

## **FDA Nanotechnology Public Meeting**

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Rockville, Maryland

### **Summary of Presentation**

Andrew D. Maynard  
Chief Science Advisor, Project on Emerging Nanotechnologies

- 1. Breakout Session:** Cosmetics
- 2. Specific Topic to be addressed:** An assessment of commercially available cosmetics allegedly using nanotechnology
- 3. Contact Details:** Andrew Maynard  
Chief Science Advisor, Project on Emerging Nanotechnologies  
Woodrow Wilson International Center for Scholars  
1300 Pennsylvania Avenue NW  
Washington DC 20004-3027  
Tel: 202 691 4311  
Fax: 202 691 4001  
Email: [Andrew.maynard@wilsoncenter.org](mailto:Andrew.maynard@wilsoncenter.org)
- 4. Approximate duration:** 10 minutes
- 5. Summary**

The Project on Emerging Nanotechnologies maintains a publicly accessible on-line inventory of consumer products that manufacturers claim to be based on nanotechnology (accessible at [www.nanotechproject.org/consumer](http://www.nanotechproject.org/consumer)). The inventory currently contains over 800 products, of which 125 are cosmetics. Sixty-two of these cosmetic products have been added to the inventory since the FDA's initial public meeting on nanotechnology in October of 2006.

Given the methodology and criteria by which products are included in the inventory, the nanotechnology-based cosmetics listed here most likely represent a small fraction of all available cosmetic products that contain engineered nanomaterials. The use

of nanoscale materials in cosmetics presents three key challenges to the products' safe use and effective regulation:

- How to respond to particle size, shape and surface properties at the nanoscale may lead to changes in exposure to a material and biologically relevant dose following exposure, when compared to non-nanoscale materials with the same chemistry;
- How to respond to human health hazards that are related to the size-dependent properties of nanoscale materials, in addition to their chemical identity; and
- How to delineate the boundary between purely cosmetic functions and biological activity that is more closely related to drugs.

A closer examination of the cosmetics products listed in the PEN consumer product inventory provides a useful context to addressing these challenges. As of September 2008, 117 of the cosmetics products listed have applications that broadly fall within 13 categories: anti-ageing products, cleansers, conditioners, complexion-enhancing products, cosmetics, disinfectant products, breast enlargement products, exfoliators, hair styling products, moisturizers, perfumes, lip enhancement products, and skin whiteners. The remaining eight products are either associated with multiple uses, or the use is not clearly identifiable. Most of the products (81) are designed to be applied generally to the skin. In addition, 8 products are explicitly designed for face-application, 6 for application around the eyes, 3 for lips, 3 for hands, and one each for the neck, breasts and cuticles. Thirteen products are associated with hair styling; most of these employ the use of engineered nanomaterials in hair curlers or straighteners. The

nanomaterials being used in these products fall into five broad categories: carbon nanoparticles (including fullerenes), metal nanoparticles, metal oxide nanoparticles, organic nanoparticles and nano-capsules. In many cases the nano-capsules appear to be nanoscale liposomes, designed for the efficient delivery and timed release of ingredients. More specifically, 13 nanomaterials are identified as being incorporated into these products: alumina, carbon (excluding fullerenes), collagen, copper, fullerenes, gold, mica, platinum, silica, silver, titanium dioxide, titanium metal, and zinc oxide. Over half of the cosmetics products listed either contain a mixture of these materials, or it is unclear what the material being used consists of.

Many manufacturers claim that added functionality is derived from the inclusion of nanoscale materials in their products. In addition, the current state of science strongly suggests that, in some cases, engineering materials at the nanoscale can change their potential to cause harm. This leads to the possibility of unconventional risks associated with the use of some nanomaterials that are not predictable from the chemical identity of ingredients alone. Yet there are few checks and balances in the regulatory and oversight systems governing cosmetics to ensure novel or unconventional risks are managed appropriately. This was highlighted by Mike Taylor in the report *Regulating the Products of Nanotechnology: Does FDA Have the Tools it Needs?*<sup>1</sup>

In moving towards more effective regulation of nanotechnology-enabled cosmetics, three steps in particular are needed:

- Criteria need to be established for determining when nanotechnology-based materials and products are new for regulatory purposes and new for

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<sup>1</sup> Michael R. Taylor. *Regulating the Products of Nanotechnology: Does FDA Have the Tools it Needs?* Washington, D.C.: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2006.

safety evaluation purposes. Relying on chemical identity alone to define new materials and products is not sufficient where a material's physical form can also influence possible risk. The definition of nanotechnology frequently used to describe the science and commercialization of engineered nanomaterials does not address the needs and concerns of regulators and others managing the responsible use of new materials and products.

- New knowledge is needed on the uses of nanomaterials in cosmetics, potential risks that may be associated with these uses, and approaches to ensuring safe use. This needs to come through targeted research, and requires an increase in funding for research within FDA, together with an internal research strategy that complements national and international nanotechnology risk-research strategies. In addition, an exchange of information on potential nanotechnology-based product risks needs to be facilitated within and between the cosmetics industry and FDA.
- Greater transparency is needed in identifying where nanotechnology is being used in cosmetics, and the nature of its use, including the functionality it brings to products, and the nature of the material being used. Information should be readily available for all decision-makers, whether regulators, companies or consumers.

The hope is that extensive environmental health and safety testing has been conducted on the products already on the market and those in the future. But without

transparency or FDA oversight, consumers must take industry at its word that cosmetics incorporating manufactured nanoparticles are safe.