

NANOTECHNOLOGY AND U.S.
PERSPECTIVES: FDA REPORT BY
THE NANOTECHNOLOGY TASK
FORCE

Global Harmonization Task Force
Conference
October 3-4, 2007

Norris E. Alderson, PhD
Food and Drug Administration

BRIEFLY -- TODAY

- FDA Mission
- Nanotechnology
- Regulation of Nanoscale Materials
- FDA Nanotechnology Task Force Report
- Conclusions

FDA MISSION

FDA is responsible for ensuring that human and animal medications, blood products, tissues for transplantation, and medical devices are safe and effective; that food and dietary supplements are safe and truthfully labeled; and that animal feed, cosmetics, and radiation-emitting equipment do no harm.

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

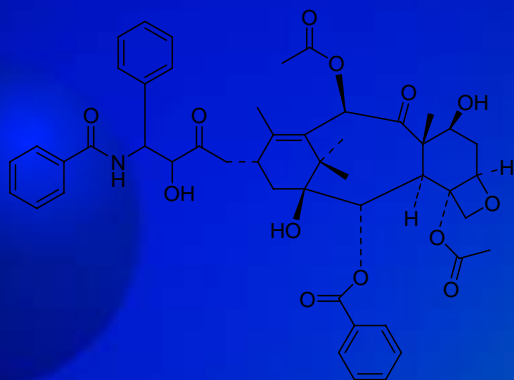
WHAT IS NANOTECHNOLOGY?

“Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.” (NNI)

NANO-ENGINEERED MATERIALS FDA STATUS

- Regulation driven by statutory classification rather than technology
- Range of regulatory authority
- Review of products, not technology
- Increased knowledge may lead to change
- Review challenges
 - Metrology
 - Testing
 - Physical characterization
 - Safety and industrialization

Physical Characterization



Small molecules

- Elemental analysis
- Mass
- NMR
- UV-Vis
- IR
- HPLC
- GC
- Polarimetry



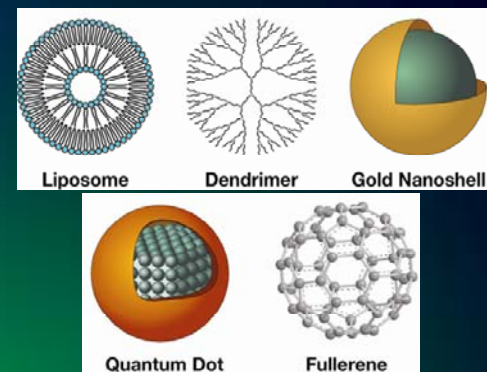
Physicochemical Parameters

- **Composition**
- **Physical properties**
- **Chemical properties**
- **Identification**
- **Quality**
- **Purity**
- **Stability**



Nanomaterial

- Microscopy (AFM, TEM, SEM)
- Light scattering (Static, Dynamic)
- SEC, FFF
- Electrophoresis (CE, PAGE)
- Zeta sizer
- Fluorimetry



Same parameters – different/additional characterization methods

(Source – NCI/NCL)

FDA NANOTECHNOLOGY TASK FORCE

- Encourage development of safe and effective products
- Address knowledge or policy gaps
- Guide science and technology
- Assess current state of science
- Strengthen collaboration with federal agencies
- Communication with public
- October 10, 2006 public meeting
- Report to Commissioner – July 2007

NANOTECHNOLOGY DEFINITION CONSIDERATIONS

- Adopted no definition
- Broad inclusive approach
- Importance of material size and state of the science
- Need to know more before having a fixed definition

SCIENCE RECOMMENDATIONS

- Efforts to understand biological interaction and properties
- Promoting measurement and detection
- Data analysis for specific product review categories
- Building in-house expertise
- Regulatory coordination for products containing nanoscale materials

SCIENCE RECOMMENDATIONS

(cont'd)

- Adequacy of safety, efficacy, and quality of products
- Standardize characterization procedures and approved standards

REGULATORY POLICY RECOMMENDATIONS

- Request information on effects of nanoscale materials on manufacturing process of products subject to premarket authorization
- Provide guidance regarding identification of particle size for premarket authorization and non-premarket authorization products
- Request data to identify OTC products and for nanoscale versions of previously approved products that contain or may contain nanoscale materials
- Request data on the effects of nanoscale materials on product safety and effectiveness on products requiring premarket authorization

REGULATORY POLICY

(cont'd)

- Provide guidance for information needs for new food or color additives and for previously approved food and color additives
- Provide guidance for 510(k) products when containing a nanoscale material, including when a new 510(k) would be required
- Request data on effects of nanoscale materials on product safety of products not subject to premarket authorization, including food ingredients and dietary supplements
- Provide guidance on safety issues for consideration by cosmetic manufacturers to ensure products are not adulterated

LABELING

- Relates to definition
- Labeling must include material information
- Premarket product – adequate to support safe and effective use
- Products not subject to premarket authorization – same with no false or misleading information
- Current knowledge does not support conclusion that these materials present a greater safety risk than products without these materials
- Case-by-case decision on labeling

NATIONAL ENVIRONMENTAL POLICY ACT

- On case-by-case basis, determine whether a nanoscale product qualifies for an exemption
- Designate an FDA lead to coordinate this activity.

CONCLUSIONS

- No new regulations needed at this time
- FDA regulates a range of potential nanoscale material products based on a range of regulatory authorities
- Premarket authority provides comprehensive approach to evaluating safety, effectiveness, quality of products
- Products not subject to premarket authority do not have the same level of information available to FDA

CONCLUSIONS (cont'd)

- Task force recommends issuance of guidances and data with public input
- FDA will continue to review products on case-by-case basis
- FDA continues to stress the importance of early communication with industry

THANK YOU

norris.alderson@fda.hhs.gov

- 301-827-3340