

A large green decorative shape on the left side of the slide, resembling a stylized letter 'E' with a rounded top-left corner. It has a white cutout on the left side.

FDA Import Alerts

January 16, 2008

A thick, dark blue horizontal bar with rounded ends, positioned below the date.

FDA Import Alerts

- Identifies problem commodities, shippers & importers (may also be country wide, seasonal, etc.)
- Provides guidance to District offices for Detention Without Physical Examination (DWPE) of products which appear to be in violation
- Based on historical data
- Issued by Division of Import Operations and Policy (DIOP)

Import Alert Recommendations

- Submitted to DIOP by District Offices or Centers
- DIOP reviews all IA recommendations nationwide
- DIOP ensures IA's are timely disseminated and revoked as appropriate
- Improves uniformity of enforcement

Recommendation for IA Based on One Incident

- Adverse health consequences
- Actionable levels of a pesticide, aflatoxin, or chemical contaminant
- Violative in a way that is expected to continue (allergen, unapproved color, unapproved new drug, etc.)
- Violative foreign inspection

Recommendation for IA based on Multiple Entries

- Filth
- Decomposition
- Labeling

FDA Import Law

“appearance” and “or otherwise”

- These form the basis for our Import Alert system:
 - Detention
 - Without
 - Physical
 - Examination

Detention Without Physical Examination

- Upon arrival of a product subject to IA, product may be DWPE
- Product subject to DWPE does not mean the product is in violation
- DWPE places responsibility to demonstrate compliance on the importer

Obtaining Release from IA

- Importer offers information that this shipment is not in violation
- Usually in the form of private lab analysis

FDA Import Alerts - Removal

- Agency may require a certain number of consecutive non-violative shipments
- Routine commercial entries
- Re-inspection
- Filing of proper application (NDA, 510k, etc.)
- Division of Import Operations and Policy (DIOP)

FDA Import Alerts - Prevention

- Importers bear responsibility of ensuring products are in compliance
- Be proactive:
 - If feasible, audit foreign manufacturer
 - Privately examine or analyze product
 - Review labeling for compliance
 - Assure proper applications have been filed

FDA Import Alerts

- FDA's Import Alerts are public documents that can be found on the world-wide-web at:

http://www.fda.gov/ora/fiars/ora_import_alerts.html



FIARS

Import Alerts

option 1: [INTRODUCTION](#)

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- option 4: [IMPORT ALERTS BY NUMBER](#)
- option 5: [IMPORT ALERTS BY REVISED TEXT DATE](#)
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