STRAUS-EDWARDS ASSOCIATES ARCHITECTS

September 21, 2006

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

Subject: Comments on Docket No. 2006N-0107 (Public meeting and FDA regulation of nanotechnology materials)

Dear Commissioner:

I write to encourage stringent FDA regulatory oversight of nanomaterials in consumer products. Many consumer products containing engineered nanomaterials are already available on U.S. market shelves, including food and food packaging products, including a canola oil, a chocolate "slim" shake, a nano-bread, and several nano-food additives and supplements used in soft drinks, lemonades, fruit juices, margarines . Millions of dollars are being spent by government and industry to apply nanotechnology in areas of food processing, food packaging, and agricultural production .

In addition, if industry observers are correct, hundreds of more new food and agriculture products are under development and many could be on the market in as few as two years. By 2010 the nano-food market will be $20 billion. Many of the world's leading food companies - including H.J. Heinz, Nestle, Hershey, Unilever, and Kraft - are investing heavily in nanotechnology applications.

Of concern to me is that scientists have found that the fundamental properties of matter can change at the nano-scale, creating physical and chemical properties distinct from those of the same material in bulk form. We know that the new properties of nanomaterials create new risks, like enhanced toxicity. Studies have raised numerous red flags, and many types of nanoparticles have proven to be toxic to human tissue and cells.

I have learned that nanoparticles can gain assess to the blood stream following ingestion. Once inside the body, the super-tiny size of these materials gives them unprecedented mobility and access to the human body; they can access cells, tissues, and organs that larger particles cannot. The length of time that nanoparticles remain in organs and what dose may cause harmful effects remains unknown.

2006N-0107 C2

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I am very concerned about the rapid introduction of these potentially hazardous nanomaterials into our bodies and into our environment without adequate scientific study to ensure that we understand their risks and can prevent harm occurring to people and the environment. The FDA's has failed to undertake or review new testing of these nanomaterials despite these known and foreseeable dangers suggests the agency's review process is not acting to ensure consumer health and safety. Thus, it does not appear that FDA is ready for this wave of nano-food products.

For these reasons, I strongly request that FDA act quickly to shore up its regulation of these substances to account for their fundamentally different properties and their associated dangers, including require new nano-specific testing and the labeling of all nanomaterial products, including nano-food products.

Currently, FDA's reliance on manufacturers' assurances of safety make me and my family into guinea pigs. FDA must instead independently review all testing and assess the safety of these products as well as force manufacturers to label their nanomaterial products. Only with labeling can I make educated decisions about what I buy and put in and on my body.

Until such actions are taken, I fully support a moratorium on the manufacture of nanomaterial consumer products and the recall of products currently on the market. I hereby urge the FDA to implement such a moratorium and undertake the necessary investigation to protect public safety.

Sincerely,

Lydia Straus-Edwards, AIA

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