



October 5, 2006

Division of Dockets Management (HFA—305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

SUBMITTER: David Rejeski

ORGANIZATION: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

SUBJECT: **Submission Update:** FDA-Regulated Products Containing Nanotechnology Materials [Docket No. 2006N-0107]

On July 19, 2006, the Project on Emerging Nanotechnologies submitted comments in advance of the FDA's Nanotechnology Public Workshop, to be held on October 10, 2006 in the Washington, DC area. Since our comments were submitted, a number of key developments with respect to nanotechnology have taken place, including the formation of an internal FDA Nanotechnology Task Force, congressional hearings related to what federal agencies are doing with respect to nanotechnology environmental, health and safety risk research and the launch of a Voluntary Reporting Scheme by the Department for Environment Food & Rural Affairs (Defra) in the United Kingdom.

In the intervening timeframe, the Project has continued to address a variety of issues surrounding nanotechnology. By way of this update to our initial set of comments, the Project is submitting additional materials related to topics at the heart of the upcoming public meeting, including nanotechnology and FDA oversight, nanotechnology commercialization in consumer products, nanotechnology public engagement and trust in government, and nanotechnology in agriculture and food. The chief resource is a comprehensive overview report prepared by Michael R. Taylor that focuses on whether FDA possesses the capacity and necessary legal, regulatory and resource tools to adequately oversee nanotechnology products. In short, these materials address:

- ***Nanotechnology and FDA oversight.*** The October 2006 report, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?*, by former FDA official Michael R. Taylor, analyzes FDA's ability to properly protect the American public from the potential hazards associated with nanotechnology. Taylor finds gaps in legal authority and fundamental inadequacies in resources that FDA faces as it attempts to better understand and manage the potential risks from hundreds of new products utilizing nanotechnology entering the marketplace in areas such as cosmetics, dietary supplements, food and drugs.

Project on Emerging Nanotechnologies



Taylor sets out a necessary course of action for the FDA, Congress and industry to address these gaps and examines whether FDA should classify some nanoscale materials as “new” for legal, regulatory and safety purposes.

- ***Nanotechnology commercialization in consumer products.*** The Project has regularly updated the Nanotechnology Consumer Products Inventory, and as of October 2006, it contains over 320 manufacturer self-identified products that are on the market in 17 countries. The inventory is publicly accessible, fully searchable and available on-line at <http://nanotechproject.org/consumerproducts>. A similar inventory has been developed in Japan under the auspices of the National Institute of Advanced Industrial Science and Technology (AIST) and categorizes over 200 manufacturer self identified products—including over 85 cosmetics and 10 products associated with food, dietary supplements and food packaging—in that country alone. Though currently only available in Japanese, that inventory can be found online at <http://staff.aist.go.jp/kishimoto-atsuo/nano/index.htm>.
- ***Nanotechnology public engagement and trust in government.*** The September 2006 report, *Attitudes Toward Nanotechnology and Federal Regulatory Agencies: Report Findings* by Peter D. Hart Research Associates, Inc., describes results from the first major national poll on nanotechnology in more than two years. The report indicates that that while more Americans are now aware of nanotechnology, the majority of the public still has heard little to nothing about it. The poll also finds that the public looks to the federal government and independent parties to oversee nanotechnology research and development. These results, according to experts, necessitate increased education and stronger oversight as a means to increase public confidence in nanotechnology.
- ***Nanotechnology in agriculture and food.*** The September 2006 report, *Nanotechnology in Agriculture and Food Production: Anticipated Applications*, by Jennifer Kuzma and Peter VerHage from the University of Minnesota’s Center for Science, Technology and Public Policy, for the first time analyzes the publicly available data on federally funded projects in agrifood nanotechnology, supplemented with data from the U.S. Patent and Trademark Office. This report estimates possible areas and timeframes for future nanotechnology-based food and agriculture applications, takes an early look at potential benefits and risks and explores possible areas and needs for environmental, health and safety oversight.

We hope that, taken together, these additional resources, in conjunction with the comments and other materials we submitted previously, will provide useful insight into critical issues in need of continued attention by FDA and other government regulatory agencies. As FDA moves forward to address nanotechnology and implement new strategies that emerge for the public meeting and the work of its internal task force, it is critical that findings from the aforementioned documents are systematically considered and integrated into its future activities.