March 2012
FDA was substantially underfunded for two decades. We thank Congress for recent increases.

FDA’s responsibilities (and the world it regulates) continue to grow rapidly in size and complexity.

FDA will be required to carry out new activities in FY 13 that are not paid for in the FY12 base funding.

FDA needs to transform itself into a 21\textsuperscript{st} Century regulatory agency.

FDA should be a true priority for our nation, deserving exceptional status when appropriations decisions are made.
FDA Regulates . . . 25% of Consumer Spending

- Pet food and animal feed
- Food additives
- Cosmetics
- Infant formulas
- Medical devices
- Drugs
- Vaccines, blood products, biologics
- 80% of nation’s food supply

Dietary supplements
Microwaves and x-ray equipment
## New mandates and responsibilities are not in FY 12 base funding

### New Congressional Mandates
- Biosimilars
- Food Safety and Modernization Act (FSMA)
- National Security (MCM)
- Potential new requirements in user fee reauthorization

### Additional Growth in Responsibilities
- Globalization
- Conversion to risk-based inspections
- Scientific complexity
- Promoting Innovation
- Public Health Emergencies
GLOBALIZATION
Globalization Challenges

• **Food**
  - 10-15% of all food consumed by U.S. households is imported
  - Nearly 50% of fresh fruits and 20% of vegetables are imported
  - 80% of seafood eaten domestically come from outside the U.S.
  - Food imports have increased an average of 10% per year from 2005-2011

• **Devices**
  - Medical device imports have grown at over 10% per year from 2005-2011
  - Half of all medical devices used in the U.S. are imported

• **Drugs**
  - 80% of pharmaceutical ingredients used in the U.S. are manufactured abroad
  - 40% of finished drug products are manufactured abroad
  - Pharmaceutical product imports increased nearly 13%/year from 2005-2011
More than 300,000 Foreign Facilities in 200 Countries

Inspections of Foreign Establishments* have Increased

To meet this significant challenge, FDA is:

• Further increasing inspections
• Focusing on high-risk facilities
• Entering into more agreements with foreign regulators

* Includes food, drug and device establishments
FOOD AND MEDICAL PRODUCTS
Transforming the Way FDA Regulates Food

**Risk-based inspections**
- Target high-risk food facilities for more frequent inspection
- Train state/local inspectors on Federal requirements
- Use a new, risk-based system (PREDICT) to identify imported foods that require additional scrutiny

**Change from Re-active to Pro-active System**
- Implementation of preventive controls for known food safety hazards
- Establish monitoring systems to ensure effectiveness
- Establish performance targets for food facilities

**Accelerate number of inspections**
- Perform a greater number of foreign food facility inspections
- Increase inspections at ports of entry
- Expand agreements with states and with foreign agencies
Transforming the Way FDA Regulates Medical Products

Development of regulations and guidance
- Improve and modernize FDA processes to promote biomedical innovation and product development
- Accelerate FDA guidance development and regulatory reforms to improve predictability/transparency

Expansion of Pre- and Post-Market Safety
- Enhance in vitro and pre-clinical safety methodologies
- Develop and validate modern clinical trial methodologies and drug development tools
- Continued development and enhancement of surveillance systems to track adverse events

Sustain and Increase Core Programs
- Regulatory science activities & pharmacogenomics
- Facilitate drug and device development meetings
- Implement biosimilars legislation & PDUFA V add-ons
- Strengthen global activities and supply chain integrity
Conclusion

• FDA has broad mandate for a relatively small agency
• FDA is a core function of government
• FDA’s mission and responsibilities are increasing
• FDA needs funding to transform into a 21st Century regulatory agency
• FDA should be a priority…and deserves exceptional status when appropriations decisions are made
A strong FDA benefits all Americans:

Patients, consumers, health professionals, industry....and the whole world benefits, too.

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