GRMA Summit 2019

The Intersection of Customs with FDA and OGAs

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Ms. Rifkin practices in the area of customs and international trade law, with a special emphasis on food, drugs, cosmetics, and medical devices. She is the senior lead attorney for Benjamin L. England’s growing Customs and Trade Practice. She regularly represents clients before U.S. Customs and Border Protection (CBP), the U.S. Department of Commerce (DOC), and the United States Trade Representative (USTR).

With over 15 years of experience in the customs and trade area, Ms. Rifkin provides guidance on all aspects of the import and export process, including tariff classification and valuation of imported merchandise, country of origin determinations, country of origin marking, NAFTA and other free trade agreements, Customs penalties, antidumping and countervailing duty proceedings, and intellectual property issues. She routinely assists clients with prior disclosures of violations, mitigation of liquidated damages and penalties, protests, requests for binding rulings, and antidumping and countervailing duty scope ruling requests.

Ms. Rifkin regularly litigates cases before the U.S. Court of International Trade and the U.S. Court of Appeals for the Federal Circuit and has obtained a number of favorable decisions for her clients, including decisions overturning adverse classification determinations by CBP and adverse scope rulings issued by the DOC.
Agenda

• FDA’s Import Authority
• Customs Compliance Framework
• Country of Origin Marking
• Multi-Agency Actions
• What Can You Do?
• Q&A
Jurisdiction Crossover: FDA / Customs

FDA’s Authority
• Exam/sample goods
• Allow reconditioning
• Refuse articles that “appear” to violate the law
• Oversee destruction of refused goods

Custom’s Authority
• Inspect/sample goods
• Oversee exportation of refused goods
• Collect Duties
• Manage penalties on FDA Refused goods
Jurisdiction Crossover: FDA / USDA

**FDA’s Authority**
- Exam/sample foods for humans/animals
- BSE feed rule governing animal feed ingredients
- Focuses on safety of products consumed by humans and animals

**USDA’s Authority**
- Protects animals and plants in the U.S. from pests, diseases
- Promotes U.S. Ag exports and trade with other nations
- BSE risk assessments of other countries’ systems
- Permitting System
- Establish Grading Standards
PGAs Integration
Trade, Harmonization & Integration

- Practically all FDA related articles have an import component and are therefore impacted by Customs regulations
- Whether importing or buying domestic imports; something is crossing the border and affecting your supply chain
- Virtually no FDA-regulated articles remain unaffected by FDA imports and Customs legal and regulatory practice and policy
- Awareness is critical for all FDA-regulated industry
FDA’s Import Authority
What FDA uses to decide: Automated Review – information, FDA Codes, documents

- Product Code
- Intended Use Code
- Affirmation of Compliance (AOC) Codes
  - Used in automated screening to determine which entries to “May Proceed” and which to require further “FDA Review”
  - The filer (usually the customs broker) affirms the firm or product identified in an FDA line meets the requirements specific to that code
- Manufacturer/Shipper, Country
- Commercial Documents
What does FDA do at the Border?

- Examine: documents, shipments, products
- Sample: documents, products
- Detain
- Refuse admission
- Supervise destruction of refused goods
FDA’s Refusal Authority

If it “appears” from the examination “or otherwise” that an imported product:

- (1) was manufactured, processed under insanitary conditions
  
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- (3) is adulterated, misbranded, unapproved (or the importer has failed to have an adequate FSVP)

→ Refused Admission
FDA Import Alerts

- FDA’s Import Alert program is based upon FDA’s authority to refuse where imported goods even if the imported goods were NOT examined or sampled (“examine of samples or otherwise.”)
- FDA detains without physical examination (e.g., Automatically) based upon evidence that gives rise to the appearance that FUTURE shipments will be similarly violative.
- Manufacturer/product combination are placed on Import Alert
  - All future shipments “automatically detained”
- If refused, Customs enforcement authorities are triggered
Customs Release/FDA Detention?

• Imported goods are often released by Customs but NOT other agencies, such as FDA.

• When importing, the Importer of Record posts a Customs bond ensuring that IF there is a problem with Customs-released goods, the importer will redeliver them or destroy them.

• Failure to do so triggers a liquidated damages clause in the bond contract between Customs and the importer:
  – Liability could be up to three times the invoice value (up to bond limit)
  – If the problem is big enough, Customs could ALSO seize the goods.
Customs Release/USDA Problem?

- Big difference between FDA and USDA at the border
- Where goods are subject to USDA they are usually NOT subject to FDA.
- If USDA documentation or permit is required and not available, Customs Ag Officers (used to be USDA Import Inspectors) will issue Emergency Action Notification to the importer
- Under an EAN, the goods will NOT be released to the importer – the Carrier has to hold them
  - Liability includes storage and demurrage fees
  - Destruction or exportation of the goods
- Emergency permit could remedy this
Customs Compliance Framework
Key Concepts of Customs Modernization Act

• Reasonable Care
• Shared Responsibility
• Informed/Enforced Compliance
Compliance Assessments under the Mod Act

- Abandoned the concept of full audits of importer’s transactions
- Adopted the concept of Compliance Assessments using sampling techniques
- Evolved into Focused Compliance Assessment Program
Focused Compliance Assessments

- **Focused Compliance Assessments (FA)**
  - The new Customs audit process
  - Identify Risk Areas
  - Focus on internal controls used to control risks
  - Assess Compliance Levels
  - Review only those areas where compliance at risk

- **Importer Self Assessments (ISA)**
  - Only C-TPAT members eligible for ISA
  - Eligible importers can voluntarily apply for ISA participation
  - Importers selected for Focused Assessments can instead conduct ISA
Common Risk Areas

• Classification (including special tariff provisions - American Goods Returned, Assembly abroad)
• Value (Assists, royalties, commissions, first sale rule)
• Special Tariff Programs (Nafta, GSP, AGOA)
• Recordkeeping
• Country of Origin
• Antidumping/Countervailing Duties
• Drawback
CBP Import Process

• Merchandise is considered imported when it arrives from a foreign country into the “Customs territory of the United States.”
  – The Customs territory includes only the fifty states, the District of Columbia, and Puerto Rico.

• The process for an importer to obtain legal clearance from CBP to take possession of imported goods is called the “entry” process.
Types of Customs Entries

• Types of entries.
  – Consumption
  – Warehouse - entered for warehouse (in bond) at the port of importation
  – Transport (in bond) to another port of entry where it is entered for consumption or for warehouse.
  – Other common types of entries are:
    • Consumption – quota/visa
    • Consumption – Antidumping/Countervailing Duties
    • Temporary importation under bond.
Customs Entry – In Two Parts

• Entry is a two-part process.
  – Entry, which consists of the basic information or documents required by Customs to release the merchandise from Customs’ custody.
  – Entry summary
    • Includes more detailed information or documents needed by Customs to assess the correct amount of duty and fees.
Customs Release

- Customs’ release of merchandise or acceptance of a duty deposit does not mean that Customs has accepted the information as correct.
- Entry becomes final when Customs liquidates the entry.
- Releases to importer are “conditional”, and are subject to redelivery up to 30 days after the “conditional release period” ends.
- Conditional releases are subject to the terms of the Customs importation bond, which implicate liquidated damages claims if the goods are not redelivered as required.
- These provisions are additional to other government agency requirements.
FDA & Customs Actions

• Imported goods are Customs released under the Customs bond
• FDA Refusal of Admission requires exportation or destruction of the refused product
• Customs demands redelivery of the product back into its custody so exportation or destruction can be supervised
• Importer must export or destroy within 90 days
• Liquidated damages claims WILL ARISE under the Customs bond if importer fails to export or destroy or fails to properly document the process or fails to obtain the required supervision
The Law

Every article of foreign origin imported into the United States **shall** be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article will permit in such manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article.
Elements of the Marking Law

- Every article of foreign origin
- Marked in a conspicuous place
- As legibly, indelibly and permanently as the article will permit
- To indicate to an ultimate purchaser in the United States
  - The English name
  - Of the country of origin
Customs Investigations of your Imports

Form 28 – Requests for Information
• Verify entry information
• Request documentation or samples

Form 29 – Notice of Action
• When CBP isn’t satisfied with the Importer’s response to Form 28, sometimes, CBP proceeds directly to a Form 29
• May assess additional duties or begin the liquidation process
• Be prepared - this may be the start of a CBP penalty proceeding.
Multi Agency Actions
Examples of Real Multi-Agency Actions

• Imported food ingredient (multiple containers / month)
  – Import Alert (pesticide residues) led to FDA refusals, which led to
  – Liquidated damages claims ($$), which led to
  – HTS classification (CBP informal inquiries) ($$), which led to
  – Request for CBP Internal Advice (potential litigation), followed by
  – USDA NOP investigation piled on (threatened loss of certification)
  – US Dept of Commerce inquiries re HTS classification

• Competitors at first unaffected
  – FDA sampling increased across industry – additional firms affected
  – Customs & Dept of Commerce began inquiries re HTS classification and possibly AD/CVD imposed by Commerce
Examples of Real Multi-Agency Actions

- Imported finished and raw goods (multiple containers/month; 2 chains)
  - FDA Import Alert issued against common supplier but targeting finished goods only
  - Extremely broad scope affecting all supply chains (even those with no prior connection to specific finished goods of concern)
  - Overly broad FDA automatic detentions – bulk, unfinished goods going into completely different markets unrelated to finished product of concern
  - HTS classification and FDA Product Coding changes raised CBP attention
  - Based upon legal representation – Government recently BLINKED
Examples of Real Multi-Agency Actions

- Imported finished and raw goods (multiple containers/month)
  - Middle-man US importer selling to major retailer
  - Routine CBP intensive examination led to questions re speciation, which led to
  - USFW notice of violation (Rosewood), which led to
  - Potential penalty actions

- Mitigating Factors
  - USFW screening is not a part of ACE – so hundreds of shipments slipped through
    - Mitigation opportunity
    - That dog is still sleeping…
What can you do?
Considerations for your Team

• Internal crosstalk between Reg Affairs and customs/trade staff - **Critical**
• Compliance requirements of multiple agencies may require similar datasets
  – You want to think through (and address) all potential issues the FIRST TIME -- in your documentation!
    • What the inspector or compliance officer or agent might care about – and what if another agency looked them over?
    • Make sure your shipment documentation tells a **consistent** regulatory narrative
• New FDA reorganization means changing how your company units communicate and approach compliance (*i.e.* corporate governance and trade compliance procedures implemented and followed)
Where to Focus Your Energy

- Registrations of facilities, if necessary
- Product listings, if necessary
- Labels and Labeling
- Approvals, if necessary
- Formulation
- Know your foreign suppliers
  - Create contractual obligations for them to notify you as soon as they are aware of any detentions or facility inspections
  - Mine FDA refusal and Import Alert data
Other Things that should bother You

- Any Government Examination that is subjective in nature
  - Any quality-based or identity-based evaluation
  - Any misdeclaration-based testing
- Any Government Process that requires review of documents
  - FDA Doc Reviews of foreign documents/permits
  - Customs requests for information related to applicability of FTAs or ADD/CVD orders
  - USFW/PPQ/CBP Requests documenting speciation (CITES and Lacey Act)
- Any Government Inspection that is just a bit delayed
  - Attempting to catch distribution prior to releases
- Any Government Label Reviews
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?
Let us put our 100 years of direct former government experience to work for you to identify and solve problems involving approval, manufacture and movement of products in and out of the U.S. market.

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