FDA Import Holds:
New Powers to Control Products

Tuesday, Sept. 24, 2013 • 10:00 a.m. - 4:00 p.m. EDT

Agenda

10:00 a.m. – 10:15 a.m. **Introduction to the Virtual Conference**

10:15 a.m. – 11:15 a.m. **The New Enforcement Posture: PREDICT, PLAIR, Customs and 2013 FDA Trends**

Get the inside track on the emerging powers of the FDA for enforcement, screening and inspections in light of new legislation and trends. Understand the impact of PREDICT, risk data, statistics, processes and the trends affecting manufacturers, importers and distributors this year. Understand the trends, understand the FDA, and solidify your strategies.

Attendees will learn:

- What is PREDICT and how does it affect me?
- What PLAIR could do to change import holds
- FDA importation authorities and processes — what's changing and what's staying the same?
- What trends are the FDA and Customs focusing on today that could get you in hot water?
- Understanding the thresholds and severity of the new enforcement powers at play

Casper Uldriks, Counsel, Olsson Frank Weeda Law (invited)

11:15 a.m. – 11:30 a.m. Break

11:30 a.m. – 12:30 p.m. **Certified Importer Approach: Better than Transactional Controls —Assessing the Potential for Integrated Border Management Between the FDA, Customs and USDA**

Currently the FDA, Customs and USDA operate independently of each other with regards to approving goods entering the U.S. This process is very complex and is subjected to each import transaction, which can cause undue delays at the border. An integrated border management framework, where the various agencies work in concert with each other, can allow a drug to be pre-approved for distribution and help to streamline the process of crossing the border. A

promising initiative, the Qualified Trusted Importer Program (QTIP), would assess a company's internal processes and controls with respect to product quality, supply chain security and trade compliance. Upon review, companies that qualify as "trusted importers" would be afforded interagency "green-lane status". Not only would this allow a company to receive a pre-admission decision from the FDA, Customs and USDA, but it would also prevent a company from having to go through a lengthy process for each transaction. For a company that imports on a large scale, it would be a significant savings of time and resources. This session discusses the potential benefits of an integrated border management program.

Attendees will learn:

- How to apply risk management techniques to ensure compliance
- Details on the Advocate for Qualified Trusted Import Program (QTIP)
- Benefits of an account management rather than transaction system
- What's "green-lane" status?
- Best practices for achieving pre-admission decisions prior to reaching the border

Michael Mullen, Executive Director, Express Association of America

12:30 p.m. – 1:30 p.m. Lunch

1:30 p.m. – 2:30 p.m. **FDA Imports: Surviving an FDA Import Hold Crisis**

Regardless of the reason, once a shipment is held at an entry point, the shipment's owner has the right to a single, informal hearing. Should the owner be unable to prove to the FDA's satisfaction that the product meets all requirements, it will be forced to export or destroy the shipment. Should this exportation or destruction not occur within 90 days of the hearing's conclusion, Customs can seek to fine the owner three times the detained product's worth. Plus, the loss of revenue from a single shipment could represent millions in lost profits. This session will provide guidance on how to negotiate hold releases, when to bring in outside help, and what to do to prepare for the informal hearing.

Attendees will learn:

- 6 techniques for communicating with FDA personnel—slow communication and miscommunications are lethal when the clock is running on your shipments.

- How to understand and comply with documentation requirements—not having your paperwork in order is a surefire way to have your import held
- The levels of import holds and the likelihood of a successful challenge at each
- Import alerts—how to prevent the death penalty for your shipments and how to negotiate with the FDA once it is imposed
- How the PREDICT system will influence the import alert and hold process
- Best practices to assure your PREDICT profile doesn't raise red flags with the FDA

William Nychis, Senior Regulatory Advisor, Benjamin L. England & Associates

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 3:45 p.m. **How to Review Product Labeling to Avoid FDA Import Compliance Woes — 5 Steps You Need to Take**

Incorrect or confusing labeling is a key reason why many products face import holds. The authority to hold product is based upon the "appearance" of a violation, so proper labeling is critically important. This presentation will help firms understand that no matter what the product is (API, OEM, finished goods) or who it's being imported from (partner, sister company, supplier) the labeling needs to be accurate to assure smooth entry.

Attendees will learn:

- The most common problems with labeling that raise red flags for Customs and FDA staff
- 5 steps you can take to reduce any appearance of violation

Jim Johnson, Pharmaceutical and Life Sciences Group, Hogan Lovells

3:45 p.m. – 4:00 p.m. **Closing Comments and Adjournment**