# RESEARCH NEEDS AT FDA

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# Briefly Today

- FDA mission
- FDA regulated products
- Nano and FDA products
- Benefits of nanomaterials
- Regulation of nano products
- What products are we seeing?
- Nano challenges, concerns, and research needs
- FDA research

# FDA Mission

The FDA is responsible for **protecting the public health** by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

The FDA is also responsible for **advancing the public health** by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

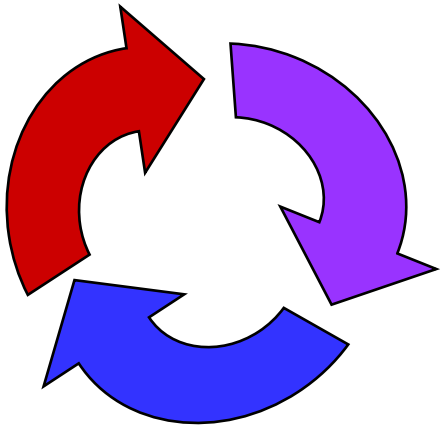
# FDA Regulated Products

- Foods
  - All interstate domestic and imported, including produce, fish, shellfish, shell eggs, milk (not meat or poultry)
  - Bottled water
  - Wine (<7 alcohol)
  - Infant formula
- Food additives
  - Colors
  - Food containers
- Cosmetics
- Dietary Supplements
- Animal Feeds
- Pharmaceuticals
  - Human
  - Animal
  - Tamper resistant packaging
- Medical devices
- Radiation emitting electronic products
- Vaccines
- Blood products
- Tissues
- Sterilants
- Counter-terrorism products

# FDA's Core Business Functions

**Pre-Market Review**

*Assessment of safety and effectiveness of new medical technology & safety of new food ingredients*



**Product Safety & Compliance**

*Inspection of manufacturing facilities and products to assure safety, quality & compliance with FDA regulations*

**Consumer & Patient Safety**

*Post-marketing surveillance to ensure the safety of consumers & patients who use FDA-regulated products*

# Nanoscale Materials and FDA - Products

- Drugs (NMEs, new formulations, Imaging agents)
- Medical devices (in contact/not in contact with human body )
- Tissue engineering, biological products (blood substitutes, virus-like particle vaccines)
- Nutritional supplements/food additives
- Cosmetics
- Combination products

# Public Health Benefits

- New treatments – not possible before
  - Solubility/absorption changes ‘bringing back” development candidates
  - Totally new concepts possible – limited only by the science
- Lower toxicity – targeted delivery
  - Increase drug concentration at needed site
  - Decrease systemic exposure to drug
- Combinations of therapies
- Serve as scaffolding to attach chemical moieties

# Cost Benefits

- Extend lifespan of products by reformulating through novel delivery systems
- Enhance effective patent protection
- Cost differential between delivery formulation vs drug discovery for NME
- Minimizing use of expensive drugs to reduce cost of product

# Nano-Engineered Materials FDA Status

- Regulation driven by statutory classification rather than technology
- Range of regulatory authority
- Review of products, not technology

# Nanoscale Materials in FDA Products

- Drugs and food ingredients
- Sunscreen materials
- Filler or bonding agents for bone and tooth repair
- Drug delivery materials
- Medical imaging
- Food and beverage containers
- Implant materials

# Challenges of Nano-Engineered Materials

- Lack of standards and reference materials
- Determining bioavailability/biodistribution
- Lack of toxicological and biocompatibility data
- Bridging preclinical– clinical gaps
- Lack of standardized physical and chemical characterization procedures
- Manufacturing scale-up

# Nano Product Assessment Concerns

- Safety Assessment
  - Adequacy of current toxicological tests
  - Potential for novel, unanticipated reactions
- Industrialization
  - Physical/chemical properties and product performance
  - Test methods and specifications for products/process
  - Scale up
  - Reference material and standards

# Research Needs

- Tools and methodologies to:
  - Assess product chemistry and unique characteristics of product
  - Enhance quality control measures
  - Produce consistent formulations with low batch-to-batch variability
  - Link product quality to performance

# Research Needs (cont'd)

- Adequacy of current safety tests
  - What could these miss depending on nano characteristics?
  - What measurements are needed that are not included in current tests?
- Product/characteristics/toxicity/ADME

# FDA Nano Research

- Dermal penetration of $TiO_2$, ZnO, liposomes, dendrimers, Qdots
- Imaging
- Standard safety tests for devices
- Phototoxicity of $TiO_2$ and ZnO
- Tumorigenicity of nanomaterials

# With Basic Data on Nano-Materials

- FDA can
  - Ask the right questions
  - Reduce risk of nanomaterials
  - Speed products to consumer
  - Reduce cost
- Improve public health

# THANK YOU

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