How FDA Conducts Import Operations at the US Ports and its Role in Consumer Protection

Authors

Presentation by **Dan SOLIS**[1], Import Operations FDA, summarized by **Charlotte MANTON** and **Dan SOLIS.**

Key Words

Food Imports; FDA Los Angeles District Office; Import Operations

Abstract

The FDA Los Angeles District Import Operations Office conducts product reviews, inspections, sampling, examinations, and investigations of regulated goods entering the US, manufactured in foreign countries, coming through aerial and maritime ports located in their jurisdiction. This enormous harbor, called the San Pedro Port Complex, which is a combination of the Port of LA and the Port of Long Beach, is the largest port of entry for shipped goods into the United States and accounts for approximately 45% of all maritime cargo entering the country. The sheer volume of goods that pass through this port in combination with the limited financial, technological, and human resources available to the FDA requires that Import Operations be strategic, proactive, and adaptive to meet their objectives.

SUMMARY

Currently, the FDA Office of Regulatory Affairs (ORA) is composed of five Regions (Pacific, Central, Northeast, Southeast, and Southwest) that cover all of the US and territories from Guam to Puerto Rico and from Alaska to the Virgin Islands. In addition to the twenty district offices

[1] Daniel **SOLIS**. Director of Import Operations - Los Angeles at US FDA. Greater Los Angeles Area, California.

Copyright ©2016 Quality Leaders Network • www.qualityleaders.org

spread across these five Regions, ORA is supported by a combination of more than 150 Resident Inspection Posts/Border Stations and a selection of Office of Criminal Investigations (OCI) sites, including field offices, resident offices, and domiciles. These locations are dispersed throughout the regions to best support ORA's efforts. ORA is the "lead office for all agency field activities" and as such is responsible for conducting inspections of regulated products and manufacturers, conducting sample analyses of regulated products, and reviewing imported products offered for entry into the United States as well as the lead in criminal and civil investigations out in the field. This means that in addition to regulating and reviewing such products marketed domestically, the FDA ORA is also responsible for reviewing all regulated goods arriving to this country - from nearly anywhere in the world.

Located in the southwest corner of the ORA's Pacific District, the FDA Los Angeles District Office conducts product reviews, inspections, and investigations of regulated goods entering the US. The LA Office is composed of Import/Port Operations (Long Beach, CA), Domestic Investigations (Irvine, CA), and the Compliance Branch (Irvine, CA). These branches oversee and inspect complex medical device, drug and food industries, as well as overseeing massive Port complexes making management of this district extremely challenging. Southern California is home to several major airports including Ontario and Los Angeles International (LAX) (the third-busiest airport in the nation) as well as the Port of Los Angeles and Long Beach. This enormous harbor is the single largest point of entry for shipped goods into the United States and accounts for approximately 45% of all maritime cargo entering the country. The sheer volume of goods that pass through this port in combination with the limited financial, technological, and human resources available to the FDA requires that Import Operations be strategic, proactive, and adaptive to meet their objectives.

The Main Import Operations mission is to prevent and investigate adulterated, unapproved, and misbranded products from entering the United States; approximately 105 dedicated public health employees from a wide range of scientific backgrounds are responsible for this crucial endeavor. Scientists, health care professionals, and officers with experience in foreign markets and public health emergencies work tirelessly to minimize the risk of adulterated, unapproved, and misbranded products from entering the country. These officers actively collaborate not only with Customs and with Border Protection (CBP) at airports and seaports, but also work with CBP at centralized examination stations (CESs) and International Mail (IMF) to monitor for illicit or adulterated goods.

The FDA as a whole regulates approximately one-quarter of the US economy – with limited resources – and so must strategically work with other offices, agencies, as well as local,

Copyright ©2016 Quality Leaders Network • www.qualityleaders.org

and international governments to protect the American public. The FDA has close relationships with more than twenty other government departments - all dedicated to the goal of protecting the public health. These include the Federal partners such as CBP, US Department of Agriculture (USDA), Fish and Wildlife Services (FWS), Drug Enforcement Administration (DEA), National Oceanic and Atmospheric Administration (NOAA), but also as expected L.A. Police Department (LAPD) and the District Attorney's (DA) Office. Additionally, the Office of Criminal Investigations (OCI), a sub-office within the FDA, acts as the organization's law enforcement arm and concentrates on significant criminal violations of federal law/statutes.

Globalization further complicates the FDA's mission of protecting and promoting public health - shifting relevant territory from a national to a global scale. An estimated 50% of fresh fruits and 80% of seafood eaten domestically come from abroad. Similarly, in medicine, an estimated 50% of all medical devices are imported and 40% of finished drugs are manufactured overseas. Increases in outsourcing, foreign production facilities, shipping speeds, and complexity of supply chains require that the FDA respond in kind – developing new enforcement and regulatory tools capable of enhancing American public health and safety. A push towards partnerships with foreign regulatory and government agencies not only reduces the burden on the US FDA but also promotes the preventative stance that the agency has taken.

The sheer amount of goods that Americans consume from abroad necessitates that the FDA use a combination of legislative and operational strategy, technology, and pure manpower to protect the public health as best they can. Legislative successes in recent years have equipped the FDA with the authority and reach to proactively address the threats brought by the modern world economy. The Food Safety Modernization Act (FSMA 2011) is one of the most striking changes to US food safety laws since the 1938 Food Drug and Cosmetics Act, and has been accompanied by the Family Smoking Prevention and Tobacco Control Act (TCA 2009), the FDA Safety & Innovation Act (FDASIA 2012), and the Drug Quality and Security Act (DQSA 2013). Collectively, these acts empower the FDA to proactively reduce risk and enhance supply chain security and transparency.

The FSMA stands out from previous Acts for several reasons: it shifts the focus of the FDA from reacting to food safety issues to preventing them. Greater onus is laid on food companies to prevent contamination within the supply chain; it authorizes the FDA to refuse imports, require certification from certain importers, and invoke mandatory recalls. The Act also promotes training and collaboration with other national and international agencies and regulatory bodies to disperse agency responsibility.

Copyright ©2016 Quality Leaders Network • www.qualityleaders.org

In a similar vein, the TCA seeks to proactively protect the public by discouraging children and young adults from tobacco use as well focusing on the health implications for current smokers. FDASIA further expands the agency's authority by empowering it to collect user fees from industry as well as destroy unapproved, counterfeit, or adulterated drugs. The 2013 DQSA is a powerful piece of legislation designed to crack down on these unwanted imports by building an electronic system to track and trace particular prescription drugs in the US market. Over the next several years, manufacturer and distribution requirements for product identification, verification, and tracing will become legal obligations. These acts enhance the FDA's ability to protect the American public from harmful goods and places legal and financial sanctions on companies who willfully disregard them.

These acts – expanding FDA authority and encouraging intra-agency collaboration at every level – have been integral to the success of recent ventures. In addition to detaining, refusing, or seizing shipments, violative importers now face a litany of penalties for non-compliance that can include injunctions, debarments, and criminal charges. The need to assuage the economic and human impact of counterfeit drugs – and products – on the US economy is serious: counterfeit drugs do not just affect the corporations involved; they can hurt or kill the people they are meant to heal. To identify and impede illicit imports, FDA strategy relies on a combination of pre-arrival intelligence and public & proprietary technology. Foreign inspections, foreign agency communications, and track and trace technologies leverages information from multiple sources to identify potentially problematic shipments. Once stateside, data from physical tools like XRF (X-ray fluorescence to identify chemical composition) and lot codes/tags (track n' trace) as well as from web-based applications and PREDICT all weigh in on import assessments. PREDICT, or the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting, is an assessment tool that has vastly enhanced FDA's screening and targeting capabilities. Its ability to accurately assess the relative risk of an imported product – accounting for its manufacturer and supply chain – has revolutionized the FDA's ability to inspect imports. The programs ability to 'learn' through pattern discovery and data mining will only continue to refine the process. □

Copyright ©2016 Quality Leaders Network • www.qualityleaders.org