BME 695L Engineering Nanomedical Systems
November 13, 2007

Lecture 21: FDA and EPA Regulatory Issues

I. Introduction and overview
   A. How does the FDA think about nanomedical systems?
   B. The 2006 Nanotechnology Task Force

II. Some details of the Nanotechnology Task Force Report
   A. General findings of the report
   B. Some initial recommendations of the Task Force
   C. Where the FDA may need to meet EPA on nanoscale materials
   D. Will FDA re-visit GRAS products containing nanomaterials?

III. How will the FDA consider nanomedical systems?
   A. Nanomedical systems are integrated nanoscale drug and drug delivery devices
   B. Either a drug or a device? How about a "Combination Product"?
   C. Drug-Biologic combination products

IV. EPA and other regulatory agency issues
   A. Assessing environmental impact of emerging nanotechnologies
   B. Concept of life cycle assessment (LCA)
   C. Toxicity of nanomaterials
   D. Some recommendations of the 2006 International Conference on Nanotechnology and Life Cycle Assessment

V. Nanotechnologies and the workplace
   A. NIOSH – Formulating workplace safety standards for nanotechnology
   B. Protecting workers in the workplace
   C. Assessing hazards in the workplace
   D. Establishing a Nanotechnology Safety System

VI. The future of nano-healthcare products

References

1. Nanotechnology A Report of the U.S. Food and Drug Administration Nanotechnology Task Force July 25, 2007 at http://www.fda.gov/nanotechnology/taskforce/report2007.pdf

2. Environmental impact of nanotechnology documents: Life Cycle Assessments - http://www.nanotechproject.org/111/32007-life-cycle-assessment-essential-to-nanotech-commercial-development

3. NIOSH workplace documents: http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf

4. Nano Healthcare Products assessment: The Freedonia Group, Inc http://www.freedoniagroup.com