FDA Import Operations Embassy Training Seminar

Presented by
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November 7, 2003

Objective of Operations

- Operate within the context of Efficient Risk Management for public health and safety
- Ensure imported regulated products that pose or appear to pose a threat or risk to public health and safety are not allowed entry, or are otherwise mitigated
- Facilitate expedited movement of imported goods of little or lesser risk to public health and safety

Currently, how is Entry Information Received?

- Most entries are made electronically via interface with Bureau of Customs and Border Protection ACS system
- Most entries are entered into the system by Customs House Brokers (also called Filers by FDA)
- Entry data from Customs goes to FDA's electronic system , OASIS

Entry Information continued

- FDA's electronic OASIS system is the primary mechanism used by the field inspectors for entry review, work flow, and generation of notices to the importers related to specific entries
- Product Center databases also used for determining admissibility
- OASIS system is primary tool for FDA HQ to implement selectivity criteria nationwide including Import Alerts
- OASIS and ACS selectivity criteria is coordinated at the HQ level of both CBP and FDA

Challenge of Numbers FY2003

- 9.4 million lines of entry of all FDA regulated products
- Products imported from 200+ (two hundred)countries
- Products made by 200,000+ declared foreign manufacturers/processors
- Products enter through approx. 300 Customs ports
- Approximately 1/3 of all exports to the U.S. are FDA regulated products
- Project approx. 11 million lines in FY 2004

Current Day to Day Import Operations

- Most industry/FDA interaction is at the FDA field district office level covering certain port areas
- If FDA entry reviewer finds product in an entry "appears" to violate provisions of the FD & C Act, local office issues appropriate notice of apparent violation
- Importer, owner, or consignee has opportunity to provide evidence to overcome the "appearance" of violation.
- If appearance of violation is not overcome, entry is refused and Customs advised.
- Refused articles are destroyed or exported under Customs rules

Current Day to Day Import HQ Operations

- Develop and implement import enforcement procedures and policies based on risk
- Implement Import Alerts and evaluate petitions for removal from import alerts
- Manage selectivity criteria in OASIS
- Coordinate import activities among various Agency components including field and headquarter units and other federal agencies (CBP, USDA, etc)
- Provide HelpDesk support for OASIS
- Identify need for and conduct training for FDA personnel

Initiatives

- Commissioner's Strategic Action Plan
- Implementing provisions of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002"
- IT improvements for management of information related to chain of supply
- Revision/Update of Regulatory Procedures Manual Chapter 9

Mutual Objective

- Ensure FDA regulated products in international trade are safe and secure.
- Ensure business practices of the foreign manufacturer to the U.S retailer (product life-cycle) are in alignment with goal of delivering products that are safe and secure
- Collaborate/partner to establish workable methods to mitigate potential risks of products prior to arrival at U.S. ports so trade is efficient and safe.

Q&A's?

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