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FDA Panel Weighing in on Device Import Issues

Moderator: Benjamin L. England, Esq.
Benjamin L. England & Associates LLC
FDAImports.com LLC

FIME | July 2018

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Speakers

- **Benjamin L. England**, CEO & Founder of FDAImports.com, LLC and Benjamin L. England & Associates, LLC
- **Carlos W. Hernandez**, Lead Compliance Officer, U.S. FDA Office of Regulatory Affairs, OEIO Division of Southeast Imports, CB
- **Roy León**, Senior Customs Attorney at FDAImports.com, LLC and Benjamin L. England & Associates, LLC

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FDA's Medical Device Import Program

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Carlos W. Hernandez

Carlos W. Hernandez has worked at the FDA for 24 years, the last 16 as a Senior Compliance Officer. He is a graduate from the Medical Science Campus at the University of Puerto Rico from which he has a BA degree in Health Sciences. Passionate about Health and Safety, he accepted the challenge of working for the FDA as a Consumer Safety Investigator conducting a wide range of inspections in food, drugs, and devices.

He has been recognized within the agency for contributing in numerous trade investigations, and regulatory compliance enforcement cases. Understanding the importance of training, he has participated in many events with FDA and Customs and Border Protection facilitating first-hand experience to optimize compliance with the most current mandatory policies, laws and regulations within FDA Imports.

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Benjamin L. England, Esq.

Mr. England is the Founder and CEO of FDAImports.com and Founding Member of Benjamin L. England & Associates, a fully integrated FDA, USDA, Customs, FTC, and EPA regulatory practice.

A 17-year veteran of FDA, he routinely represents domestic and foreign companies of all sizes, enabling them to reduce the risk of regulatory interference with products being imported, exported or distributed in interstate commerce.

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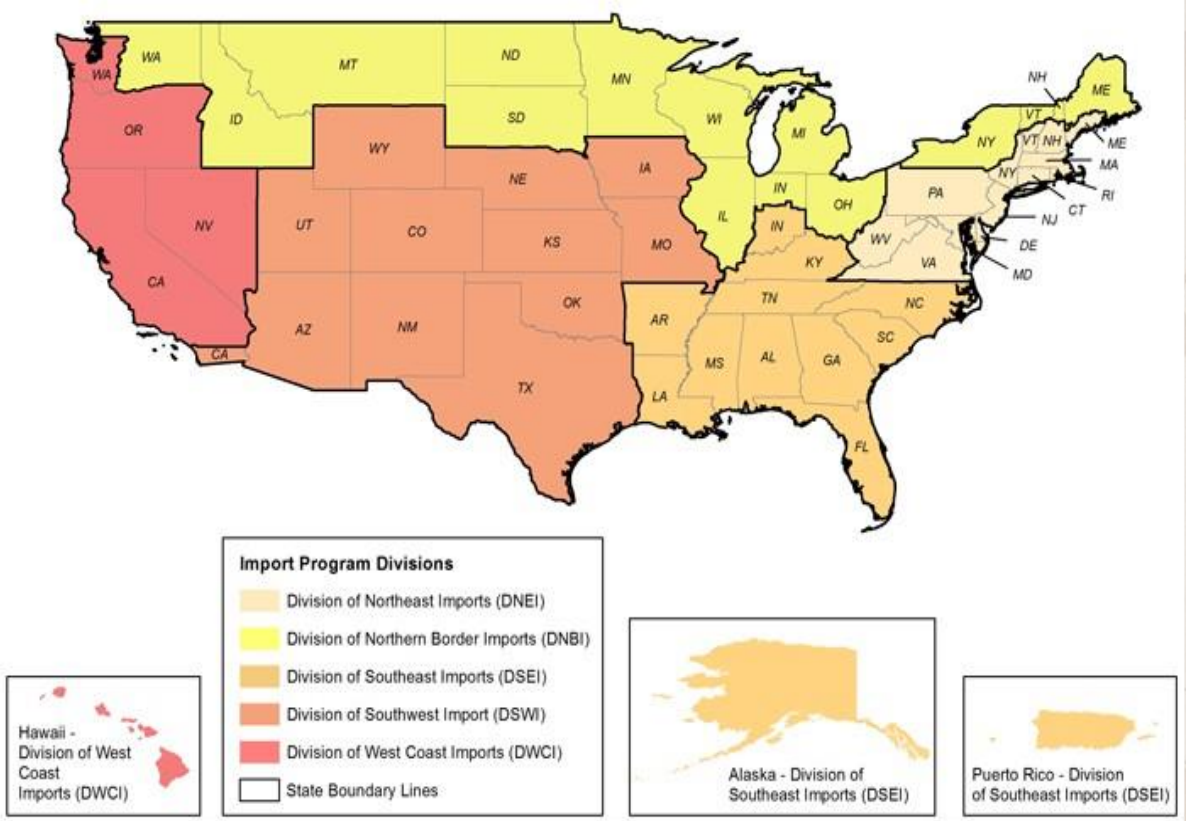
Medical devices

- Instruments, apparatus, implements, machines, contrivances, implants, in vitro reagents, or other similar or related articles, including any component, part, or accessory, which are
  - Articles recognized by USP, HPUS and NF
  - Intended for diagnosis of disease or other conditions
  - Intended to affect the structure or any function of the body of man or other animals
- Device Classification

	Safety Risk	Applicable premarket approval requirement
Class I	Low	Exempt through self-affirmation OR may require 510(k) submission
Class II	Moderate	May require 510(k) submission OR PMA submission
Class III	High	Requires PMA submission

FDA Authority: Import Divisions

5 Divisions of Import Operations



FDA Import Authorities

Authority to Examine/Inspect – pretty broad

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

- Imported article is adulterated, misbranded, unapproved, a banned device, violation of QSRs
- FDA shall refuse admission

FDA Traditional Authorities

- Administrative Detention
- Banning of Devices
- Seizure
- Civil Monetary Penalties & Disgorgement
- Criminal enforcement

Bottleneck at the Border

At the border (airport, seaport, land border)…

- Government agencies have opportunity to examine, inspect, detain, inquire, investigate:
  - The Device
  - The Parties (manufacturer, exporter, importer, distributor, companies and individuals)
  - The Marketing
  - The Records

FDA Import Activities

- Sampling, Testing, Labeling, Marketing
- If Detained
  - Release or “May Proceed”
  - Recondition, or
  - Refusal
- If Refused admission
  - Must be Destroyed or Exported within 90 days
  - Customs demand for redelivery
  - Liquidated damages
- Import alerts
  - By product or country
  - Red listing and green listing

Notice of FDA Action (Refusal)

- FDA determines product appears to not be in compliance with the Food, Drug, and Cosmetic Act.
- This is a FINAL Agency action.
  - Can be legally challenged – and not until then
- Product must be exported or destroyed within 90 days
- Refusal can be appealed/petitioned and/or rescinded
- Customs demand for redelivery can be challenged (on FDA errors)
- Customs liquidated damages for failure to redeliver can be challenged (on FDA errors)

FDA Entry Flow Process

Importer files (by Customs Broker) entry to the FDA through Customs Automated Commercial System (ACS)

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FDA Import Screening Entry System (MARCS) evaluates data submitted and scores entry; Recommends May Proceed, Exam or Detains the entry.

↓

If referred Further Review indicated: FDA Consumer Safety Officer (CSO) reviews entry for admissibility. (CSO may release, request additional documentation, conduct field exam (Labeling, Filth, Decomp) and/or sample entry).

↓

If entry is sampled (at Port of Entry or importer), then sample is collected and sent to FDA lab for analysis.

Time of sample completion depends on type of analysis requested.

↓

Compliance Officer (CO) reviews labeling, marketing (internet sites), lab data and CSO field exam results, if negative releases entry to consignee.

Average one to three weeks from entry sampled to release.

Laboratory Results captured by PREDICT for future screening

FDA Compliance Flow Process

FDA Sample Results or Field/Label Exam demonstrate Violation; Compliance Officer Detains Product

↓

FDA issues Notice of Action to Importer, Broker, Consignee

↓

Importer, Owner or Consignee have right to introduce testimony (reconditioning, arguments and/or evidence)

↓

Compliance Officer (Hearing Officer) reviews evidence, confers with Center for Devices, Applies Law/Regs to detained product

↓

If Evidence overcomes appearance of violation → **FDA Release**

If Evidence does not overcome appearance of violation → **FDA Refusal**

↓

Compliance Officer issues Notice of Action; if Refusal, Customs demands redelivery (in Miami, Customs demand is on the FDA Notice of Refusal of Admission

↓

Importer must destroy refused goods if not exported within 90 days (Customs and FDA both involved)

Common Entry/Detention Issues

- Failure to submit additional documentation when requested (Docs required). i.e. Invoice, CBP 7501, Bill of lading, Labeling or Certifications (Impact Resistance, COAs).
- Failure to submit or incorrectly submit Affirmations of compliance (A of C).
  - LST: Device Listing Number
  - REG: Device Establishment Registration Number (Initial Importer, Manufacturer &/or Foreign Exporter)
  - REG: Failure of foreign manufacturer or exporter to connect listed device to Importer
  - PMA: Device Premarket Approval #
  - PMN: Device Premarket Notification# (510K)
  - IDE: Investigational Device Exemption #
  - ACC: Accession Number (Electronic Radiation Emitting Products)
  - RAA: Rad Health Product Affirmation (FDA 2877)
- Missing any of these (or errors) can lead to detention, plus, missing required certifications (e.g., impact resistant lens testing), unapproved medical device (based on labeling/marketing claims, e.g., Import Alert 89-08)

Things that should concern You

- Any Government Examination that is subjective in nature
  - Any quality-based or identity-based evaluation
  - Any misdeclaration-based review or testing
- Any Government Process that requires review of documents or data
  - FDA Doc Reviews of foreign documents/certifications
  - FDA requests for data to support documents/certifications
  - Customs requests for information related to applicability of FTAs or ADD/CVD orders
  - Any Government Inspection that is delayed
- Any Government Label Reviews

PGA Integration

Roy León, Esq.

Mr. León is a Florida barred attorney in our Miami office.

He regularly represents clients before U.S. CBP, the Transportation and Security Administration, and the Federal Aviation Administration, providing expertise on the intricacies of international trade, transportation and security.

Mr. León was previously a Corporate Counsel, North America for LATAM Airlines Group, S.A. in their North American Headquarters in Miami, serving as a regulatory government attorney before various U.S. federal agencies. Prior to his in-house role, he was an Associate Attorney for a regulatory boutique law firm in Miami, representing individuals and corporations in various international trade matters.

Mr. León is fluent in Spanish.

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Customs investigations

Country of origin

- Defining Origin is not always simple
  - CBP vs FDA
  - CBP vs Trade Agreement definitions
  - Product specific rules and determinations by CBP
- Origin impacts
  - Import duty rates
  - FTA reduced duty treatment
  - ADD/CVD applicability
  - Trade Sanctions
  - Mode of transportation
  - Documentation that accompanies imported goods
  - Origin Marking – exposure to special duties for violations

Classification and Valuation

- Customs has a significant penalty authority and will conduct enhanced investigations to generate revenue.
- Therefore, a thorough understanding of the type of goods or commodities which you intend to import is the next step in your long term analysis.
- Importers have duty of reasonable care for classification & valuation
- “My broker gave me bad advice” not sufficient – importer always responsible
- Where CBP finds negligence (or worse) – CBP looks back 5 years to recoup lost duty plus interest – and CBP can reopen old liquidated entries and assess penalties
- Importer must KNOW products, WHAT they are made from, HOW they are processed to properly classify – and periodically review (because HTS changes)

Checklist for PGA Issues

- Which agencies are involved?
- What are the agencies saying to and requesting from you and/or your company?
- Is their communication in writing?
- What are you and/or your company required to do in response to the Agency request?
  - Do you have to respond to questions in writing?
  - Do you have to produce records and/or documents?
  - What are the time frames for the response and/or production?
  - What happens if you do not respond and/or produce information in the allotted time frame?
- Who is aware of the issue – your own operational/logistics teams, other PGAs, your surety, your Customs broker?
- What other regulatory scenarios can segue from the issue – audits, import sanctions, holds seizures, penalties?

Questions?

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