Agenda

Day 1 — Oct. 27, 2014

8:00 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 10:15 a.m. **FDA Imports**

- FDA Import History and Pirates
- Current Legal Authority
- Registering and listing with FDA
- Selecting an Import Broker
- FDA's and U.S. Custom's dual role
- Procedural fundamentals
  - Required Notice
  - Required Information
- Documentation
  - Required and voluntary forms
  - FDA Form 2877
  - CPB Form 3461
  - Affirmation of Compliance
  - Electronic Filing

10:15 a.m. – 10:30 a.m. **Break**

10:30 a.m. – 12:00 p.m. **FDA's Import/Export Technologies**

- FDA Computer Screening Program (PREDICT)
- U.S. Custom's process and computer link to FDA
  - Harmonized Tariff
  - Invoice and Shipping Records
  - Entry number and what it means
  - Bonded warehouses for possession/control
  - FDA's Notice of Action and what to do
  - May Proceed
  - Sampling
  - Detention
  - Refusal
- FDA Computer Tracking Program OASIS

- Internal database
- Violation codes

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:30 p.m. **Detention Process and Best Practices**

- FDA Automatic Detention / Import Alert List
  - Detention by:
  - Country,
  - Product type,
  - Manufacturer
- Options for detained products
  - Reconditioning Procedures
  - Form FDA 766 – reconditioning agreement
  - RE-export
  - Destruction and added government fees

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:30 p.m. **Group Break Out Interactive Exercises**

- Import Hypothetical I - technical problems (short term issues)
  - What are your options if FDA detains a product because the product code and other qualifier information is incorrect? What if the product requires a certificate of analysis? Who gets involved with the detention and what do they do? Many companies are either clueless or confused about what can to be done immediately to get the product released by FDA. What is your plan of action? Will you wing it? What are your options for storage in the meantime and what can you expect with that?
- Import Hypothetical II - enforcement problem (long term issues)
  - What are your options if FDA detains your product because it is "filthy?" What are your options and what do you do? What if you tried to clean the product, but failed. Next FDA issues you a Notice of Action for refusal. What will FDA do and what will you do next? Your next shipment of the same product is detained for the same reason. Your boss wants an explanation and how you are going to fix the problem. What is your game plan? Quitting your job is not an option.

4:30 p.m. **Session Wrap-up, End of Day One**

Day 2 — Oct. 28, 2014

8:30 a.m. – 9:00 a.m. **Continental Breakfast**

9:00 a.m. – 10:15 a.m. **Interacting with FDA**

- How to negotiate with FDA
  - What to say and what not to say
  - How to set up a telephone call or face-to-face meeting
  - How to prepare for and conduct yourself at a meeting with FDA

10:15 a.m. – 10:30 a.m. **Break**

10:30 a.m. – 12:00 p.m. **Managing Import Problems with FDA**

- Mitigating regulatory risk and FDA enforcement damage
  - Shipping strategies and cargo options
  - Foreign supplier options
  - Third party laboratories
  - Insurance
- Inspection of foreign manufacturers
  - Third party audit
  - FDA inspection
- Foreign inspection damage control
  - Responding to FDA's inspectional observations ("Form FDA 483")
    - When to respond
    - What to say and not say
    - Verification
  - Responding to the FDA's Warning Letter and manage automatic detention
    - When to respond
    - What to say and not say
    - Documentation
    - Verification
    - F/U inspection by FDA

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:30 p.m. **FDA Exports**

- Legal authority
  - Adulteration and Misbranding exemption
  - Criteria requirements for using the export exemption
    - Basic criteria (Sec. 801(e)(1) of the FD&C Act)
    - New criteria and Tier I countries (Sec. 802 of the FD&C Act)
    - Special criteria for high-risk products that do not meet new export criteria (Sec. 801(e)(2) of the FD&C Act)

- Export certificates
    - Types and qualifications for use
    - How to obtain an export certificate

Group Break Out Interactive Exercises (Class project)

- Export Hypothetical I - Selling a recalled product abroad
    - Your firm's recalled some OTC product in the U.S. because the instructions for use on the label left out storage instructions. You have lots of this product in your warehouse just waiting to be shipped. What are your options?
- Export Hypothetical II – Shipping a product abroad before approval by a foreign country
    - Your new prescription product is made for your market in France. You expect to receive your CE mark in a few days. What will you do with the product now? Your next market will be Japan and you expect approval in a few months. What can you do now? To your surprise, France does not issue a CE mark and a cargo ship will arrive in France in about 1 week. What will you do now? This shipment was valued for $2,000.000 when it left Miami, now it is worth a token amount of $1,000. What are your options.

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:30 p.m. **FDA Import-for-Export**

- Purpose and legal criteria
- Foreign Trade Zone status is for U.S. Customs, not FDA
- Procedures
    - Notification
    - Accountability
    - What is the "for further processing" criteria mean?

FDA's Special Import Provisions

- Trade Shows
- Return for Repair
- Compassionate Use
- Personal baggage

4:30 p.m. **Adjourn Workshop**