

AFDO

San Antonio, Texas

June 16, 2007

An Inside Look at Federal Import Strategies
Imported Foods

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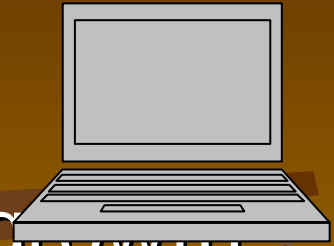


U.S. Department of Health and Human Services

Food and Drug Administration

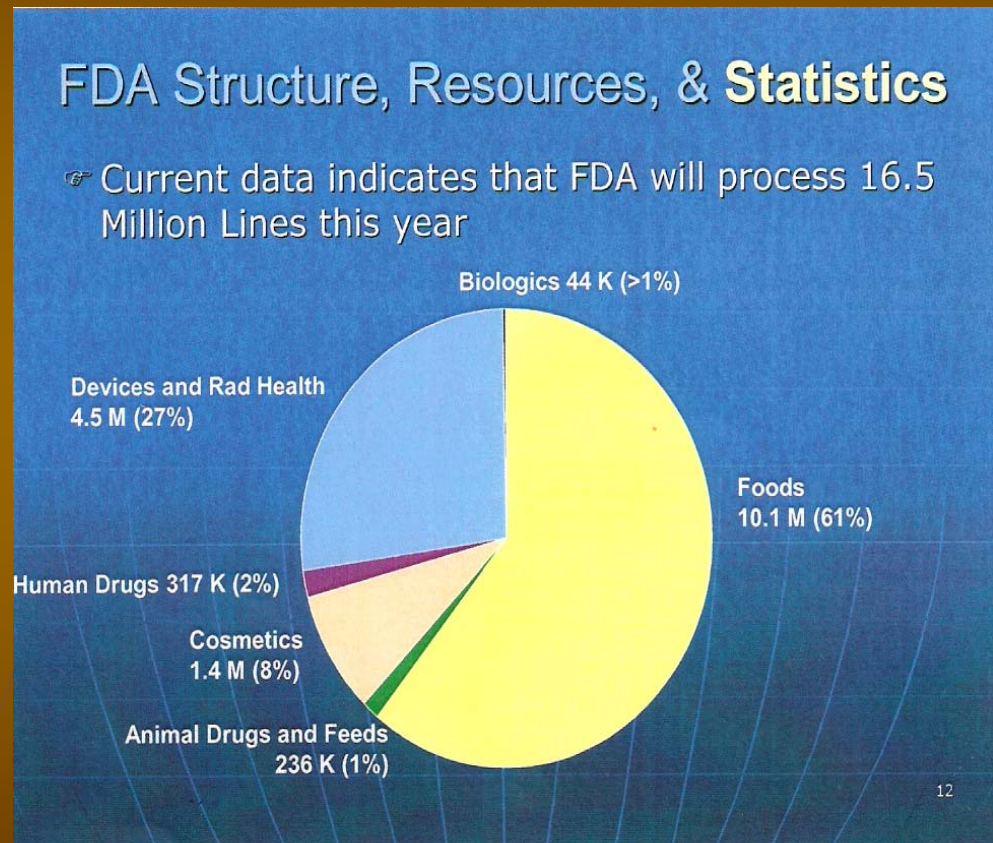
Why The Need for An Import Strategy?

- Growth, growth, growth, and more growth
- Products from all corners of the Earth
- Produce no longer seasonal – get what you want, when you want it
- It's good...right?
- With the good comes concerns & issues
- **Safety & security remain key**



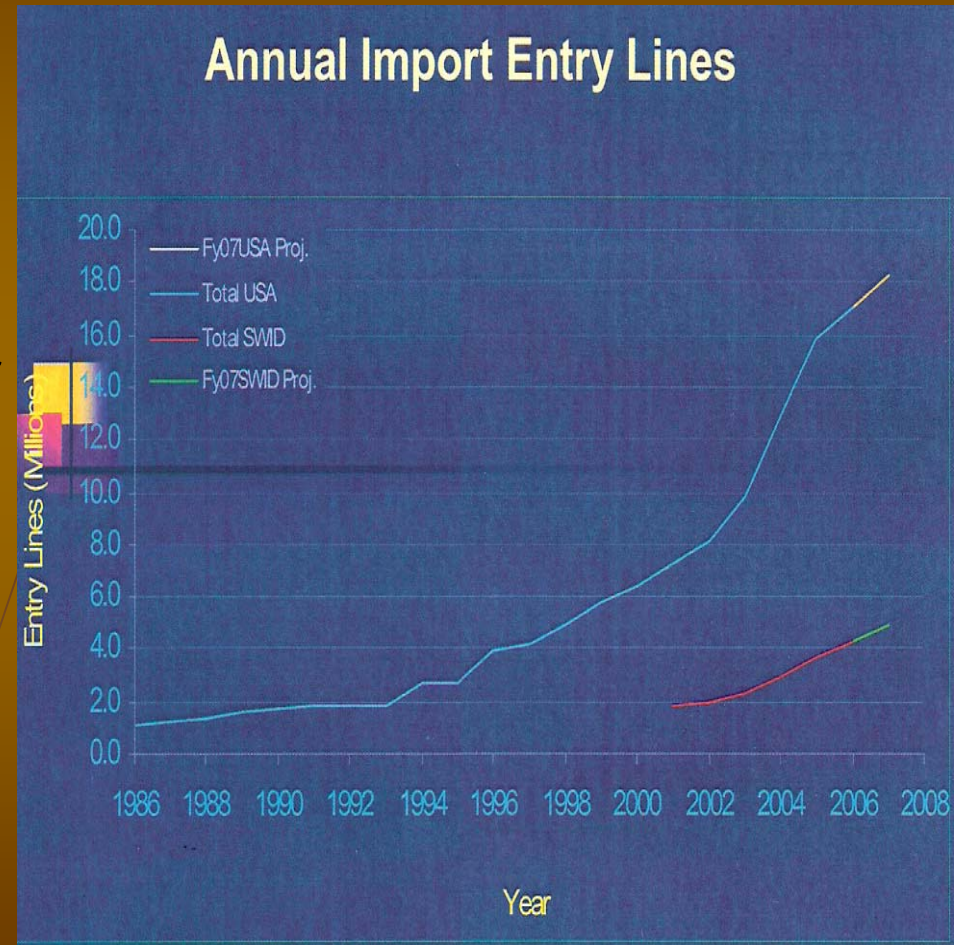
The Growth of Imports

- 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, the 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 lifecycle of the imported product
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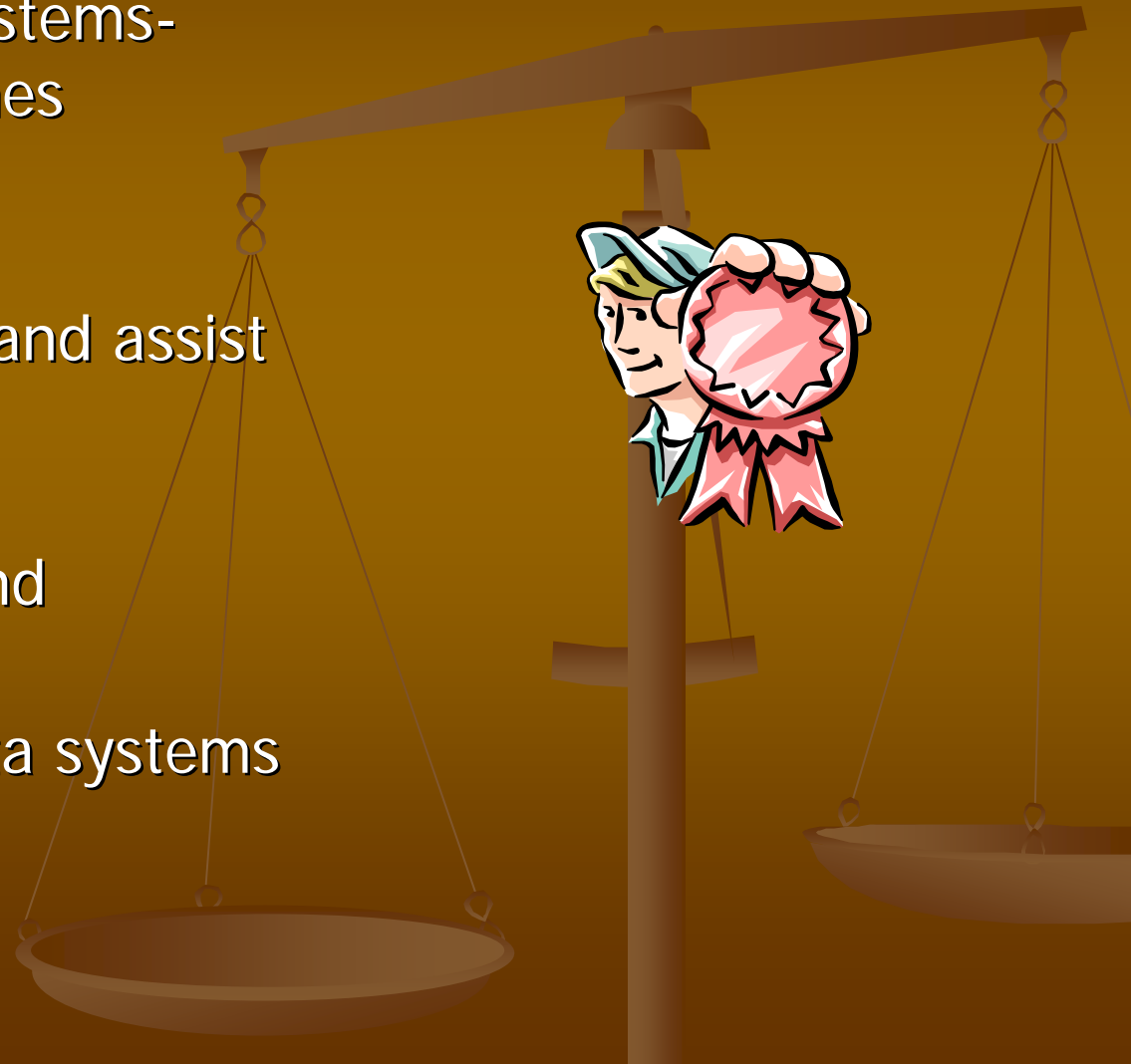
Tools & Approaches FDA Is Using

- Public Health Security And Bioterrorism 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)

- Modern quality systems-oriented approaches
 - GMP's
 - HACCP
- Cooperation with and assist foreign regulatory authorities
- Applied science and technology
- Improving our data systems



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



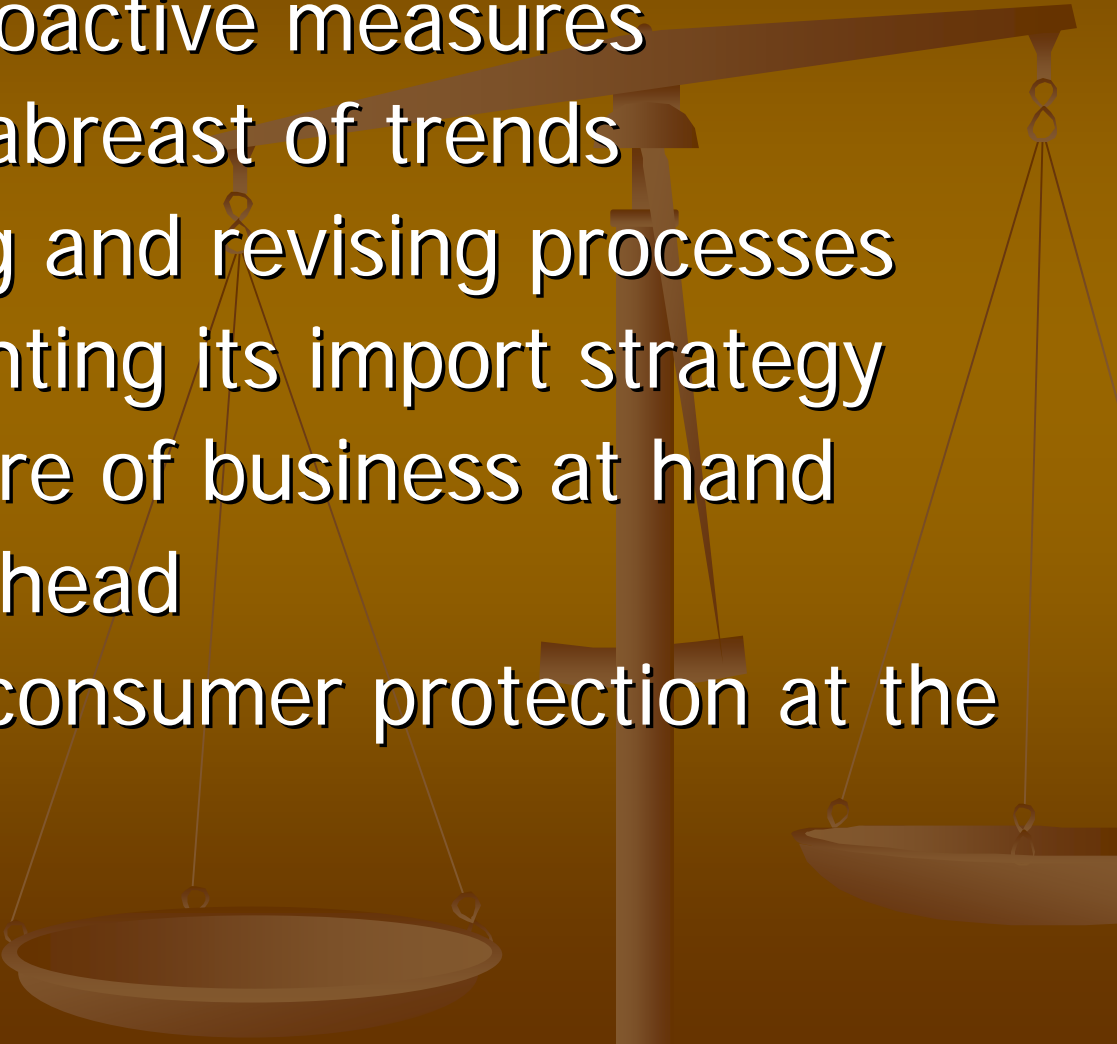
Import Strategy



Steps To Protect

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

In Conclusion

- FDA is taking proactive measures
 - FDA is keeping abreast of trends
 - FDA is reviewing and revising processes
 - FDA is implementing its import strategy
 - FDA is taking care of business at hand
 - FDA is looking ahead
 - FDA is keeping consumer protection at the forefront
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Questions

