Nanotechnology and Dietary Supplements

FDA Nanotechnology Public Meeting

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William B. Schultz

Zuckerman Spaeder LLP, on behalf of the
Project on Emerging Nanotechnologies
Woodrow Wilson International Center for Scholars

Historical Perspective

- The regulation of dietary supplements has been a significant challenge for FDA for many years.
- Congress has given FDA minimal regulatory authority to insure the safety of dietary supplements.
- Introducing the use of engineered nanoparticles into products creates an additional layer of complexity for FDA and additional risk to patients.

Market Share

- Dietary supplements are used by millions of people every day.
- Market has increased dramatically since FDA's authority to regulate them was restricted in 1994 by DSHEA.
- Technology has evolved as the market increased.
  - 44 products listed on PENs CPI
    - 26 of which were added since the FDA held its initial public meeting on nanotechnology in October of 2006

Bio-Sim
Company: Nano Health Solutions

What They Say

"This diatomaceous earth is uniquely treated and processed to help all life forms attain healthy support for their immune systems. It is then nanoized and combined with a small amount of sugar cane and kosher distilled vinegar to serve as bait for the hidden parasites."

Lypo-Spheric™ Vitamin C
Company: LivOn Labs

What They Say

"Liposomal Encapsulation Technology (LET) combines nano-technology and bio-technology in a very powerful way. Medical specialists have used Liposomal Encapsulation Technology for many years to deliver tiny amounts of therapeutic substances to specific organs or tissues without being altered and without affecting any other parts of the body… The liposomes used in Lypo-Spheric™ Vitamin C are about 300 to 400 nanometers in diameter (a nanometer is one-billionth of a meter) and are particularly suited to move quickly and efficiently to their target before releasing their contents."

Nanotrim™
Company: NanoNutra™ Labs

What They Say

"Nanotrim™ is comprised of the most powerful, nano-engineered medicinal botanicals available and contains no chemically generated compounds or fillers. Your body recognizes Nanotrim™ as food. Nanotrim™ is 100% safe and natural and will cause NO negative side effects. The nanoscaled, all-natural ingredients in Nanotrim™ have been proven to dramatically improve cellular health and the burning of fat for energy."

The Problem

- FDA has little information on the safety of many dietary supplements.
- Similarly it has little information on the safety of the use of nanomaterials in dietary supplements.
- There is no basis for concluding that the supplements industry is conducting the rigorous testing needed to understand the effects of nanomaterials in supplements.
- Consumers are potentially exposed to unknown risks.

Is FDA equipped to meet the regulatory challenges of dietary supplements that incorporate nanotechnology?

The short answer is **NO**

FDA Has Limited Regulatory Authority Over Dietary Supplements

- No pre-market approval authority
- Manufacturers are required to disclose very little information to FDA
- When safety issues are raised, FDA must meet a very high standard for removal of a product
- No authority to require post-market testing
- No mandatory recall authority

Ephedra

- In 1997, FDA issued a proposed rule, "Dietary Supplements Containing Ephedrine Alkaloids.“
- In 2002, Metabolife®, the manufacturer, reported to FDA that it had received over 15,000 complaints, including two deaths, of adverse reactions.
- December 2003, FDA recommended consumers stop buying and using Ephedra.
- April 2004, FDA banned the sale of dietary supplements containing Ephedra -- nearly 10 years after the initial reports of adverse reactions

Actions FDA Could Take Without Additional Statutory Authority

- Law requires that companies give FDA notice of new dietary ingredients 75 days before marketing them, including information that manufacturer relies on to meet the safety standard.
- After 75 days, can market, without waiting for FDA action.
- FDA should explore whether it could declare any dietary supplement made using nanotechnology to be a new dietary ingredient. This would trigger the 75-day notice requirement.
- Should consider how to apply retroactively.
- If FDA has this authority, it could issue a guidance as to its legal interpretation. Should be followed promptly by a binding regulation.
- Would be meaningless without adequate resources.

FDA Lacks Resources

- The dietary supplements program has always been understaffed.
  - Insufficient staff to examine adverse reactions, safety or support testing on products
- In recent years, the resources available for dietary supplements have been reduced even further.

Recommendation 1: Increased Regulatory Authority

- Congress should provide FDA with regulatory authority in the following areas
  1. Product Registration
  2. Establishment of Safety Standards
  3. Pre-Market Testing
  4. Pre-market Review
  5. Expanded Adverse Event Reporting

Recommendation 2: Increased Resources

- Congress should provide FDA with resources sufficient to regulate dietary supplements under the new regulatory authority described previously.
  - Scientific Staff
  - Regulatory Staff
  - Research

Recommendation 3: Interim Measures

- Before receiving additional appropriations or regulatory authority, FDA should take the following actions:
  - Increase resources dedicated to dietary supplements made with nanotechnology
  - Identify dietary supplements made using nanotechnology
  - Study the safety of dietary supplements made using nanotechnology
- Potential regulatory actions
  - Consider issuing guidance/regulations declaring dietary supplements made with nanotechnology to be new dietary ingredients
  - Consider issuing guidance/regulations declaring dietary supplements made with nanotechnology to be unsafe
  - Initiate regulatory action against products that are unsafe

Concluding Remarks

- FDA has no effective regulatory presence with regard to dietary supplements made with nanotechnology, due to its limited authority and extremely limited resources.
- This creates a public health threat that must be addressed.
- In the short run, FDA should devote resources to studying, identifying and regulating dietary supplements made with nanotechnology.
- In the long run, Congressional legislation and additional appropriations will be necessary to protect the public health.