ALLIANCE FOR A STRONGER FDA

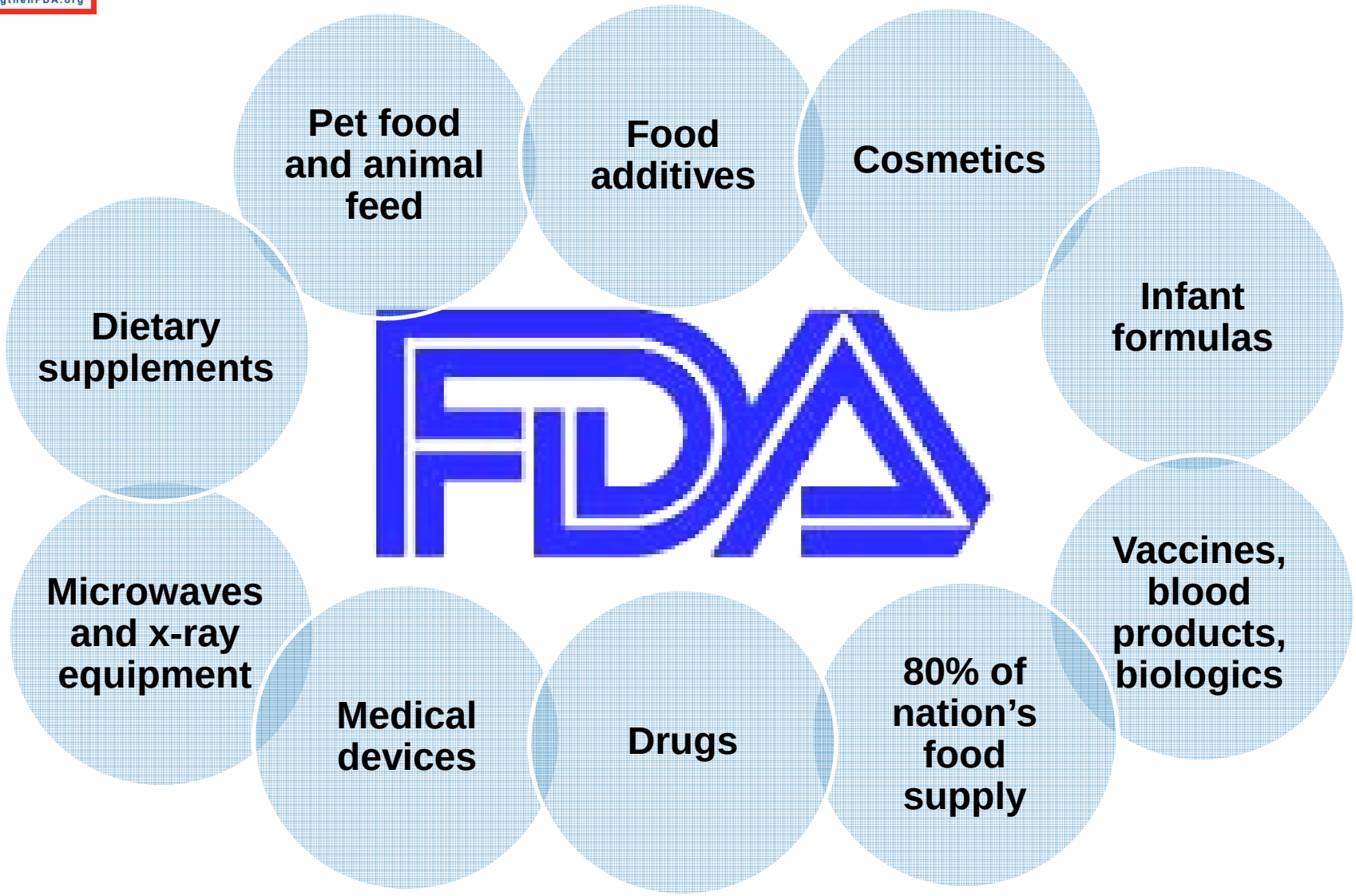
www.StrengthenFDA.org

March 2012

FDA is an Exceptional Agency

- FDA was substantially underfunded for two decades. We thank Congress for recent increases.
- FDA's responsibilities (and the world it regulates) continues 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 21st 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



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

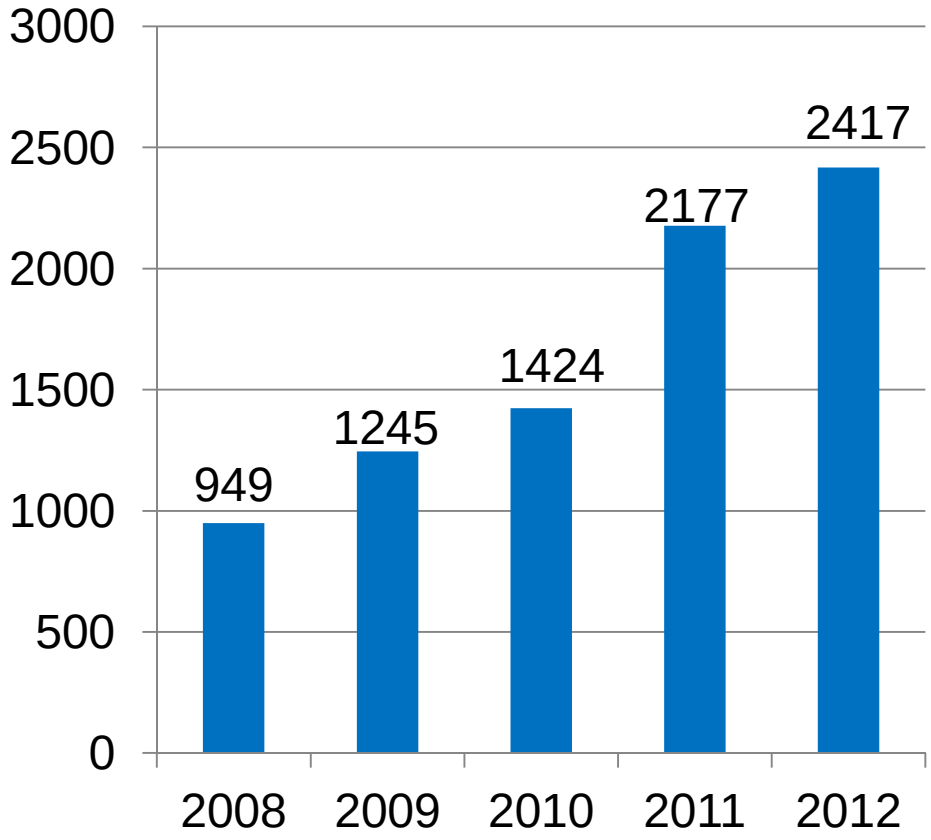
GLOBALIZATION

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.

For more information, contact:

Ladd Wiley, Executive Director, lwiley@StrengthenFDA.org , 202-887-4083

Steven Grossman, Deputy Executive Director, sgrossman@strengthenfda.org,
301-539-9660