

# **Nanotechnology Standards: Regulatory Science Applications at FDA**

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**International Workshop on Challenges to Increased Use of Documentary  
Nanotechnology Standards**

**December 13-14, 2011**

**Washington, DC.**

# Overview

- **FDA interest in nanotechnology standards**
- **Two workshop questions**
  - 1- Do currently available (or currently being developed) standards meet your needs?**
  - 2- What are the challenges to successful use of nanotechnology standards?**

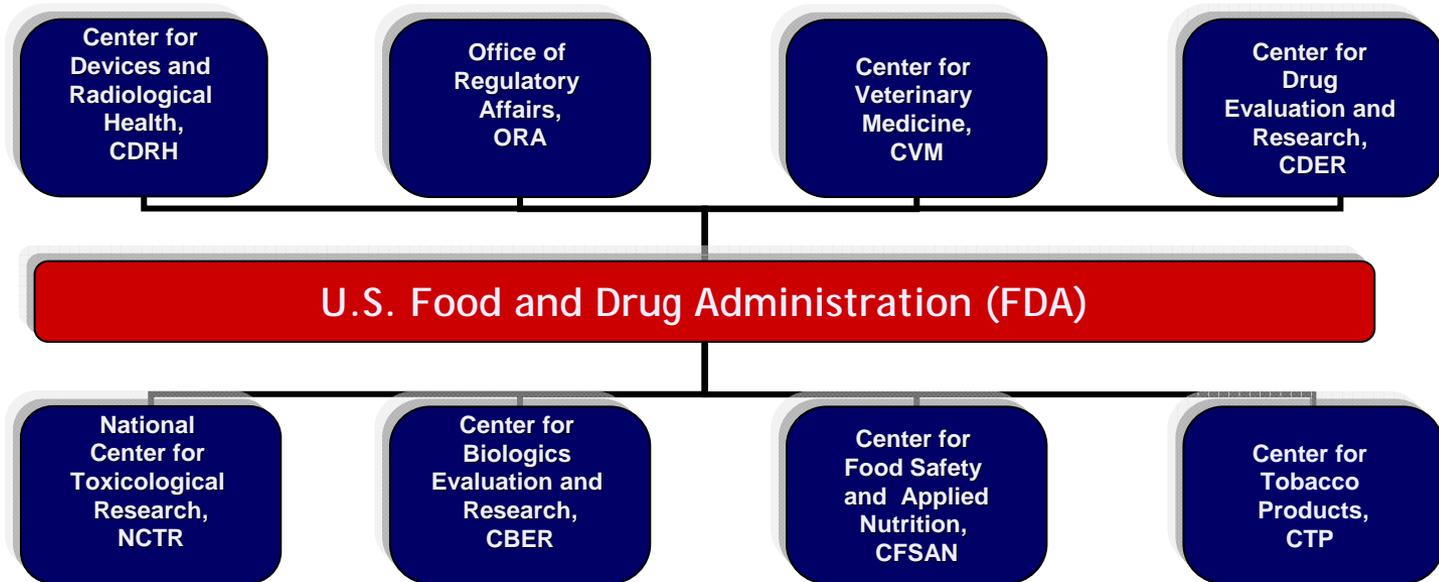
# FDA Regulated Nanomaterials and Products

## Examples as reported in literature

- **Drugs** (New molecular entities, 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**
- **Radiation emitting products**

# FDA: Mission and Centers

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.**



**Do currently available (or currently being developed) standards meet your needs?**

*Illustration with Medical devices (Center for Devices and Radiological Health)*

# CDRH/FDA use of consensus standards

## FDA uses standards because:

- Optimize the use of FDA resources
- Accomplish international trade commitments
- Enables cooperation between governments
- Encourages partnering with manufacturers
- Enables improvements in industrial productivity by basing requirements on accepted standards
- National Technology Transfer Act (PL104-113) & OMB Circular A119
- FDA Policy

## Food & Drug Administration Modernization Act (FDAMA)

....., recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable

# The Concept of Declaration of Conformity

**Signifies “Certification to Consensus Standards is Sufficient Evidence of Safety in Regulatory Submissions”**

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

# CDRH Standards Program

- **Participate in approximately 550 national and international standards committees**
- **~ 250 staff participate in standards development**
- **~ 1000 currently recognized standards**

# Requirements and applicability of currently available (or currently being developed) standards

- **Some requirements for CDRH to recognize a standard**
  1. developed by consensus SDO
  2. preferably test method should have been validated in R-R studies
  3. meet “use of standards criteria” for recognition -  
Reduces time to market for safe and effective medical devices and other health care products
    - Facilitates product design and performance
    - Continually raises the bar on safety and effectiveness based on new technologies
- **Very few available standards meet the above requirement #2**

# Risk management challenges

- Understanding **general risks** of products using nanomaterials
- Greater **need for understanding risks** of:
  - free nanomaterials because of potential for altered biological (toxicological) behavior
  - solid materials with surface nanomaterials features as in surface coatings, or nanotopography

# What are the challenges to successful use of nanotechnology standards?

## Needs

1. “Testing approaches for assessing safety, effectiveness, and quality of products containing nanomaterials”
2. “Understanding of interactions of nanomaterials with biological systems”

## Challenges

- Does the product contain nanomaterials?
- Does the product release particles, and what are their properties?
- Standards should address
  - Physical and chemical characterization of starting materials and those released from products
  - Bicompatibility assessment
  - Toxicity of released particles
  - Characterization of nanomaterials surfaces

# Summary

- **Primary Focus**
  - Protecting and promoting public health, and fostering innovation
  - Laws and regulation to carryout science based regulatory mission
  - Consensus standards play an important role in CDRH
- **Gaps remain in developing test methods and standards**
  - Identification and assessment of nanomaterials in products
  - characterization methods
  - biocompatibility and toxicity assessment

 **U.S. Food and Drug Administration**

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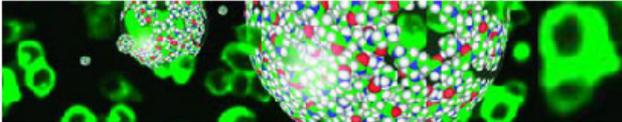
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**Science and Research Special Topics**

- Nanotechnology**
  - Nanotechnology Task Force
  - Nanotechnology Task Force Report 2007

**Resources for You**

- Animal
- Cosmetics
- Drugs
- Foods
- Medical Devices
- Radiation-Emitting Products
- Tobacco
- Vaccines, Blood & Biologics

**Nanotechnology**

The U.S. Food and Drug Administration (FDA) regulates a wide range of products, including foods, cosmetics, drugs, devices, veterinary products, and tobacco products some of which may utilize nanotechnology or contain nanomaterials. Nanotechnology allows scientists to create, explore, and manipulate materials measured in nanometers (billionths of a meter). Such materials can have chemical, physical, and biological properties that differ from those of their larger counterparts.

**Spotlight**

- FDA Opens Dialogue on 'Nano' Regulation
- Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology: Draft Guidance
- Nanotechnology Regulatory Science Research Plan
- FDA Nanotechnology Regulatory Science Research Categories
- Combination Products

**Related Links**

- Public Engagement
- National Activities
- International Activities
- Nanotechnology Partnerships at FDA

**FDA Activities**

- Nanotechnology Task Force
- Nanotechnology Task Force Report 2007
- New - Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology  
FDA's issuance of this guidance is a first step toward providing greater regulatory clarity on FDA's approach to nanotechnology.

**Contact Us**

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