

Import Operations Los Angeles District

QLN Network FSVP Update

September 22, 2016

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Los Angeles District Import Operations
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Los Angeles District Import Operations



FDA LEADERSHIP



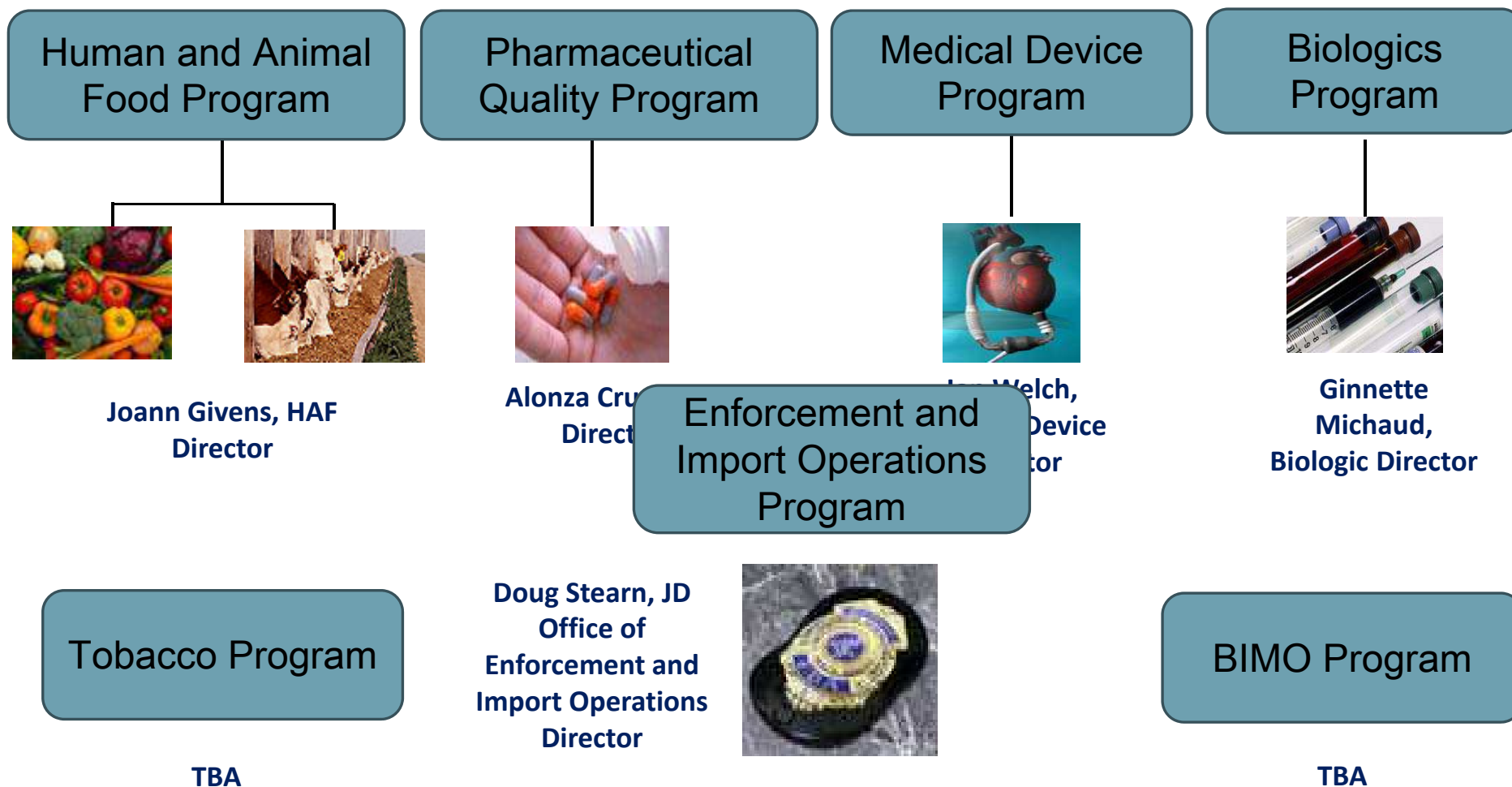
“...we must do everything possible to rapidly adapt our national and global systems of evidence generation to meet the challenges and opportunities presented by technological advances.”

Robert Califf, MD

FDA COMMISSIONER

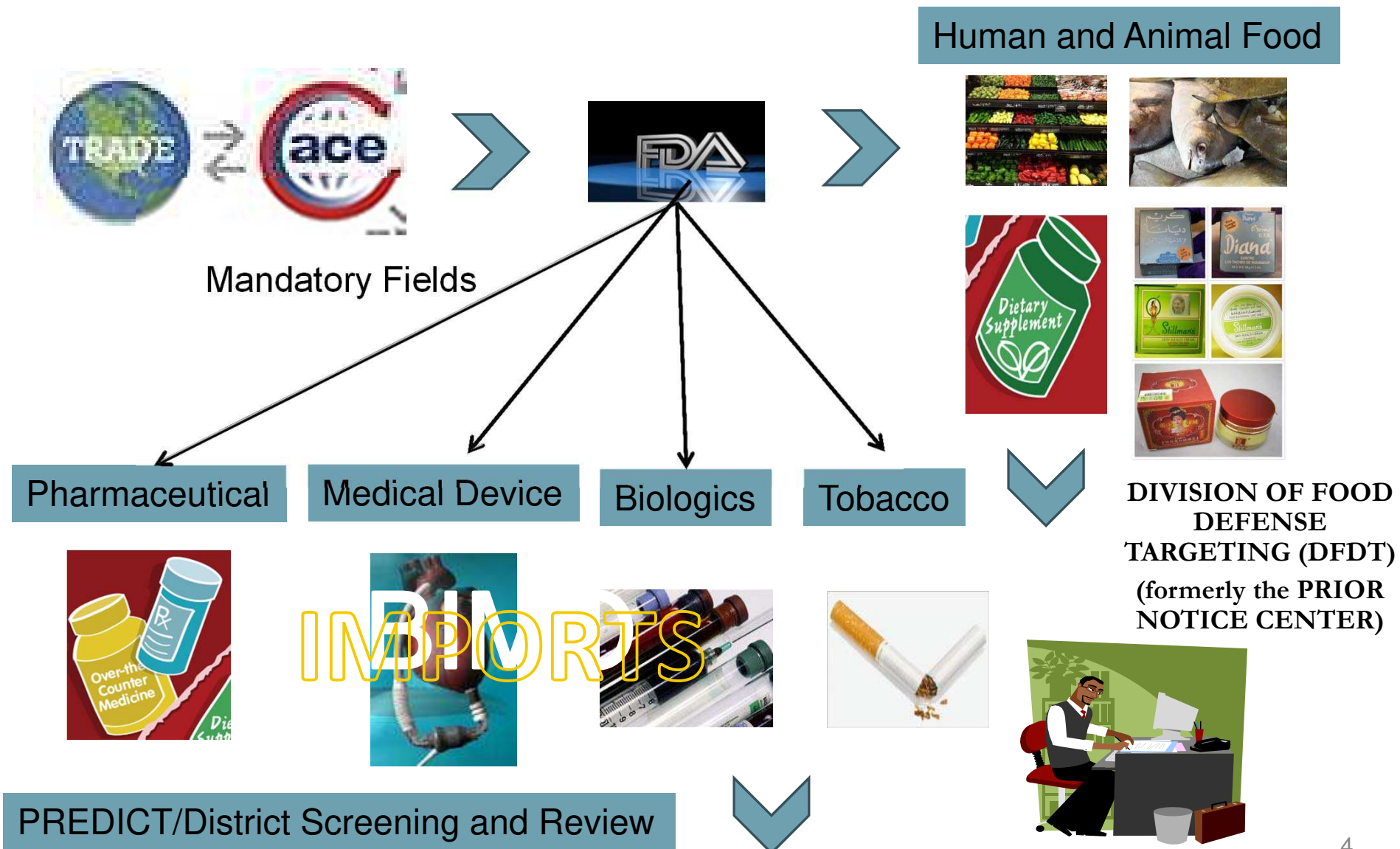


ORA PROGRAMS



GENERAL IMPORT PROCESS

FDA



New FDA Import Operations Website

- New Imports Program website:

<http://www.fda.gov/ForIndustry/ImportProgram/default.htm>

- New Product Code Builder website:

<http://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm>

New Import Alerts Website



- **Import Alerts** = Import alerts **inform FDA field staff** and the public that the agency has enough evidence to allow for Detention Without Physical Examination (**DWPE**) of products that appear to be in violation of FDA laws and regulations. These violations could be related to the **product, manufacturer, shipper and/or other information**. Before importing into the United States, importers should know if their products are subject to DWPE. DWPE allows the agency to detain a product without physically examining it at the time of entry.

LINK

<http://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm>

FDA's New Legislations



- **Food Safety Modernization Act (FSMA)**. Signed into law on January 4, 2011.
- The most sweeping reform of **our food safety laws in more than 70 years**.
- It aims to ensure the U.S. food supply is safe by shifting the focus **from responding to contamination to preventing it**.

- Seven Foundational Rules:

- Produce Safety
- Preventive Controls for Human Food
- Preventive Controls for Animal Foods
- Foreign Supplier Verification Program (FSVP)
- Accreditation of third-party auditors for foreign facilities
- Mitigation for Intentional Adulteration of Food
- Sanitary transportation of Human and Animal Food





Guidance and Outreach

- Developing FSVP draft guidance for industry
- Food Safety Preventive Controls Alliance will develop course materials for FSVP
- Webinars and meetings
- Developing the “FDA Data Dashboard” to assist importers

FSMA

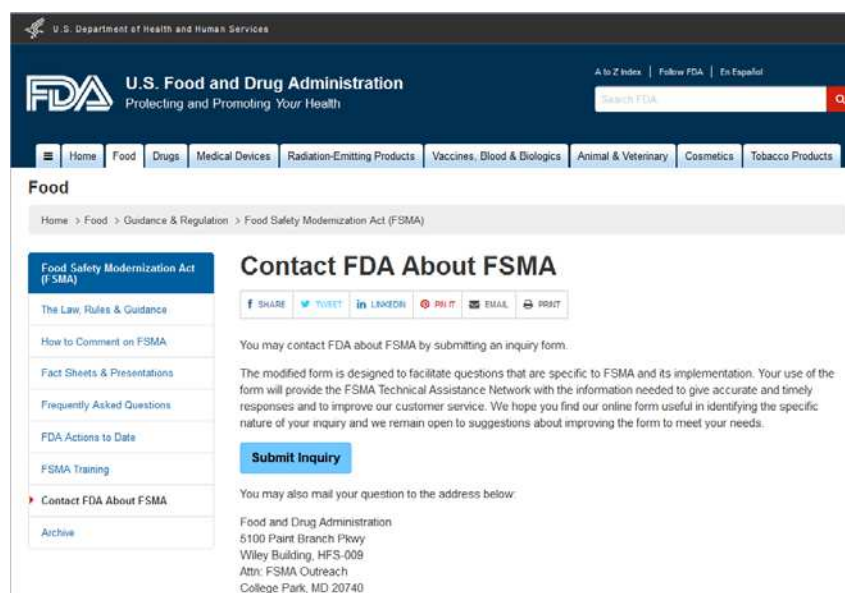
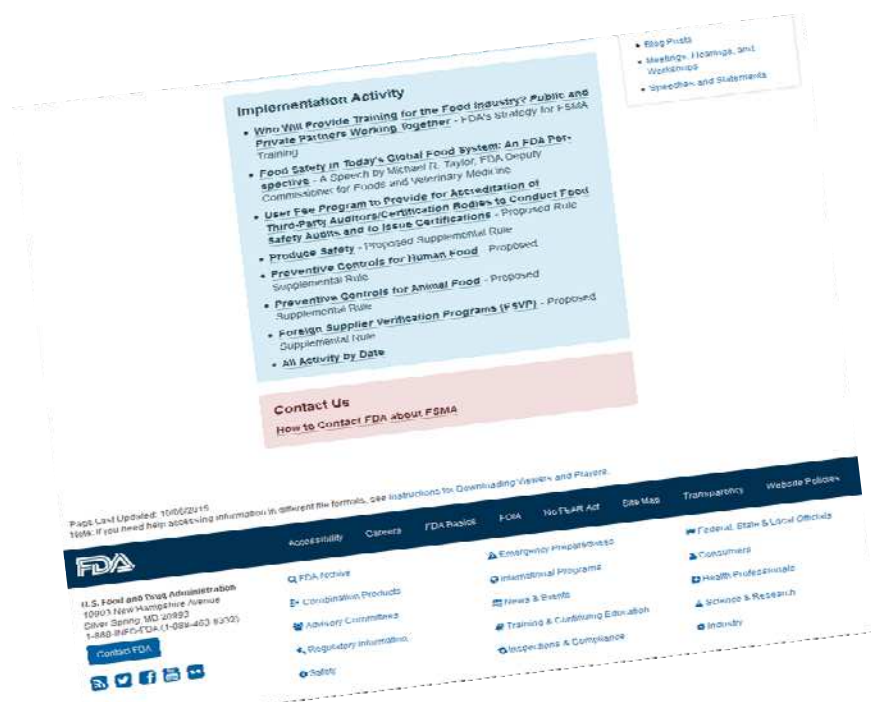


- **Compliance Dates?**
 - What does it mean to me?
 - The first major compliance dates have arrived for the preventive controls rules for human and animal food under the FDA Food Safety Modernization Act (FSMA). **September 19, 2016.** That's the date when larger businesses must comply with certain new standards. Human food facilities must meet preventive controls and Current Good Manufacturing Practice requirements (CGMPs); animal food facilities must meet CGMPs. (The larger animal food businesses have an additional year to meet the preventive controls standards.)
 - Do I have a PCQI person and do I have a Food Safety Plan?
- **What is the ultimate goal?**
 - The purpose of these rules is to create a preventive, food safety system that is self-sustaining. Everybody in a food facility should be systematically operating in a way that complies with the law.
 - The preventive controls requirements fulfill the paradigm shift toward prevention that was envisioned in FSMA and, in combination with CGMPs, will help protect consumers into the future.
 - It's a marathon, not a sprint.

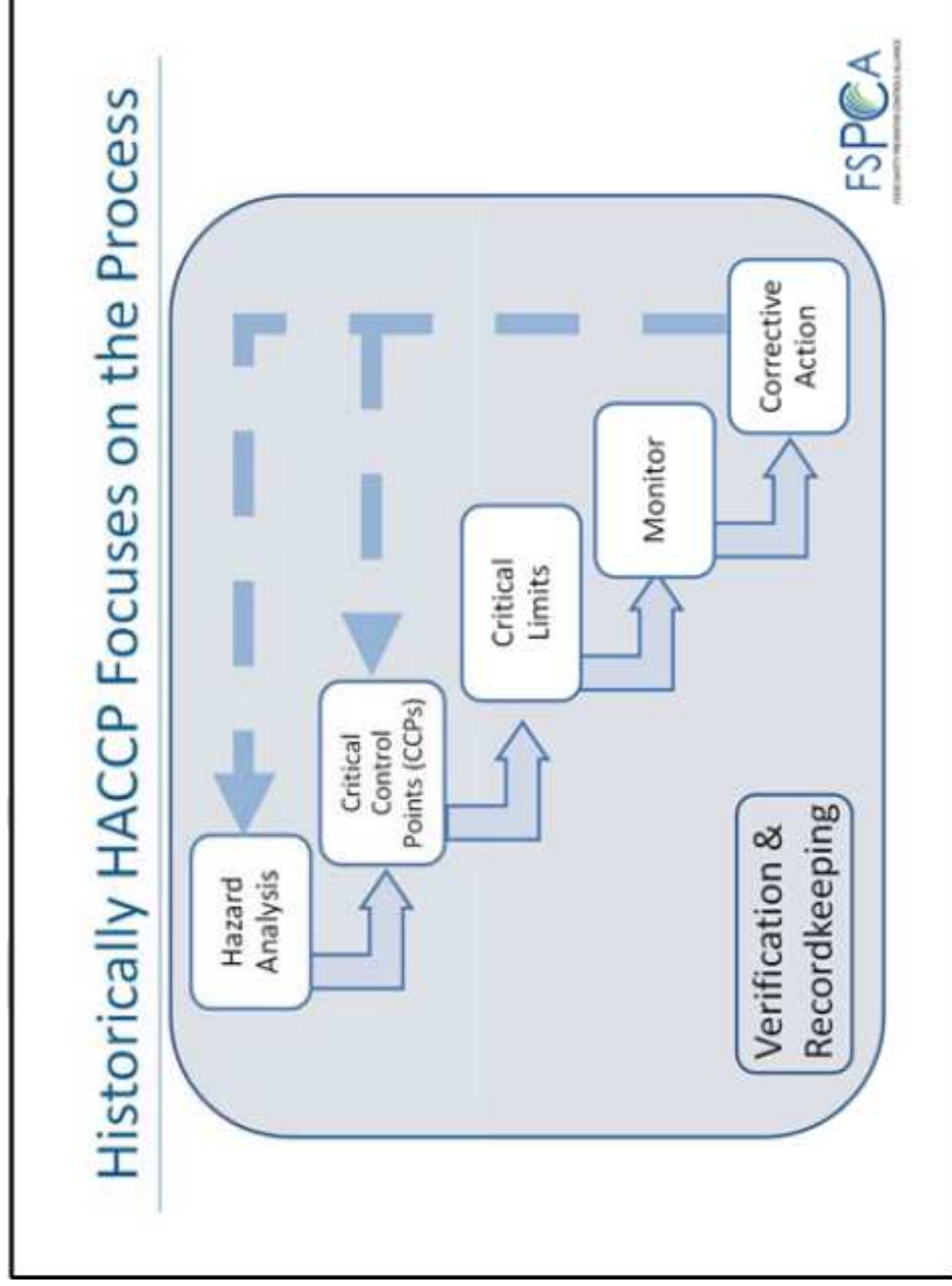


For More Information

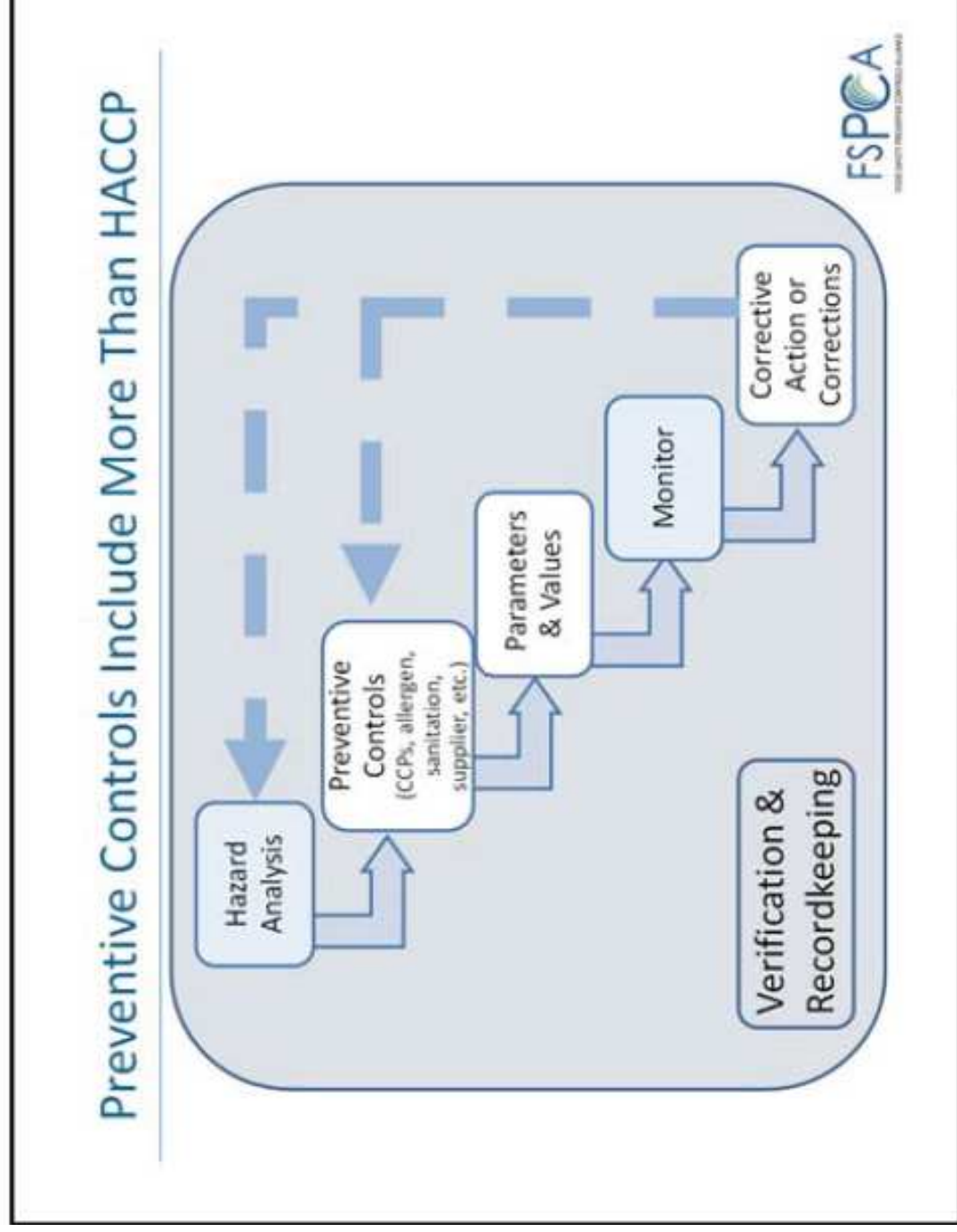
- Web site:
- Subscription feature available
- To submit a question about FSMA, visit and go to Contact Us



Why FSMA is a Game Changer



Why FSMA is a Game Changer



FSVP Requirements

- In general, importers would need to conduct the following activities as part of their FSVPs:
 - Hazard analysis
 - Risk evaluation
 - Supplier verification activities
 - Complaint investigation and corrective actions
 - Periodic reassessment of the FSVP
 - Importer identification at entry (UFI)
 - Recordkeeping



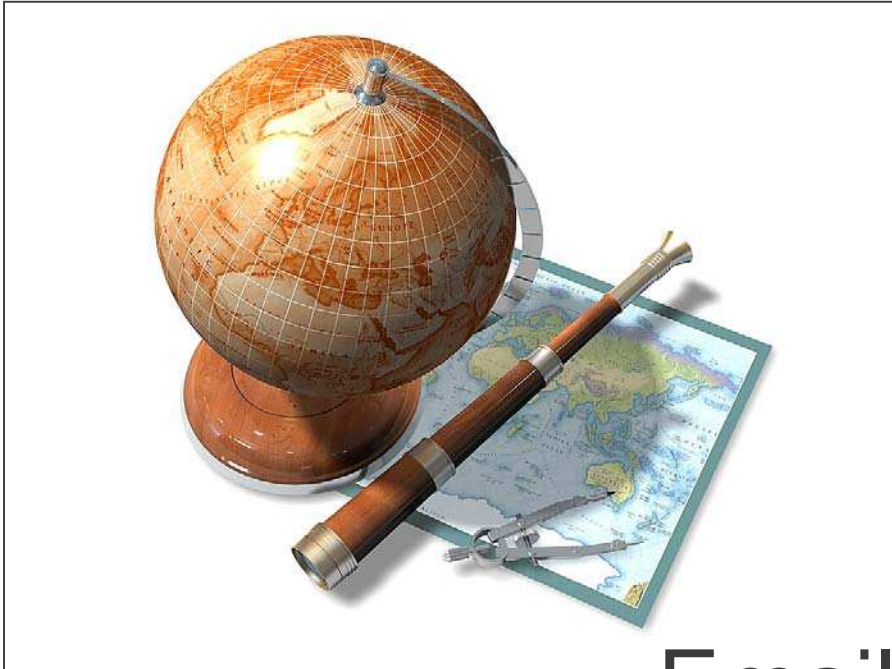
FORMS OF COMMUNICATION WITH FDA in LOS ANGELES IMPORTS

- **Phone Numbers for LOS-DO Import Operations (Long Beach, Ca)**
 - General status line (562) 256-7700
 - Compliance status line (562) 256-7707
 - Fax line (562) 256- 7701
- **General email address:** LAIMPORTS@fda.hhs.gov
- **LAX Office email address:** LAXImports@fda.hhs.gov
- **Los Angeles District Consumer Complaint Hotline:** (949) 608-3530
- **FDA National Emergency Operations Number:** 1-866-300-4374 or (301) 796-8240
- **FDA General Inquiry:** 1-888-INFO-FDA
- **For Adverse Event of illness call** 1-800-FDA-1088 or [online](#)
- **For Drug Inquiries:** CDERSmallBusiness@fda.hhs.gov or (866)-405-5367
- **For Medical Device Inquiries:** industry.device@fda.hhs.gov or (800) 638-2041
- **To report e-mails promoting medical products that you think might be illegal, forward the email to:** webcomplaints@ora.fda.gov.

Note: Fastest response is email.

Thank You For Your Attention!

FDA



Thank you for coming
for your interest
for taking responsibility
for your diligence and accuracy
for using this information
for sharing this information
for educating yourself via www.fda.gov

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And

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