

## **New FDA Nanotech Task Force May Foretell Change In Regulation**

FDA is forming an internal task force to determine if new regulations or authorities are needed for oversight of nanotechnology, a move consumer advocates hope the agency will use to seek expanded regulatory powers through legislation. The task force will deliver policy recommendations in nine months, after reaching out to other federal agencies and holding a public meeting in October.

Jay Dee Hanson of the International Center for Technology Assessment, which has petitioned FDA to strictly regulate products containing nanoparticles, said the agency may be changing its tone. The agency previously stated that there is no reason to regulate products differently just because they include very small structures. Now the agency stresses that nanomaterials may pose a greater risk because they have different physical properties than conventional materials.

“We're happy that they're taking the step,” Hanson said. “If this means they're going to ask for more authority, it's about time.”

An FDA release states that the task force will “evaluate the effectiveness of the agency's regulator approaches and authorities to meet any unique challenge that may be presented by the use of nanotechnology materials in FDA-regulated products.”

Hanson added that he believes the task force was created in part because ICTA in May petitioned FDA to regulate sunscreens with nanoparticles as new drugs instead of over-the-counter drugs.

Last week, the Center for Regulatory Effectiveness warned FDA that ICTA's petition puts the agency in the middle of the international debate on how to regulate nanotechnology. CRE said FDA should hold a public meeting and solicit input from across the government on the sunscreen petition, warning that FDA's decision on the petition could have domestic and international implications for nanotechnology regulation.

One of the task force's stated goals is to hold a public meeting to improve FDA's knowledge of nanotechnology on FDA-regulated products, and new and emerging scientific issues. This meeting is scheduled for Oct. 10, and the task force will be expected to report its findings to acting FDA Commissioner Andrew von Eschenbach within nine months.

Bruce Levinson at CRE said the public meeting was “absolutely the right move” on FDA's part.

He also commended FDA “for taking steps to ensure that all data used by the agency complies with the data quality act.”

Hanson said FDA especially needs more regulatory power over cosmetics that use nanotechnology. FDA's drug regulations are fairly extensive, he says, but the agency's reach is much shorter for cosmetics.

The Woodrow Wilson International Center for Scholars in January released a report calling for a new law to regulate nanotechnology in cosmetics, though the report recognizes the technology is used across many industries in different ways and such a law would be difficult to write.

As part of its sunscreen petition, ICTA also asked FDA May 16 to require labeling of nanomaterials in cosmetics, create toxicology testing specific to nanotechnology, define nanomaterials and conduct environmental studies that comply with the National Environmental Policy Act. Other advocacy groups also signed the petition.

At least for now, FDA has not developed a new regulatory approach for nanotechnology products, though it has reviewed nanotechnology issues for years. After a British government report released in 2004 found that nanoparticles used in cosmetic products seep through skin and into vital organs and could potentially cause harm, an FDA official told FDA Week the agency was undertaking a two-year study of nanoparticles in cosmetics to determine what, if any health effects they caused.

The Cosmetic Toiletry and Fragrance Association said at the time that there is no link between nanoparticles used in cosmetics and adverse health effects.

The new FDA task force's other responsibilities will include:

Reviewing current scientific knowledge of nanotechnology relevant to FDA.

Investigating opportunities where nanotechnology could be used to develop new products.

Strengthening FDA's relationship with other government agencies and foreign government regulatory bodies. Levinson said he believes FDA is on the cutting edge of federal government agencies dealing with nanotechnology.

Considering ways to communicate with the public on nanotechnology in FDA-regulated products.