

# **FDA Oversight of Nanotechnology Applications in Foods, Food Packaging, and Nutrient Delivery**

**Laura M. Tarantino, Ph.D.**

**Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition (CFSAN)**

**US FOOD AND DRUG ADMINISTRATION**

**The National Academies Keck Center  
Washington, DC  
December 10, 2008**



# **FDA NANOTECHNOLOGY TASK FORCE REPORT**

JULY 25, 2007

[http://www.fda.gov/nanotechnology/  
taskforce/report2007.html](http://www.fda.gov/nanotechnology/taskforce/report2007.html)



# Nanotechnology Report

- Includes
  - A synopsis of the state of the science for biological interactions of nanoscale materials
  - Analysis and recommendations for science issues; and
  - Analysis and recommendations for regulatory policy issues.



# Nanotechnology Report

## Regulatory Issues

- Can FDA identify products containing nanoscale materials?
- What is the scope of FDA's authorities to evaluate the safety and effectiveness of such products?
  - The scope of FDA's authorities depends on whether a product is subject to premarket authorization or not



- Dietary Ingredients in Dietary Supplements
- Colors added to food
- Food Additives and Ingredients
  - “Direct” food additives
  - Food additives that are food contact substances
  - Food ingredients whose use is Generally Recognized as Safe



# Food Drug & Cosmetic Act



## 1958 Amendment to the Act

- Defines “food additive”
- Establishes the standard of safety
- Requires premarket approval of new uses of food additives
- Provides for a GRAS exemption

## 1960 Amendment to the Act

- Defines ‘color additive’
- Requires premarket approval of new uses of color additives



# **Scope of FDA Regulatory Authority Pertaining to Food Additives that are Food Contact Substances**

- Require approval before marketing
- Results in an “effective” notification
- Approval is restricted to notifier



## Scope of FDA Regulatory Authority Pertaining to Food and Color Additives

- Require approval before marketing
- Result in a regulation prescribing the conditions under which the additive may be safely used
- Regulations are “generic” – that is, they are not licenses and approvals cover all manufacturers



# Scope of FDA Regulatory Authority Pertaining to Food Ingredients Whose Use is Generally Recognized as Safe (GRAS)

- Do not require approval before marketing
- Safety must be generally recognized by qualified experts
- Voluntary notification



## Scope of FDA Regulatory Authority Pertaining to Dietary Supplements

- Dietary ingredients in dietary supplements are exempt from the definition of food additive
- Do not require approval before marketing
- “New dietary ingredients” subject to required notification



- Dietary Ingredients in Dietary Supplements
- Colors added to food
- Food Additives and Ingredients
  - “Direct” food additives
  - Food additives that are food contact substances
  - Food ingredients whose use is Generally Recognized as Safe



# Nanotechnology and Regulatory Status

Questions to consider

Has changing the size affected the safety?

Is it the same substance?

Industry is responsible for ensuring that any necessary data are developed and that premarket approval is obtained if required for “nanosized” ingredients



# Nanotechnology and Regulatory Status

The use of a substance in the nano form may or may not be GRAS even if the use of a substance in the macro form is GRAS

Information underpinning safety must be

- Generally available

- Generally recognized

- Must relate to the substance under consideration



# Nanotechnology: The Path Forward

**Case studies:** In collaboration with the Woodrow Wilson Institute to consider potential issues related to nanotechnology and active packaging

**Public Meeting:** September 8, 2008, FDA sponsored a meeting to seek input on determining the data and test methods that are available, and to hear public comments and concerns regarding this class of compounds.



# Chemistry Guidance for Food Contact Notifications December, 2007

## Section II.A.5. Physical/Chemical Specifications:

"...In cases where particle size is important to achieving the technical effect or may relate to toxicity, sponsors should describe particle size, size distribution, and morphology, as well as any size-dependent properties."

## Section II.C. Technical Effect:

"...If technical effect is dependent on particle size, sponsors should present data that demonstrate the specific properties of the particles that make them useful for food-contact applications."



# Nanotechnology and Guidance

The potential for rapid development and introduction of FDA-regulated nanomaterials highlights the need for a transparent, consistent, and predictable regulatory pathway.

The FDA Nanotechnology Task Force Report recommended development of appropriate guidance documents. In the interim, FDA is updating existing guidance for new submissions to include considerations relevant to nanoscale materials.

Consult with us early and often

