

# **FDA Activities in Nanotechnology** **Report to PCAST November 2011**

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**U.S. Food and Drug Administration**  
Advancing Regulatory Science



# What is Special about Nanotechnology Regulation

- Evolving state of science on biological interactions and methodologies for assessing safety, effectiveness, performance, and product quality
- Different applications and routes of exposure
- High degree of interest among academia, industry, and trade stakeholders
- Regulatory approaches continue to evolve within federal agencies and international counterparts



# **FDA's Moving Parts**

*Protecting and Promoting the Public Health*

- FDA's Enterprise Program on Nanotechnology
  - Nanotechnology Task Force
- Intramural Regulatory Science Programs
  - Center-specific Activities
  - External Collaborations
- Product Specific Guidance/Policy
- Domestic Activities
  - Scientific forums and other fora
- International Engagement
- *Ongoing Review of Product Submissions*



# A few FDA Updates

## *Protecting and Promoting the Public Health*

- FY11/FY12 Regulatory Science Program on Nanotechnology
  - Staff Training and Professional Development
  - FDA Laboratory Facilities
  - The CORES Regulatory Science ProgramNanotechnology Regulatory Science Research Plan

[www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm273325.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm273325.htm)

- Draft Guidance on Nanotechnology

[www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm257926.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm257926.htm)

- Strategic Plan for Regulatory Science

[www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm)

- Driving Biomedical Innovation

[www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm](http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm)



# **FDA Message to Stakeholders**

## *Protecting and Promoting the Public Health*

- FDA will continue to take a science-based and science led approach to decision making
- FDA will continue to evaluate size and properties of nanomaterials or products otherwise involving the application of nanotechnology
- FDA will continue to encourage industry to consult with the agency early in the product development process to address questions about safety and/or regulatory status



# Coordination Across the United States Government

## CPSC, EPA, FDA, OSHA, USDA

### Topic Areas

- Education about each agency's vision, mission
- Cooperation on joint activities and initiatives
- Collaboration on regulatory science research

### Where does this happen?

- National Nanotechnology Initiative (NNI) Consortium
- Emerging Technologies Interagency Policy Coordination (ETIPC) Committee



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