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An Inside Look at Federal Import Strategies

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Topics

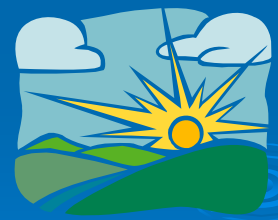
- Why the need for an import strategy
- Growth of imports
- Nature of imports has changed
- Manpower and resources
- Full-circle view of imports
- Tools and approaches
- Import strategy and its components
- Timeline
- Next steps
- Q&A

Why The Need for An Import Strategy?

- Align ORA's structure
  - Dollars
  - People
  - Priorities

- Risk-based targeting

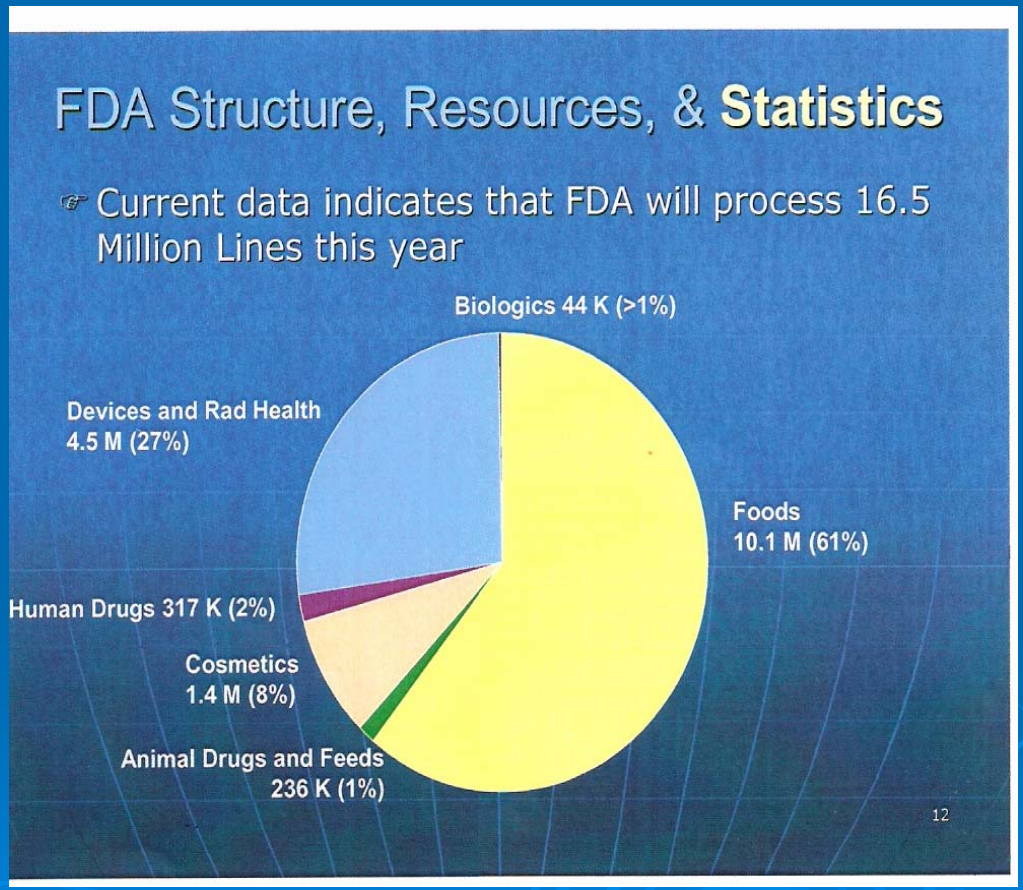
- Full life-cycle of goods



- Meet the needs of today's environment

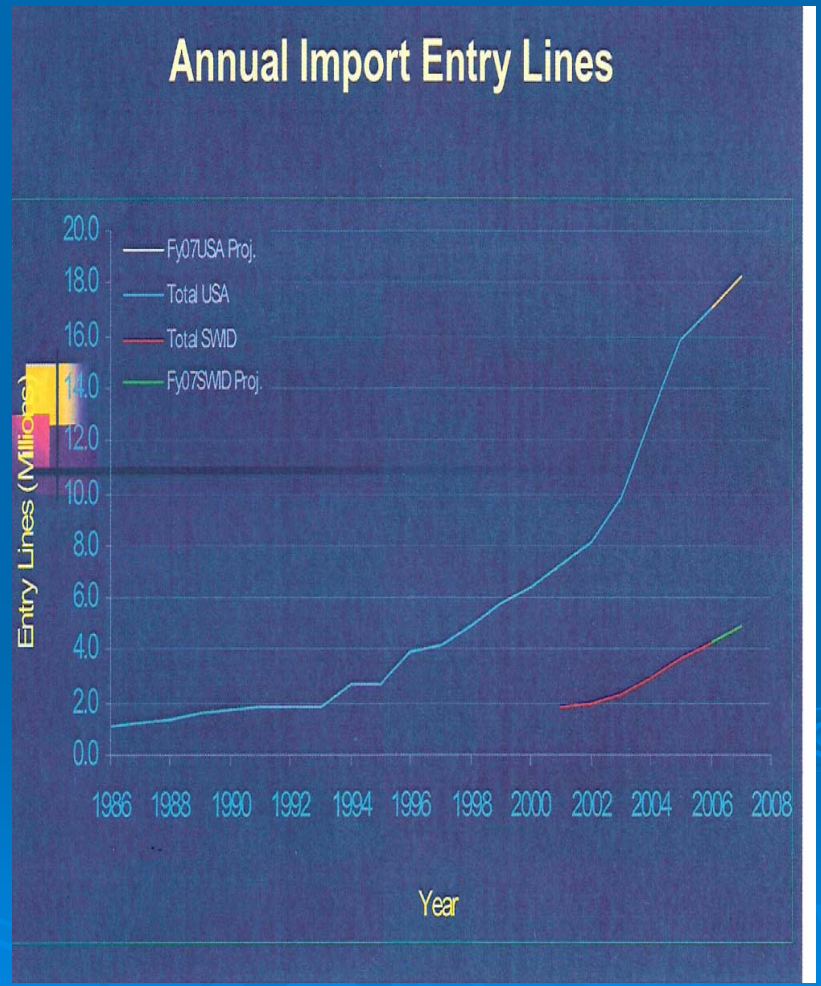
The Growth of Imports

- 11.6 Million lines of entries in 2004
  - 5 times as many as in 1994
  - Represents an annual increase of 15%
- Entries from more than 230 countries
- More than 220,000 manufacturers
- 65% of imported entries are food



The Nature of Imports Has Changed

- Imports have changed
  - We must change how we do business
- Traditionally, bulk of FDA products consisted of unprocessed food ingredients
  - Today, finished, ready-to-eat food products and fresh produce account for an increasing proportion of all FDA-regulated imported food products



Manpower & Resources

- Growth in imports is outpacing the manpower & resources available to FDA
  - Traditional border operations not enough
    - Border operations must become an integrated checkpoint of safety
  - Must identify & prioritize import risks
    - Consider the full life cycle of the imported product
    - Risk-based targeting

Full Circle View

- Looking in & looking out
  - Looking in – ORA's organizational structure
    - The right people doing the right jobs in the current environment
    - The right locations
      - Brick & mortar locations
      - Virtual locations
  - Looking out
    - Meeting consumer protection needs
      - Keeping current of trends in growth
      - Keeping current of safety & security issues
    - Meeting industry needs

Tools & Approaches FDA Is Using

- Public Health Security And Bioterroism Preparedness And Response Act of 2002
  - Prior notice
  - Coordinate import efforts with other U.S. And foreign government authorities
  - Increase number and scope of foreign inspections

Tools & Approaches FDA Is Using (cont)

- FDA is working and coordinating with other federal and state agencies
  - FERN
  - eLEXNET
    - 113 labs participating
    - 50 states and the district of columbia

Tools & Approaches FDA Is Using (cont)

- The FD&C Act is the law and the procedures that we use to conduct our day-to-day business
  - 801(a) Entry Data
  - 801(m) Prior Notice Information

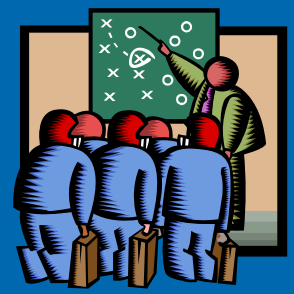
Import Strategy

- We recognized that we needed an import strategy that speaks to today's environment in the import arena
- State-of-the-art approach to manage imports
- A comprehensive, science-based strategy for re-engineering FDA's agency-wide import-related polices and procedures

Import Strategy (cont)

- Workgroup tasked with developing an implementation plan
  - Dennis E. Baker, Chair, FDA/Southwest Region
  - Domenic Veneziano, Co-Chair, ORA/ORO/DIOP
  - Blake Bevill, ORA/Headquarters
  - Todd Cato, Southwest Import District/Compliance Branch
  - Dean Cook, Baltimore District/Compliance Branch
  - Robert J. Deininger, Southwest Import District
  - Tom Gardine, Philadelphia District
  - Joe McCallion, ORA/ORO/Headquarters
  - Mark Prusak, New York Import Operations Branch
  - Barbara Wood, Southeast Region

Import Strategy (cont)



- Five (5) components of import strategy
  - Foreign operations
  - Border operations and entry admissibility
  - Imported goods in domestic commerce
  - Information technology
  - Applied science and technology

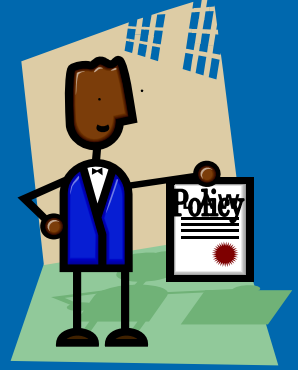
Import Strategy (cont)

- Foreign Operations
  - Use relevant foreign inspectional data to make entry admissibility decisions
  - Work with foreign governments and industry about FDA regulatory requirements.

Import Strategy (cont)

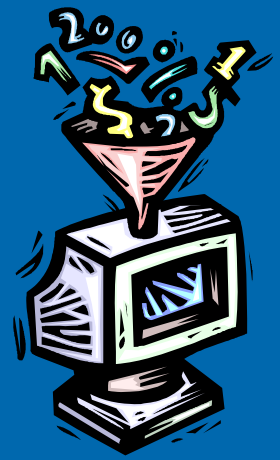
- Border Operations and Entry Admissibility
  - Develop and issue guidance to assist FDA and industry in determining when there is an appearance of A violation that would justify refusing entry into the U.S.
  - Expedite the entry of low risk products
  - Improve data received about imported products
  - Develop a system that keeps refused goods at one port from being re-offered at another port

Import Strategy (cont)



- Imported Goods in Domestic Commerce
  - Assure that inspectional data, complaint information, and other relevant data is made available to and utilized by FDA personnel making entry review decisions
  - Develop policies and procedures allowing FDA to utilize state evidence and lab results for enforcement, admissibility, and to assist foreign suppliers to take corrective action

Import Strategy (Cont)



- Information Technology
  - Improve on database usage
  - Link with relevant center databases to facilitate access to risk-based information about imported products
  - Improve the quality of registration and listing data provided by those who import products
    - Entered correctly
    - No duplications of entries
    - Consistent with data currently in FDA databases
  - Screening systems at border that flags entries that appear to be high risk
  - Develop an automated entry examination system that incorporates relevant risk data from all points in the life cycle

Import Strategy (Cont)

- Applied Science and Technology
  - Develop private lab rule to help ensure the quality of test results from non-FDA labs chosen by industry to obtain entry of regulated products
  - Develop and/or validate new rapid test methods that can be used for screening at the point-of-entry
  - Develop and validate scientific methods to analyze emerging or anticipated threats to FDA-regulated products for which there is currently no test method

Timeline

- A tremendous amount of work, thought, research, and discussion have already gone into the development of the import strategy
- A lot has been accomplished
- There is a lot yet to be accomplished!
- We continue to fine tune all aspects of the import strategy
- A number of deliverables have already been submitted to the ACRA
- Import strategy workgroup subcommittees continue to meet
- Implementation – in stages over the next 3 – 5 years

Next Steps

- Continue to meet with Associate Commissioner for Regulatory Affairs (ACRA), & Deputy ACRA (DACRA) regarding progress of plan, and feedback from workgroups
- Run pilots and proof of concepts of recommendations from workgroups
- Keep tuned to the import environment & make mid-course corrections as needed

Conclusion

- Imports are growing
- We continue to explore ways to keep up with the growth
- We are committed to keeping our stakeholders informed during the process
- FDA is committed to the safety & security of imported goods entering the country

Questions & Answers