FDA Nanotechnology Public Meeting

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Rockville, Maryland

Summary of Presentation

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On behalf of
The Project on Emerging Nanotechnologies
Woodrow Wilson International Center for Scholars

1. **Breakout Session:** Dietary Supplements

2. **Specific Topic to be addressed:** An assessment of the FDA's ability to regulate dietary supplements containing nanomaterials

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4. **Approximate duration:** 15 minutes

5. **Summary**

Dietary supplements are used by millions of people every day. This market has increased dramatically since FDA's authority to regulate dietary supplements was restricted in 1994 by the passage of the Dietary Supplement Health and Education Act (DSHEA). As the market has increased, technology has evolved and the use of nanomaterials in such products has increased. According to the Project on Emerging Nanotechnologies Consumer Products Inventory, there are 44 dietary supplements on the market which claim to utilize nanotechnology. Twenty-six of those products have been added since the FDA held its first public meeting on nanotechnology in October of 2006. Bio-Slim produced by Nano Health Solutions, one example of a more recent addition to the inventory, claims:

"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."[1] (Emphasis added.)

Use of nanomaterials in these products has raised serious questions about how products are metabolized, the rate of absorption, and the internal barriers that may be crossed by these products, *e.g.*, the placenta and/or brain. Unlike drugs, medical devices, food additives and foods, supplements are not subject to premarket approval. With regard to supplements:

1. There is no pre-market approval authority—generally no testing is required prior to marketing to the public (except for notification regarding new dietary ingredients);
2. Manufacturers are required to disclose very little information-- FDA has very little knowledge about what's out there, what's being developed;
3. When safety issues are raised about a product, FDA must meet a very high standard for removal of a product -- "a significant or unreasonable risk of illness or injury";
4. FDA has burden to meet that standard—the Agency must provide persuasive evidence before taking any action, which can be extremely difficult; and
5. FDA has no authority to require post-market testing or mandatory recall of defective products.

For many years, the dietary supplement program has always been understaffed and underfunded. It never has had the capacity to systematically examine adverse reactions, safety or support testing on products. FDA has faced severe resource problems in recent years for all products, and during this period of time the dietary supplement program has been cut even further. Companies may generally market these products without pre-

[1] http://www.fulvic.org/html/nano_bio-sim.html last accessed August 28, 2008

market review and approval. FDA has no program or resources to monitor the safety of products.

The use of nanomaterials in dietary supplements adds an additional level of complexity and heightened safety risk. For these reasons, the following steps should be taken to protect the public health:

1. Increased Resources—Acquiring adequate resources to support its regulation of dietary supplements using nanomaterials is essential. Such funds should be used:
    a. To develop and implement a risk research strategy regarding the safety of nanomaterials in dietary supplements;
    b. To gather information on what products containing nanomaterials currently are being marketed; and
    c. To provide the staffing to implement new (and existing) regulatory authority over such products.
2. Increased Regulatory Authority—Congress should require that manufacturers of dietary supplements made with nanotechnology demonstrate that their products are safe, and it should provide FDA with regulatory authority in the following areas:
    a. Registration of dietary supplements containing nanomaterials;
    b. Establishment of safety standards; and
    c. Review and pre-market approval of the safety of new dietary supplements containing nanomaterials prior to marketing.