

Association of Food and Drug Officials Annual Education Conference

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Import Update

Presentation by:

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Division of Import Operations & Policy



Overview of Presentation



- A look at FY 2009
- ORA Import Operations Strategic Plan
- Development of a National Import Program
- Questions

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Looking back at FY2009



➤ The Following Slides Include:

- ✓ Definition of Categories with Share of Lines
- ✓ FY 2009 Lines
- ✓ FY 2009 Refusals
- ✓ FY 2009 Field & Label Exams
- ✓ FY 2009 Samples
- ✓ FY 2009 – TOP TEN IMPORTED DRUG PRODUCTS
- ✓ FY 2009 – TOP TEN IMPORTED BIOLOGICS PRODUCTS

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FY 2009 - Categories of Products with Total Lines & Share of Imported Lines – 18,474,256



| Category | Description | GPI Codes | Total Lines | Share of Imported Lines |
|-----------------------------------|---|--------------------|-------------|-------------------------|
| Human Foods | Human food, vitamins and dietary supplements, food & color additives | FO, IF, VI, FA, CA | 8,157,040 | 44.2% |
| Animal Foods | Animal feeds (non- medicated) | FE | 199,958 | 1.1% |
| Housewares and Food-Related Items | Tableware, cookware, utensils, storage containers, corn husks, etc. | HW, FR | 874,817 | 4.7% |
| Cosmetics | Cosmetics | CO | 1,690,016 | 9.2% |
| Drugs and Biologics* | Drugs (including antibiotics), biologics, and medicated feeds | DR, AB, FM, BI | 429,840 | 2.3% |
| Devices | Devices (including those for veterinary use), diagnostics, and miscellaneous veterinary products | DE, DI, VD | 6,560,761 | 35.5% |
| Electronics | X- ray systems, TVs and monitors with cathode ray tubes, microwave devices, lasers, tanning beds, etc. Includes electronic radiation- based medical devices | RH | 561,461 | 3.0% |
| Tobacco Products | | TP | 399 | |

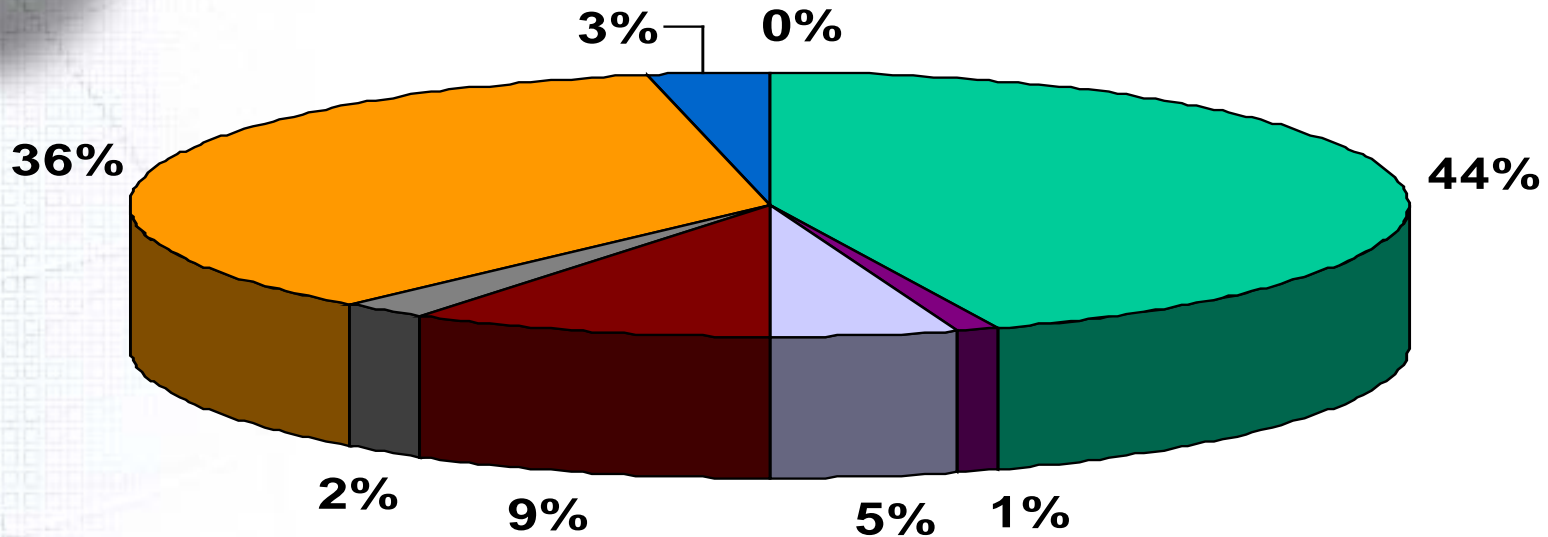
*Total Lines and Drugs and Biologics' counts - Includes lines from Imports Unplugged Database

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FY 2009 LINES BY CATEGORIES

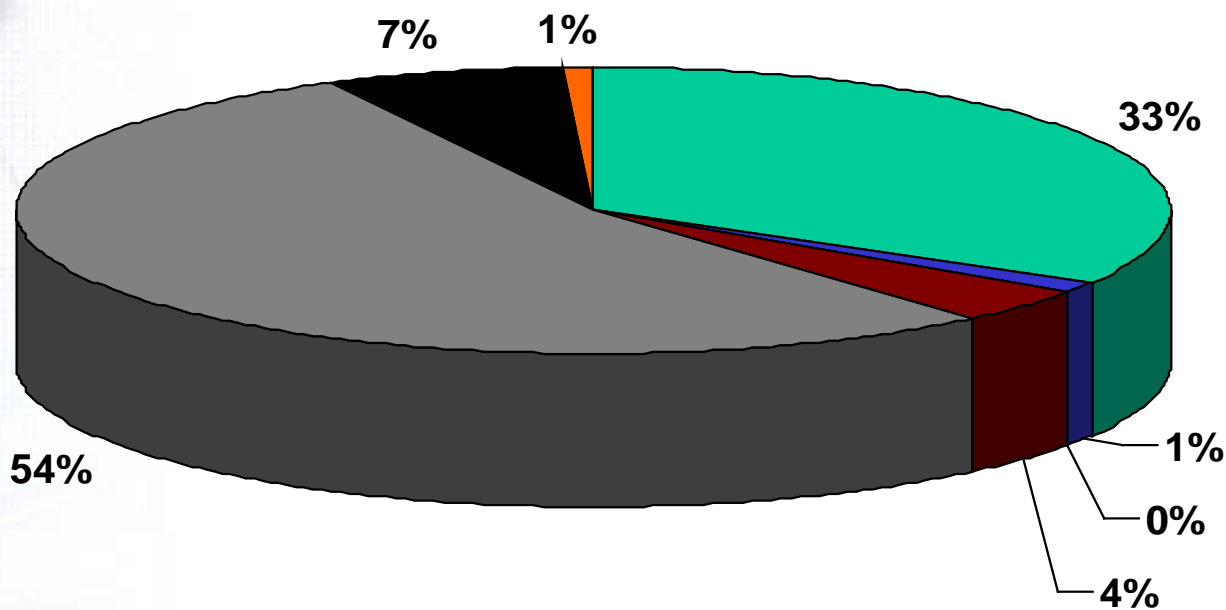


- HUMAN FOODS
- ANIMAL FEED
- HOUSEWARES & FOOD-RELATED ITEMS
- COSMETICS
- DRUGS & BIOLOGICS
- DEVICES
- ELECTRONICS
- TOBACCO PRODUCTS

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FY 2009 REFUSALS BY CATEGORIES



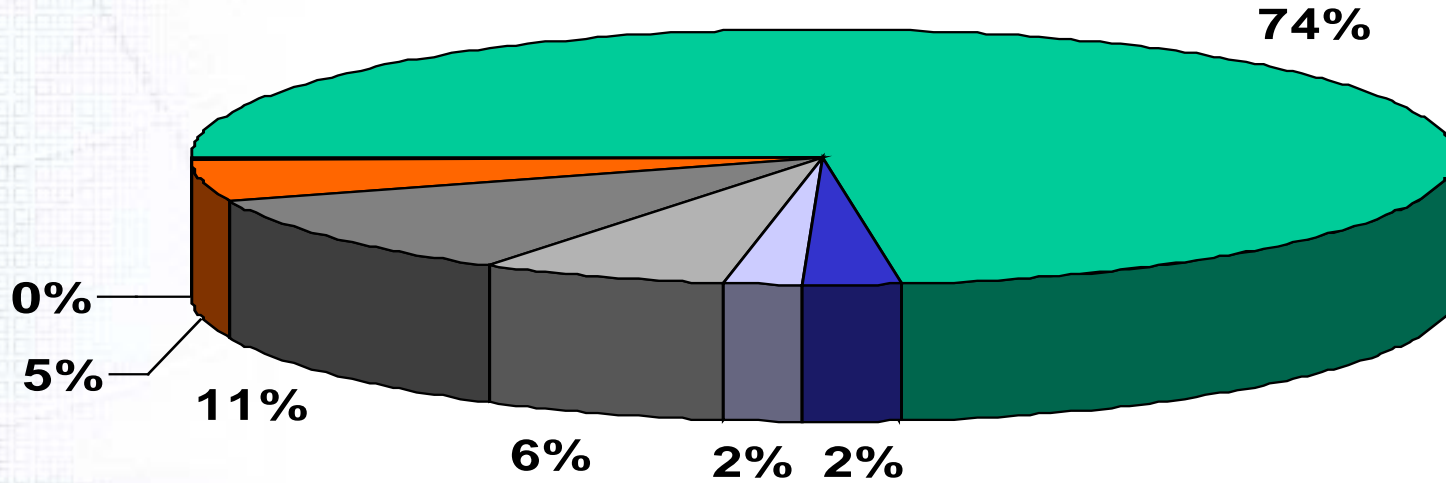
- Human Foods
- Housewares and Food-Related Items
- Drugs and Biologics
- Electronics
- Animal Foods
- Cosmetics
- Devices

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FY 2009 FIELD & LABEL EXAMS BY CATEGORIES

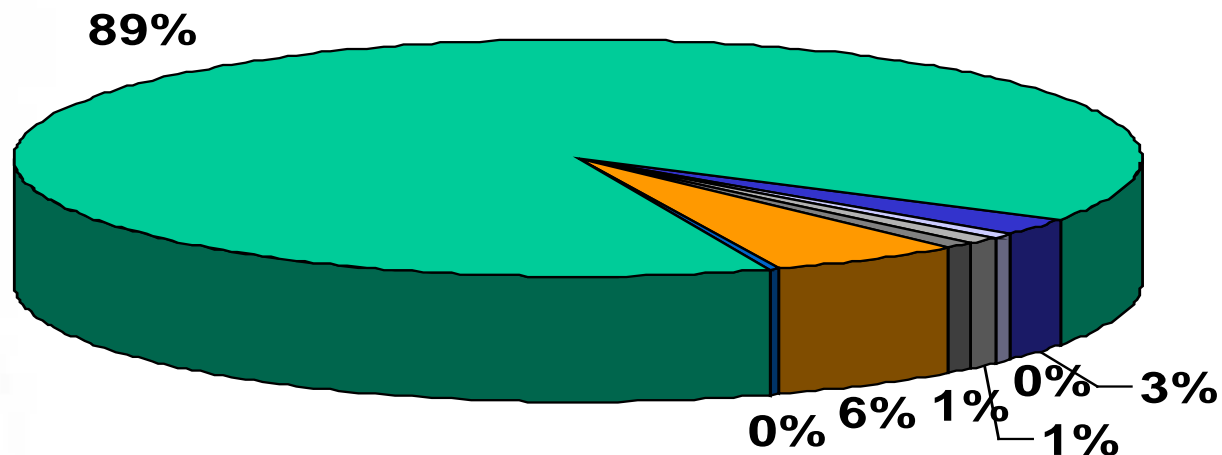


- Human Foods
- Housewares & Food-Related Items
- Drugs & Biologics
- Electronics
- Animal Foods
- Cosmetics
- Devices

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FY 2009 SAMPLES BY CATEGORIES

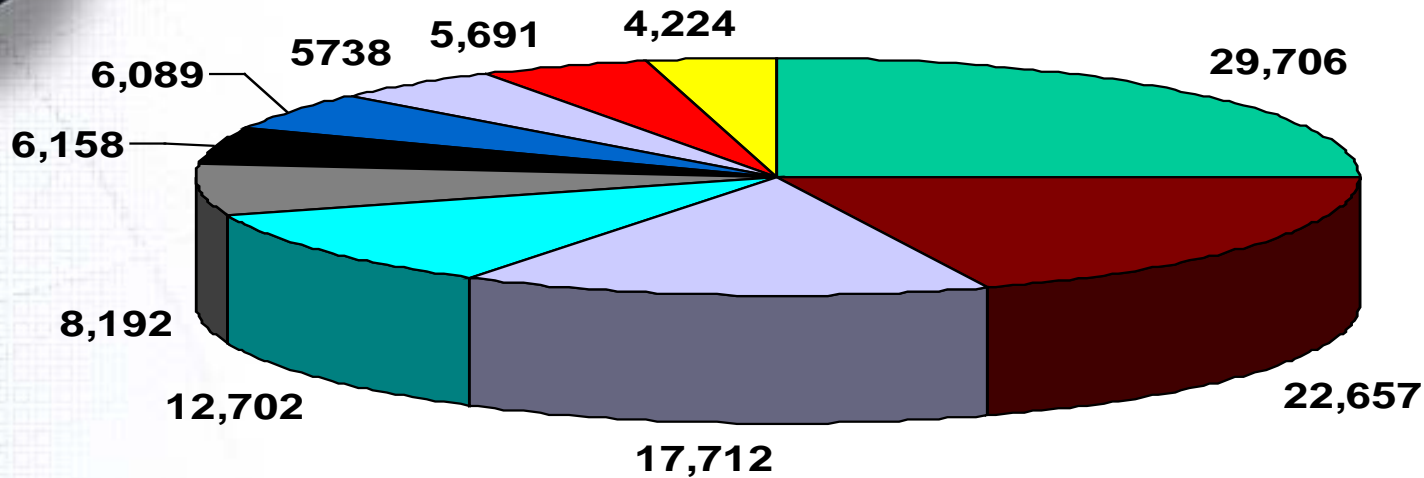


- HUMAN FOODS
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FY 2009 – TOP TEN IMPORTED DRUG PRODUCTS

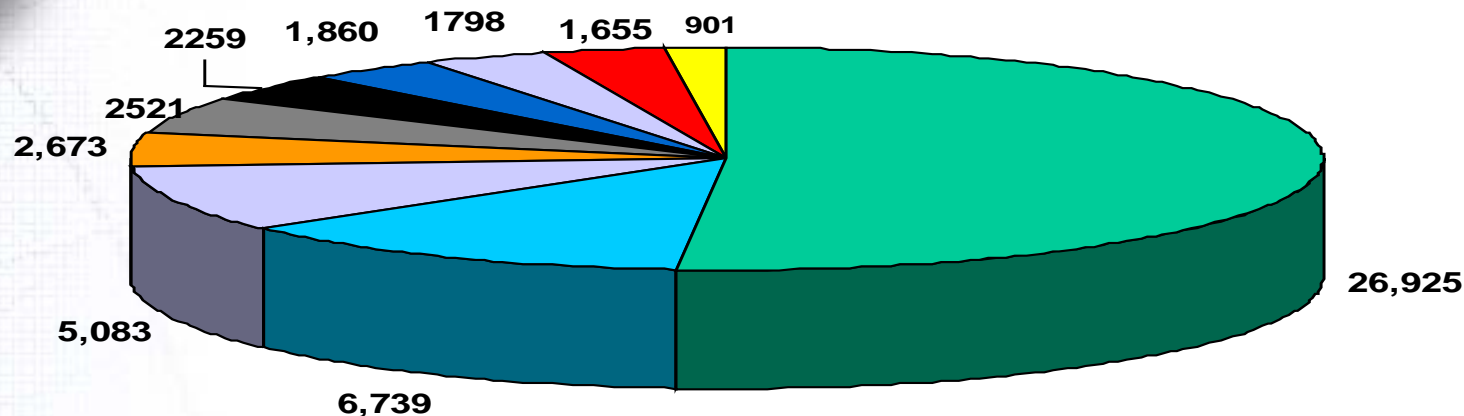


- Ultraviolet Screen
- Miscellaneous Patent Medicines
- Sodium Fluoride
- Sodium Iodide I 131 (Radioactive Agent)
- Pharmaceutical Necessities
- Anti-Tussive, Cold
- Oxybenzone (Ultraviolet Screen)
- Triclosan (Disinfectant)
- Pharmaceutical Necessities & Containers
- Metformin HCL (Anti-Diabetic)

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FY 2009 – TOP TEN IMPORTED BIOLOGICS PRODUCTS



- Biologics In-Vivo and In-Vitro Diagnostics
- Whole Blood Modified - Platelets Removed
- Human Serum
- Human Tissue
- Anti-Human Serum, Anti C3d
- Normal Human Plasma
- Immune Serum Globulin, Human
- Peripheral Blood Stem Cells
- Whole Blood, Human (ACD)
- Plasma Protein Fraction, Human

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ORA Import Operations Strategic Plan

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Development of a National Import Program

ORA is currently developing a strategy for a new model of operations



- The job of managing imports is increasingly global and complex...
 - ✓ More outsourcing of manufacturing
 - ✓ Greater complexity in supply chains
 - ✓ Imports coming from countries with less developed regulatory systems
 - ✓ Greater opportunities for economic fraud

- The current model for managing imports is struggling to meet these challenges

- This project will address these challenges – our goals include:
 - ✓ To be more efficient, effective and uniform
 - ✓ Develop a National Import Program
 - ✓ To leverage resources across states, localities, and other federal agencies
 - ✓ To increase the authority FDA has over imports
 - ✓ To take a look at new legislation and planning for the future

➤ Background:

- ✓ ORA has developed a draft Import Operations Strategic Plan and associated “strawman” concept of operations. ORA proposes to analyze FDA’s National Import Operations Program to ensure that import operations operate in an increasingly **uniform, effective** and **efficient** manner.

➤ Scope:

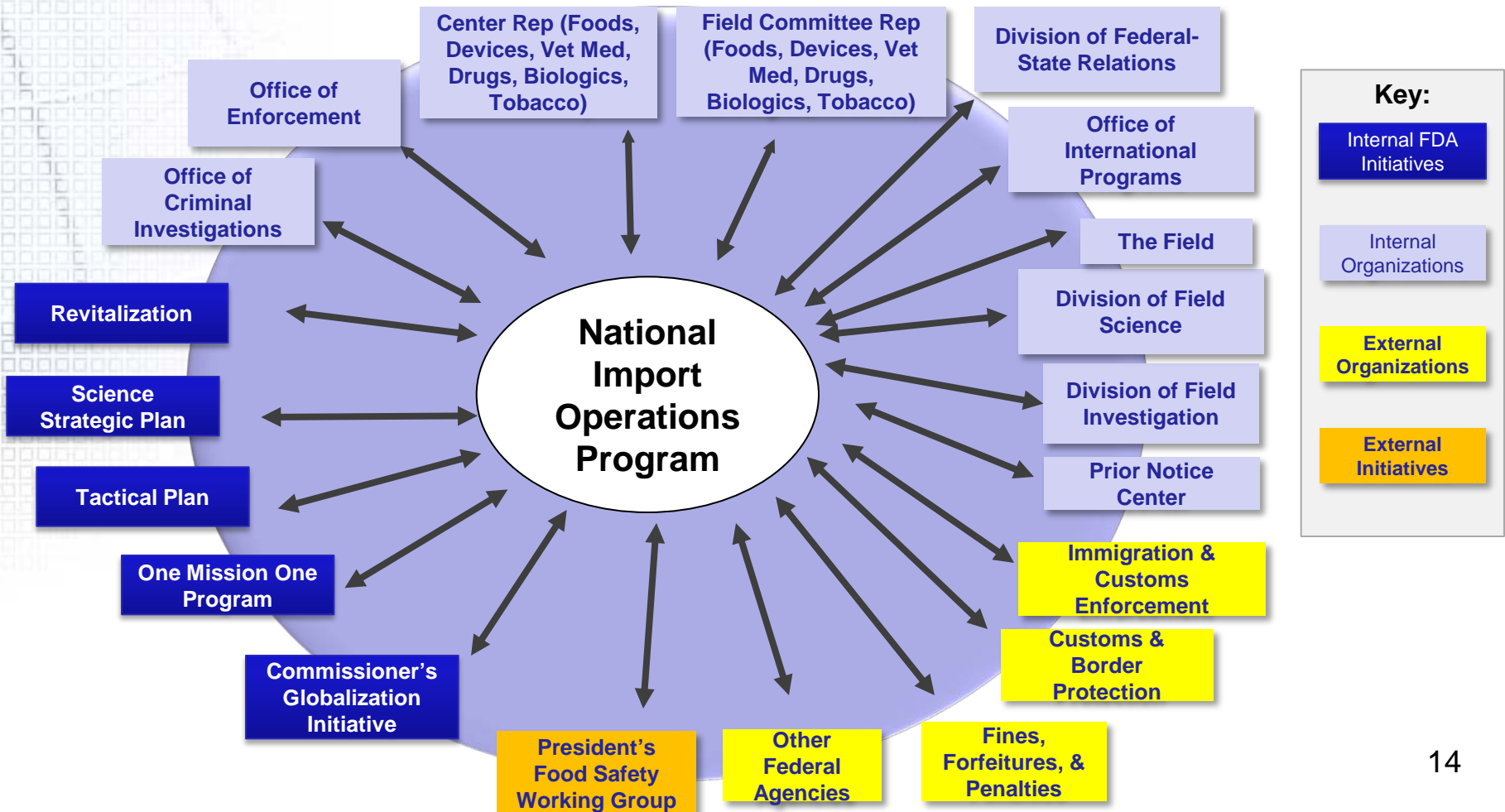
- ✓ The analysis will encompass organization/people, processes, technology, physical infrastructure and performance measurement
- ✓ The analysis will take into account a number of initiatives to improve ORA operations and to enhance ORA’s ability to protect the public health of the American consumer by being more proactive in addressing potential health issues, utilizing a more priority-focused and risk-based approach across the entire life-cycle of products.



High level stakeholder and initiative map



- Many stakeholders and initiatives with roles in import operations need to be considered and/or addressed



Considerations for external stakeholders



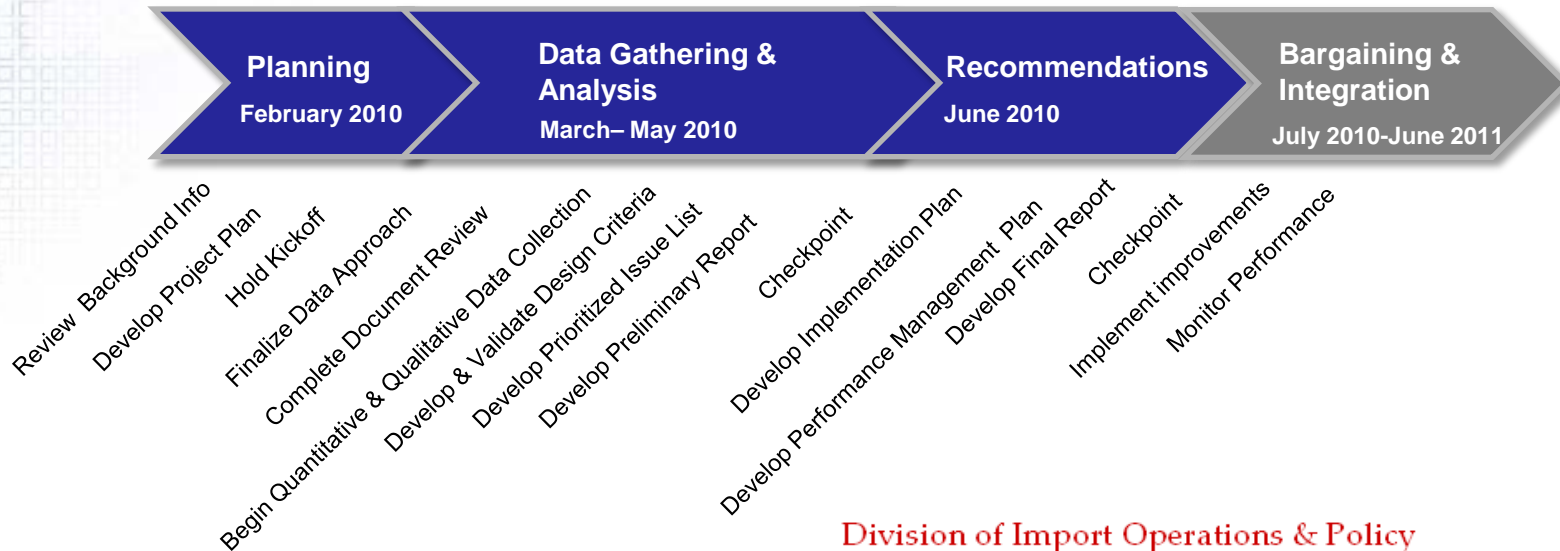
- What would you want to see changed?
- What would you not want changed?
- What performance measures are most important to you?
- What do you think would be a change that can be implemented quickly?



The project approach

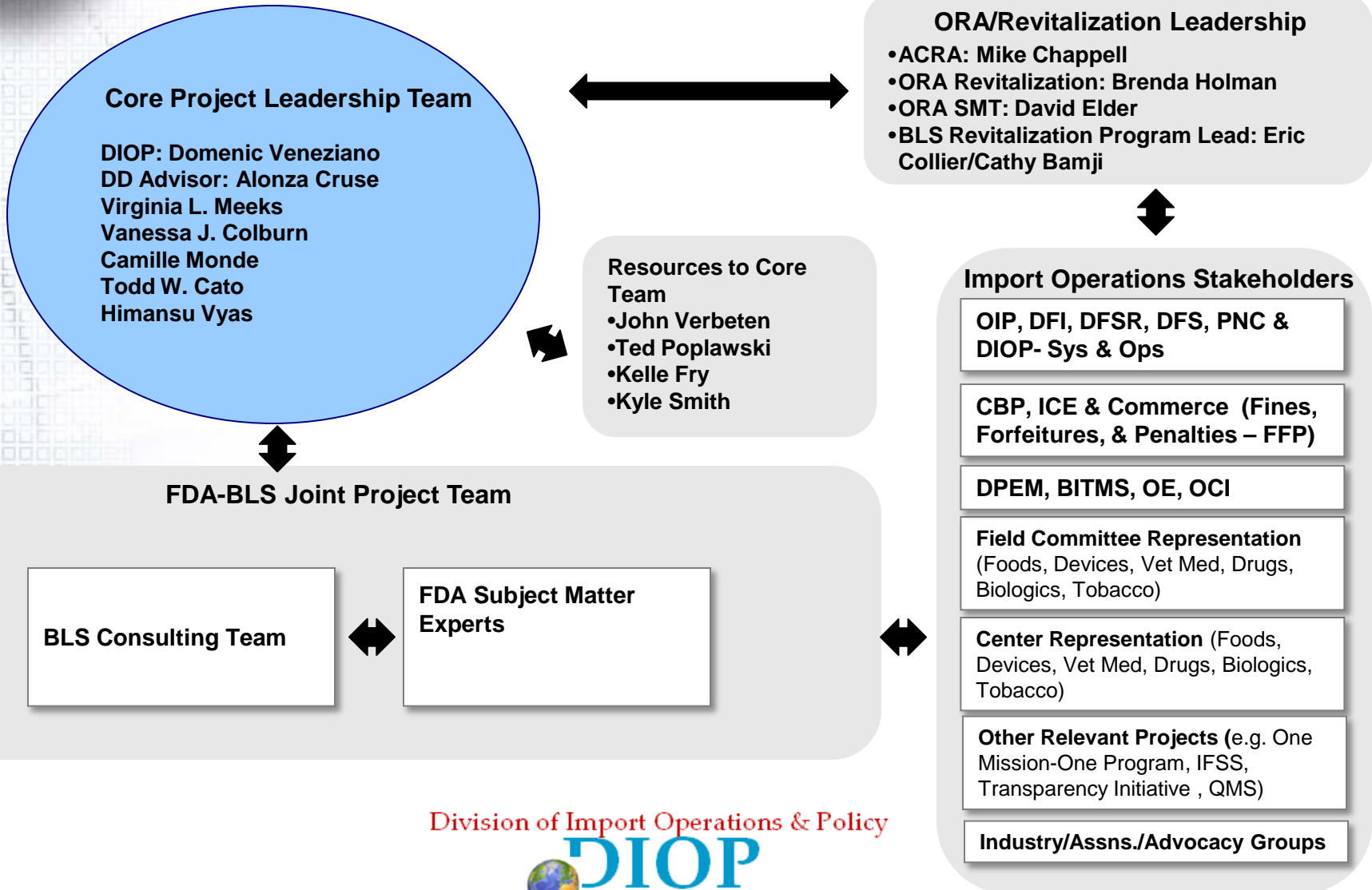


- We are using the phased approach shown below
- We are on an aggressive timeline
- We have identified three key sources of information and participation:
 - ✓ Subject matter experts
 - ✓ Data systems and key documents for analysis
 - ✓ Participation of key stakeholders (ORA, Centers, USDA, CBP, Other Federal Agencies, States and Localities, Industry)





Import operations project team structure



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➤ Recommendations:

- ✓ **Prioritized issues list** – list of issues prioritized using criteria (e.g., impact, ease of change)
- ✓ **High level concept of operations/ process model** – graphically rich slides with key considerations and recommendations for each area of the operations process model (people, process, systems, organization/ infrastructure, performance metrics)
- ✓ **Preliminary report** – summarized findings and trends, and initial approaches for solutions

➤ Recommendations:

- ✓ **Detailed recommendations report** – detailed recommendations based on analysis of data collected, as well as detailed to-be process flows documenting current and to-be processes
- ✓ **Performance management plan** – high level approach for implementing effective performance measurements
- ✓ **Implementation plan** – high level approach for next steps in implementing operations process model



Work accomplished



- ✓ Presented to SMT
- ✓ Briefed One Mission One Program & Globalization Initiative
- ✓ Conducted Core Team kickoff at ORAU 3/30-3/31
- ✓ Weekly core team conference calls
- ✓ High-level process validated with Core Team 4/12/10
- ✓ Participated in DFS call 4/14/10
- ✓ Presented to the NCBFAA Annual Conference 4/14/10
- ✓ Held meetings with multiple CBP staff 4/15
- ✓ Sites visits planned starting week of 4/19/10 (Detroit, Miami, LA, Memphis, Buffalo, New York, Philadelphia, Dallas and Washington DC)
- ✓ Planning for remote interviews and face-to-face meetings with key stakeholders underway



QUESTIONS?