

FDA Begins to Tackle Nanotech Challenge

By Beryl Lieff Benderly*

Hundreds of nanotech products, including foods, medicines and medical devices, now have reached the market, and their number will grow exponentially in the years ahead. The main regulating body, the Food and Drug Administration, is just beginning to address the unique issues presented by this groundbreaking technology.

According to a July 2007 report prepared by a special FDA nanotechnology task force, while the agency has the capability to meet these challenges, it needs to take specific action soon to get ready. To date, FDA has not made public its plans for responding to the task force report. "We are beginning the planning for the priority activities defined in the task force report," FDA spokesperson Crystal Rice told Food and Drug Law Institute (FDLI) in mid-January.

"FDA has not done much, if anything, publicly.... They are in an information-gathering and internal assessment phase," said Julia A. Moore, Deputy Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars (WWC) in Washington, DC, during an interview with FDLI. Nonetheless, "I'm very sure that they are doing things. This is a high priority of [Commissioner Andrew] von Eschenbach and the agency," she continued. "It's really a matter of making sure that they have the resources and the expertise and ...of taking a look at their statues and ensuring that they are nano-ready."

"Nanoscale materials present regulatory challenges similar to those posed by products using other emerging technologies," states the task force report. "These challenges may be magnified," however, because "properties of a material relevant to the safety and (as applicable) effectiveness of FDA-regulated products might change repeatedly as size enters into or varies within the nanoscale range." The "emerging and uncertain" science and the "potential for rapid development of applications for FDA-regulated products highlights" require "timely development of a transparent, consistent, and predictable regulatory pathway," the report continues.

Achieving this will require both scientific and regulatory efforts, the report notes. In the scientific realm, it recommends:

- FDA "focus on improving scientific knowledge of nanotechnology" ;
- Research to "evaluate whether the tools available to describe and evaluate nanoscale materials are sufficient,"; and
- "Development of additional tools where necessary."

FDA's existing regulatory authorities are "generally comprehensive for products subject to premarket authorization requirements," the task force found, although FDA "oversight capacity is less comprehensive" for products not subject to those requirements. In the regulatory realm, the task force recommends that FDA

- Request from manufacturers "information about effects of nanoscale materials on safety and, as appropriate, effectiveness of products";
- "Provide guidance to manufacturers about when the use of nanoscale ingredients may require submission of additional data, change the product's regulatory status or pathway, or merit taking additional or special steps to address potential safety or product quality issues";
- Seek "public input on the adequacy of FDA's policies and procedures"; and
- Encourage "manufacturers to communicate with the agency early in the development process for products using nanoscale materials."

Many "nano materials will turn out to be good and wonderful and beneficial," Moore said. Given the newness and complexity of nano techniques and materials, however, "it would be unprecedented" if they did not present some risks, she continued. Despite this, "there has not been major investment" in looking for such risks, and FDA "needs to have the resources and the capacity to explore them."

Other experts also question FDA's current nano preparedness. *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?*, a report by former FDA Deputy Commissioner for Policy Michael R. Taylor published in 2006 by the WWC nanotechnology project, states that "FDA is not 'nano ready'" because "gaps exist in FDA's legal toolbox" and "FDA lacks necessary resources." But, Taylor adds, "even within its current authority and resources, FDA can and should take some immediate steps to address the first wave of nanotechnology products now entering the market, including perhaps the most fundamental one of setting the criteria for determining when a nanoscale material is 'new for legal and regulatory purposes' and 'new for safety evaluation purposes.'"

Nanotechnology ranks among the "eight emerging science and technologies that are most challenging" to FDA, according to *FDA Science and Mission at Risk*, a report issued in November 2007, by the Subcommittee on Science and Technology of the FDA Science Board. "Due to constrained resources and lack of adequate staff, the FDA cannot adequately monitor development of food and medical products because it is unable to keep up with scientific advances," the report warns. "The lack of new science capability/capacity places the FDA mission at risk for those many products at the leading edge of innovation."

To fulfill its mission, Moore concludes "the agency is going to have to make changes in its oversight of nanotechnology because nanotechnology presents novel risks."

The Food and Drug Law Institute and the Woodrow Wilson Center Project on Emerging Nanotechnologies, in partnership with Burdock Group and Arizona State University, are sponsoring the 1st Annual Conference on Nanotechnology Law, Regulation and Policy Feb. 28-29, in Washington, D.C.

For more information on the conference, visit www.fdpi.org/conf/431

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