FDA REGULATION OF PRODUCTS CONTAINING NANOENGINEERED MATERIALS

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CSL/JIFSAN Joint Symposium on Food Safety and Nutrition
Nanotechnology in Foods and Cosmetics
BRIEFLY -- TODAY

• FDA Mission
• Nanotechnology
• Regulation of Nanoscale Materials
• FDA Nanotechnology Task Force
• FDA/Federal Nano Public Coordination
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)
## Field Defining Technologies

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Molecule/Drop</th>
<th>Detection/Targets/Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10^{-3}$ - Millimolar</td>
<td>Quadrillions</td>
<td>Colorimetric/Enzymatic Chemistry, Blood Sugar (Diabetes)</td>
</tr>
<tr>
<td>$10^{-6}$ - Micromolar</td>
<td>Trillions</td>
<td>ELISA &amp; Chemiluminescence, Troponin, CK-MB, BNP, βHCG</td>
</tr>
<tr>
<td>$10^{-9}$ - Nanomolar</td>
<td>Billions</td>
<td></td>
</tr>
<tr>
<td>$10^{-12}$ - Picomolar</td>
<td>Millions</td>
<td></td>
</tr>
<tr>
<td>$10^{-15}$ - Femtomolar</td>
<td>Thousands</td>
<td>Bio-barcode Technology, Alzheimer’s Disease, Mad Cow, Ovarian, Breast, and many other cancers, Pulmonary Disease, Cardiovascular Disease</td>
</tr>
<tr>
<td>$10^{-18}$ - Attomolar</td>
<td>Tens</td>
<td></td>
</tr>
<tr>
<td>$10^{-21}$ - Zeptomolar</td>
<td>&lt;1</td>
<td></td>
</tr>
</tbody>
</table>

Source - Chad Mirken, Northwestern Univ, 2007
REGULATION OF NANOENGINEERED PRODUCTS

- FDA regulation is driven by statutory classification rather than technology
- FDA has limited regulatory authority over certain products
RISK MANAGEMENT APPROACH

• Review of products—not the technology
  – Safety
  – Effective
  – Manufacturing controls

• Review process is not static
  – As we learn, we evolve the process
  – Early engagement with FDA
REVIEW CHALLENGES

• Metrology
  – What
  – How much
  – Dose
  – ADME

• Testing
  – Screening
  – Environmental release
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)
NANO PRODUCTS ASSESSMENT CONCERNS

• Safety Assessment
  – Adequacy of current toxicology
  – 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
STATUS OF REGULATIONS

• Nanomaterials present similar regulatory challenges
• Challenges may be magnified
• Size may make a difference
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
TASK FORCE RECOMMENDATIONS

• FDA expectations of products
• Predictability of regulation
• Enable innovation and enhance Transparency
• Safety
Definition of technology is less important than being able to recognize a novel property caused by the technology.

Technology vs nanomaterial.
SCIENCE AND REGULATION CONSIDERATIONS

• What do we know; what do we need to know?
• Does a change in size/properties dictate a different approach to safety assessment?
• Can FDA define regulatory approaches for nanomaterials based on class of product, size of material, etc?
• Is product by product approach appropriate?
REGULATORY CHALLENGES

• Does nanomaterials pose different challenges than other emerging technologies?
• Are normal regulatory schemes for safety evaluation adequate?
• Considering the range of regulatory authority and products, what can FDA do to fill the gaps?
• Should the label of products containing nano-materials provide nano-information?
FDA/FEDERAL NANO-POLICY COORDINATION

• Subcommittee on Nanoscale Science, Engineering and Technology (NSET) of the National Science and Technology Council (DOE/OSTP Co-Chair)
• Working Group on Nanotechnology Environmental and Health Implications (NEHI) (FDA Chair)
• Global Issues in Nanotechnology Working Group (GIN) (State Chair)
• Nanotechnology Public Engagement Working Group (NPEG) (NIH Chair)
• NTP, NCI and NIST Collaboration
CONCLUSIONS

• New technology – unknown risks
• Stakeholder involvement
  – Early involvement of all parties
  – Risk communication
• Communication with new manufacturers
• Timely reporting of relevant scientific findings
• Product by product evaluation
THANK YOU

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