority to deny entry**
- **Expanded administrative detention**
- **Suspension of registration**

FDLI



# DFDT Enforcement Hold

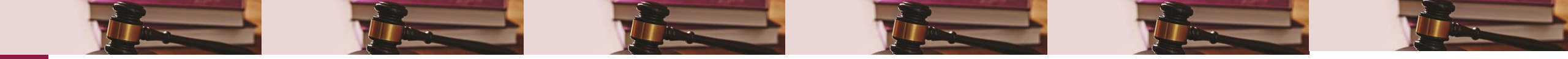
- **Enforcement Hold**
  - Enforcement hold under 801(l)
  - Enforcement hold under 801(m)
- **Bioterrorism Hold**
  - Evidence or information supporting the detention order is classified under the applicable Executive Order (**EO 12356)** as requiring protection from unauthorized disclosure in the interest of national security (“classified information”)

FDLI

# Food Facility Registration

- Biennial Food Facility Registration
  - October 1 – December 31
  - US Agent required
  - Email address for registration
  - Registrations must have assurance that FDA will be allowed to inspect the facility at any time
- 2020
  - Requirement of electronic submission of facility registrations takes effect January 4, 2020.
  - Unique Facility Identifier
    - DUNS
    - Other identifier (to be published before October 1)

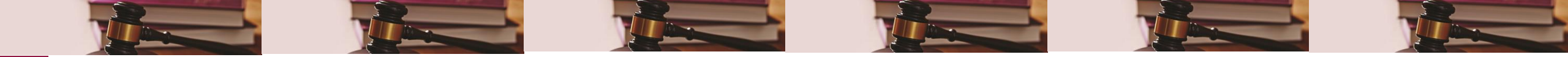
FDLI



# Import Alerts

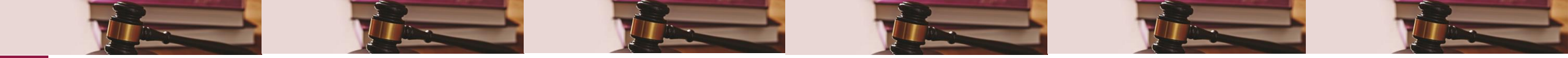
- FDA import alerts to enforce its regulations
- Updates and modifies the alerts as needed
- FSVP – requires more active engagement from the importer into meeting requirements for corrections
- Response should address the specific to correct the violation

FDLI



# Import Challenges

- Development of an FSVP as required by section 805 of the FD&C Act and 21 CFR part 1 subpart L
- Verify supplier Hazard Analysis and Risk-Based Preventive Controls (HARPC) or HACCP plans (ex seafood, juice products)
- Perform supplier audits (or hire an experienced consultant) to ensure FSVP in addition to quality and safety of ingredients, additives, packaging and products meet specifications
- Monitor risks throughout the supply chain, including the compliance history of the suppliers (ex. Import Alerts, Warning Letters)



# Import Challenges

- Have corrective action procedures in the event of compliance action related to importing or offering for import adulterated food that presented a threat of serious adverse health consequences or death to humans or animals.
- Remain in continuous communication with suppliers and importers to stay up to date on incident follow-up, corrective action, supplier document requests, and specification changes.
- Obtaining a Foreign Supplier's Food safety plan
- Technical background to analyze foreign supplier's food safety plan

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

# Enforcement, Litigation, and Compliance Conference

## December 12, 2019

Presentation by:
Ted Poplawski, Special Assistant
Division of Import Operations

# FDA
# Import Alerts
# and
# Bulletins

# Food Drug & Cosmetic Act

- The Federal Food Drug & Cosmetic Act (FFD&C Act) gives FDA its authority to act.

- Section 801 of the FFD&CA contains the law specific to Imports.

# Food Drug & Cosmetic Act

## Chapter VIII – Imports and Exports

Section 801(a) of the FFD&CA

"If it appears from the examination of such samples *or otherwise* that…"

(1) such article has been manufactured, processed, or packed under insanitary conditions… or

(2) such article is forbidden or restricted in sale in the country in which it was produced … or

(3) such article is adulterated, misbranded, or in violation of section 505 or the importer is in violation of section 805 or prohibited from introduction or delivery for introduction into Interstate commerce under Section 301(ll)

(4) The recordkeeping requirements under section 204 of the FSMA (other than the requirements, under subsection (f) of such act) have not been complied with regarding such article

"then such article shall be refused admission…"

# Food Drug & Cosmetic Act

## Chapter VIII – Imports and Exports

### The Appearance Standard

"**appears**" is interpreted to mean that the appearance of a violation provides FDA's standard of proof

FDA can refuse entry to goods that:

- Appear to be adulterated or misbranded;
- Appear to be unapproved new drugs;
- Appear to have been manufactured not in accordance with GMPs.

Based on examination of sampling **or otherwise**

- **"or otherwise"** – allows FDA to make admissibility decisions using other tools such as:
  - historical data
  - examinations (vs. sample collections)
  - information from other sources
  - other evidence

# Import Alerts

- Published documents that inform FDA field staff and the public that FDA has enough evidence about specific products that appear to be in violation of the FFD&C Act to allow us to Detain without Physical Examination (DWPE)
  - DWPE allows FDA to detain the product without physically examining it at the time of entry.

- Criteria for DWPE can be found in Chapter 9-15 “Import Information Directives” of FDA’s Regulatory Procedures Manual
  - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual

# Import Alerts

- Import Alerts do not create new requirements
- The requirements already exist:
  - FFD&CA defines what adulterated and misbranded mean
  - Import Alerts identify firms and products for which the available evidence supports the appearance products are adulterated or misbranded
- Currently there are about 213 active Import Alerts
  - http://www.accessdata.fda.gov/cms_ia/ialist.html

# Import Alerts

- Prevents potential violative products from being distributed into the United States
- Frees up Agency resources to examine other shipments
- Provides uniform coverage across all ports of entry
- Places the responsibility back on the importer
  - It is the responsibility of the importer to ensure that the products he is importing in the U.S. is in compliance with our laws and regulations

# Import Alerts

- Each import alert describes the conditions that may result in the product being subject to DWPE. When a product and/or firm is violative and meets the criteria, the import alert will be modified by addition to the red list or removal from the green list of the alert.

- The following are some of the common reasons a product or firm may be subject to DWPE (not all inclusive):
  - FDA has sampled the product and it tested violative for a pathogen
  - FDA has sampled the product and it contains illegal colors or food additives
  - The product contains pesticides that are not allowed or do not meet tolerance levels

# Import Alerts

## Adding a firm/product

- Subjecting a firm, product, or importer to DWPE:
  - Based on evidence from our field offices
  - Based on evidence from foreign inspections
  - Other sources of information, e.g. foreign governments, states, other agencies

- Violative history of:
  - Commodities
  - Manufacturers/shippers
  - Growers
  - Geographic area
  - Countries of origin
  - Importers
  - Or combinations of the above

# Import Alerts

## Removing a firm, product, or importer from DWPE

- FDA needs assurance the cause of the violation has been corrected

- Firms or importers may petition to be removed from DWPE
  - Industry submits the petition
  - FDA reviews the petition

- Generally requires evidence of non-violative shipments but depends on the Import alert
  - Firms with GMP violations may need an inspection to get off an IA
  - Analyzed by laboratory at importer expense
  - Documentation showing it isn't subject to the Alert

# Import Bulletins

- Import Bulletins are generally informational only
- Import Bulletins on an as-needed basis.
- Advisory only and may not disseminate policy or procedures.
- Intended to identify new or developing problems
- Not available or posted to the public
- Generally valid for 90 days after issuance

# Division of Import Operations

## Responsibilities

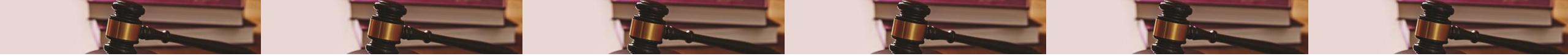
- **Issuance, maintenance, monitoring, and analysis of Import Alerts, Import Bulletins, import field assignments, and other increased surveillance activities**;
- Case review and concurrence for extraordinary import cases (seizures, civil money penalties, importer malfeasance, etc.) from divisions;
- CBP joint procedure/process/program development;
- Issuance and maintenance of instruction to the field including Regulatory Procedures Manual, Investigations Operations Manual, and DIO/ORA Field Import procedures;
- New Regulatory/Statutory program development (FSMA, FDASIA, etc.);
- Development and implementation of investigational processes (including hand held tools);
- Issuance and maintenance of training materials to FDA Import Staff

# The Import Screening Process

**Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)**

- PREDICT Risk Score
  - inherent product risk
  - previous history of importers, manufacturers and shippers
  - automated data mining
  - pattern discovery
  - automated queries of FDA databases
- PREDICT Risk Percentile
  - Based on commodity grouping
  - Comparative over past 30 days
- PREDICT Flags
  - Import Alerts, Import Bulletins, specific screening criteria
  - Database query failure

# Questions



# Importing Products into the US and Navigating Import Alerts

**Desmond Brown**, Division of Food Defense Targeting, ORA, FDA
**Ted Poplawski**, Special Assistant, Division of Import Operations, ORA, FDA
**Angel Suarez**, Independent Consultant, EAS Consulting Group LLC
*Moderated by* **Robert Durkin**, Of Counsel, Arnall Golden Gregory LLP

FDLI