Center for the Study of Responsive Law (CSRL)
P.O. Box 19367, Washington, DC 20036
Tel. (202) 387-8030, Fax (202) 234-5176

October 24, 2008

Commissioner Andrew C. von Eschenbach, M.D.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5603 Fishers Lane, Rm. 1061
Rockville, MD 20857

Re: Request for Comments and Data to Assist FDA in its Consideration of Agency-Regulated Products that May Contain Nanoscale Materials, Docket No. FDA-2008-N-0416

Dear FDA Commissioner Andrew von Eschenbach:

These comments to Docket No. FDA-2008-N-0416 are in response to the Food and Drug Administration's (FDA) August 7, 2008 notice of public meeting and request for comments. The meeting was organized, and the comments and data requested, to assist the agency in further implementing the recommendations of the 2006 Nanotechnology Task Force report on what the agency should do about FDA-regulated products that may contain nanoscale materials. We appreciate this opportunity to provide comments to the FDA on this important and pressing issue.

The Center for the Study of Responsive Law (CSRL or "the Center") is a nonprofit organization, founded by Ralph Nader in 1969, that supports and conducts a wide variety of research and educational projects to encourage the political, economic and social institutions of this country to be more aware of the needs of the citizen-consumer. The Center serves to empower citizens, guard the environment, protect consumers and monitor worker health and safety issues. The Center advocates for the safe and responsible regulation of nanotechnology.

We started to work on the issue of nanotechnology because of our concerns that this wide-ranging, transformative technology was developing with inadequate oversight and insufficient consideration of its potential impacts (e.g., environmental, health, safety, economic, social, medical, military, agricultural). Unfortunately, the decision-making process that has shaped policy on nanotechnology has not adequately involved all the stakeholders, namely the citizen-consumer.

In August, 2007, we endorsed the *Principles for the Oversight of Nanotechnologies and Nanomaterials*, a document developed by a consortium of nonprofit groups, including the International Center for Technology Assessment and Friends of the Earth USA, declaring eight principles we believe must provide the foundation for adequate and effective oversight and assessment of the emerging field of nanotechnology, including those nanomaterials that are already in widespread commercial use.

Principles for the Oversight of Nanotechnologies and Nanomaterials[1]

I. **A Precautionary Foundation**: Product manufacturers and distributors must bear the burden of proof to demonstrate the safety of their products: if no independent health and safety data review, then no market approval.
II. **Mandatory Nano-specific Regulations**: Nanomaterials should be classified as new substances and subject to nano-specific oversight. Voluntary initiatives are not sufficient.
III. **Health and Safety of the Public and Workers**: The prevention of exposure to nanomaterials that have not been proven safe must be undertaken to protect the public and workers.
IV. **Environmental Protection**: A full lifecycle analysis of environmental impacts must be completed prior to commercialization**.**
V. **Transparency**: All nano-products must be labeled and safety data made publicly available.
VI. **Public Participation**: There must be open, meaningful, and full public participation at every level.
VII. **Inclusion of Broader Impacts**: Nanotechnology's wide-ranging effects, including ethical and social impacts, must be considered.
VIII. **Manufacturer Liability**: Nano-industries must be accountable for liabilities incurred from their products.

More than 60 groups on six continents have already signed on to the *Principles*. They provide a good starting point of reference in approaching nanotechnology regulation and policymaking.[2]

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[1] See: More information: http://www.nanoaction.org/nanoaction/page.cfm?id=223. Accessed Oct 13, 2008.
[2] The initial endorsing organizations were:
Acción Ecológica (Ecuador), African Centre for Biosafety, American Federation of Labor and Congress of Industrial Organizations (U.S.), Bakery, Confectionery, Tobacco Workers and Grain Millers International Union, Beyond Pesticides (U.S.), Biological Farmers of Australia, Center for Biological Diversity (U.S.) Center for Community Action and Environmental Justice (U.S.), Center for Food Safety (U.S.), Center for Environmental Health (U.S.), Center for Genetics and Society (U.S.), Center for the Study of Responsive Law (U.S.), Clean Production Action (Canada), Ecological Club Eremurus (Russia), EcoNexus (United Kingdom), Edmonds Institute (U.S.), Environmental Research Foundation (U.S.), Essential Action (U.S.) ETC Group (Canada), Forum for Biotechnology and Food Security (India), Friends of the Earth Australia, Friends of the Earth Europe, Friends of the Earth United States, GeneEthics (Australia), Greenpeace (U.S.), Health and Environment Alliance (Belgium), India Institute for Critical Action-Centre in Movement, Institute for Agriculture and Trade Policy (U.S.), Institute for Sustainable Development (Ethiopia), International Center for Technology Assessment (U.S.), International Society of Doctors for the Environment (Austria), International Trade Union Confederation, International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations, Loka Institute (U.S.), National Toxics Network (Australia), Public Employees for Environmental Responsibility (U.S.), Science and Environmental Health Network (U.S.), Silicon Valley Toxics Coalition (U.S.), Tebtebba Foundation - Indigenous Peoples' International Centre for Policy Research and Education (Philippines), The Soils Association (United Kingdom), Third World Network (China), United Steelworkers (U.S.), Vivagora (France)

We are encouraged that the FDA recognizes that nanoscale materials in FDA-regulated products pose new challenges to the current regulatory and testing regimes. The FDA's Nanotechnology Task Force report provides an informative analysis of the new scientific and regulatory issues associated with nanomaterials and the agency's pertinent authorities over their use. Further, the report provides a number of recommendations to help the FDA address the widening use of nanoscale materials.

We, however, urge the agency to go further than the actions recommended in the Task Force report and to promptly establish binding nano-specific regulations. While the report acknowledges the fundamental and consequential differences between nanoscale materials and conventional materials, it fails to go the next logical step and call for concrete action to flag nanomaterials and identify and address their risks through nano-specific regulations, testing procedures and labeling.

Following the filing of a legal petition[3] in 2006 by the International Center of Technology Assessment and a coalition of other organizations calling on the FDA to take immediate action to regulate nanotechnology, the agency convened the Task Force and held its first public meeting to collect thousands of comments. After that encouraging start, a year passed before the Task Force issued its reports in July, 2007. Now the FDA has called a second public meeting to collect information on implementing the Task Force recommendations—more than a year after the report was released. While the agency has fritted away the valuable time to get ahead of the technology's large-scale deployment, 3 to 4 nano-enabled products have been hitting the market *per week*.[4] The body of evidence is clear, as detailed below, and the recommendations and comments have been made. The time to act is now.

Our comments can be summarized into four groups of recommendations to the agency.

Summary of Recommendations

1. DEFINE - Recognize nanoscale materials as "new" for legal, regulatory and safety purposes, differentiating them from bulk materials; and immediately develop formal definitions for nanotechnology terms—such as "nanotechnology," "nanomaterials" and "engineered nanoscale particles."
2. SEPARATE - Remove nanoscale ingredients or components from all FDA listings of approved substances, such as generally recognized as safe (GRAS) foods and drugs included in the over-the-counter (OTC) drug monograph.
3. DISCLOSE – Require the presence of nanomaterials to be disclosed in all premarket authorization or notification processes; require premarket notifications

[3] The 2006 petitioners were ICTA, Friends of the Earth (FoE), Greenpeace International, The Action Group on Erosion, Technology, and Concentration (ETC Group), Clean Production Action (CPA), The Center for Environmental Health (CEH), Our Bodies Ourselves, and The Silicon Valley Toxics Coalition (SVTC).
[4] Project on Emerging Nanotechnologies (2008). "New Nanotech Products Hitting the Market at the Rate of 3-4 Per Week." Press release, Apr 24. http://www.nanotechproject.org/news/archive/6697. Accessed Oct 23, 2008.

of nanoscale dietary supplement ingredients by declaring them "new ingredients"; and make nanomaterial labeling mandatory.

4. ASSESS – Require the safety of nanomaterials to be fully assessed before they are approved for use. Nanomaterials should be characterized by all features known to impact their safety, and nano-specific standard risk assessment and testing procedures should be developed, including revised toxicological endpoints and thresholds.

These recommendations would help fill the current regulatory void, and diminish the ambiguity regarding the FDA's position on nanomaterials by clearly differentiating them from conventional materials and chemicals. The increased disclosure, scrutiny and testing would lead to better policies and guidance, and ultimately a safer public and environment.

Below you will find an expanded explanation of our recommendations.

Recommendations In-Depth

1. DEFINE -

- **Recognize nanoscale materials as "new" for legal, regulatory and safety purposes, differentiating them from bulk materials; and immediately develop formal definitions for nanotechnology terms—such as "nanotechnology," "nanomaterials" and "engineered nanoscale particles.**"

In its report, the Task Force rejects developing "formal, fixed definitions" [5] of nanotechnology and nanomaterials, in the same way that the FDA as a whole continues to assert that pharmacotoxicity tests for bulk materials are "probably adequate for most nanotechnology products." [6] The growing consensus among experts nationally and internationally is that nanomaterials, with their unique and unpredictable properties, need to be differentiated so they can be subjected to appropriate scrutiny, assessment and regulation. Furthermore, the unsubstantiated and misleading use of nanotechnology terms needs to be addressed as it muddles and frustrates effective communication among stakeholders, including the public and policymakers.

FDA must codify what scientific evidence makes clear: Nanomaterials are different from conventional materials

Traditional regulations and safety assessments must be tailored or supplemented to provide a nano-specific approach. There cannot be effective regulation absent established, codified definitions to differentiate nanomaterials to begin with.

[5] FDA Task Force (2006). "Nanotechnology: A Report of the U.S. Food & Drug Administration Task Force." 25 Jul: 19. http://www.fda.gov/nanotechnology/taskforce/report2007.pdf. Accessed Sep 23, 2008.
[6] FDA (undated). "FDA Regulation of Nanotechnology Products." FDA website. http://www.fda.gov/nanotechnology/regulation.html. Accessed Oct 23, 2008.

Nanomaterials have gained attention—and raised concerns—precisely because they differ from their bulk counterparts. At the nanoscale, surface area increases dramatically compared to volume and the rules of quantum physics supplant those of Newtonian physics. As a result, many substances at the nanoscale exhibit dramatically different physical and mechanical properties. Nanomaterials have exhibited differences in electrical conductivity, strength, reactivity, elasticity and color. Silicon, for example, an insulator at the macro scale becomes a conductor at the nanoscale; carbon turns from a weak material to stronger than steel; aluminum changes from being stable to being combustible; zinc oxide changes from white or opaque to transparent.

And new physical and chemical properties mean potentially new biological toxicity. Moreover, nanoparticles' exceptionally small size increases the likelihood for human and environmental exposure. Studies have shown that nanomaterials can migrate between different media in the environment and can pass through many physical and biological barriers that stop larger particles, including the skin and the blood-brain barrier.

Indeed, there are many ways nanoparticles can enter the body (i.e., exposure): through inhalation, ingestion, absorption or, for medicinal purposes, injection. In the environment, nanomaterials are difficult to remediate, can harm aquatic life and are being investigated for their potential to bioaccumulate—a frightening feature of toxins such as mercury, DDT and PCB.

A sample of studies highlight the potential risks of nanomaterials:

- A study this year found that certain types of *carbon nanotubes*, a commonly manufactured nanoparticle, had similar pathogenicity when introduced into mice as asbestos.[7] Inhalation exposure to asbestos has been infamously linked to mesothelioma, a fatal form of lung cancer.
- A 2004 study by a leading nanotoxicity researcher in Europe found that *gold nanoparticles* injected into a pregnant rat may transfer into her fetus.[8]
- A case described in the *Canadian Journal of Cardiology* in May 2008 associated the ingestion of *colloidal* ("nano") *gold and silver* in "health supplements" to "dilated cardiomyopathy and left bundle branch block," a weakening of the heart's walls and malfunctions of the heart's electrical conduction system.[9]
- Experiments in 2004 at the University of Rochester showed that *carbon nanotubes* could make their way from a rat's throat into its brain by way of the nasal cavities and olfactory bulb.[10]

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[7] Poland C. et al. (2008). "Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study." Nature Nanotechnology, Jul 1, 3: 423 – 428. http://www.nature.com/nnano/journal/vaop/ncurrent/abs/nnano.2008.111.html. Accessed Sep 16, 2008.

[8] Wootliff, B. (2004). "Bristish Scientist: Nanoparticles Might Move from Mom to Fetus." Small Times, Jan 14. http://www.smalltimes.com/articles/article_display.cfm?Section=ARCHI&C=Bio&ARTICLE_ID=269201&p=109. Accessed Oct 10, 2008.

[9] Archer, SL (2008). "Dilated cardiomyopathy and left bundle branch…" Can J Cardiol. May, 24(5): 397-9. http://www.ncbi.nlm.nih.gov/pubmed/18464946. Accessed Oct 14, 2008.

[10] Oberdorster, G. et al. (2004). "Translocation of inhaled ultrafine particles to the brain." Inhal Toxicol. 16(6–7):437–445. http://www.ncbi.nlm.nih.gov/pubmed/15204759. Accessed Sep 16, 2008.

- In 2003, *Nature* reported on studies showing that *fullerene* (or "*buckyballs*") could move unimpeded through soil—and might be absorbed by earthworms, "possibly allowing them to move up the food-chain and reach humans."[11]
- A study published in the September, 2008 issue of *Nano Letters* demonstrated that nanoparticles (in this case, *quantum dots*) can seep through skin, especially if the skin has been damaged, such as by a sunburn.[12] The study "raised concern" that nanoparticles "such as *metal oxide* [nanoparticles] found in sunscreens, may…penetrate UV damaged skin."[13] This is particularly relevant given the widespread inclusion of nanomaterials in creams and cosmetics, all without premarket government review.
- Several studies have found that *Nano-iron oxide*, which has been considered for possible use in gene therapy, magnetic resonance imaging, drug delivery and other medical uses, can be toxic to nerve cells, killing some and reducing others' ability to form neuritis—essential for transmitting neuronal signals. Previously it had been assumed to be safe because iron is an essential nutrient.[14]
- *Nanometals* of various kinds were found to cause oxidative damage on human blood serum, as found by a 2008 study at the University of Massachusetts, Lowell. The blood's antioxidant capacity was "significantly decreased" by the introduction of nano-silver, nano-carbon blacks, fullerene soot and nano-titanium dioxide—all commonly used nanomaterials.[15]

Scientific, governmental and nongovernmental bodies support treating nano as new

Despite the clear material differences between nanomaterials and bulk materials, the FDA has not developed formal definitions. This is significant as definitions underpin meaningful regulation.

Faced with troubling scientific findings while nanomaterials appear in more and more products and applications, some governmental bodies outside the United States, along with many academic and nongovernmental organizations, are trying to move the debate forward in hopes of preventing an avoidable potential environmental and public health disaster.

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[11] Brumfiel, Geoff (2003). "A Little Knowledge..." *Nature*, Vol. 424, no. 6946, 17 July:246.

[12] Mortensen, Luke J. et al. (2008). "In Vivo Skin Penetration of Quantum Dot Nanoparticles in the Murine Model: The Effect of UVR," Nano Lett., 8 (9), 2779–2787. 10.1021/nl801323y. http://pubs.acs.org/cgi-bin/abstract.cgi/nalefd/2008/8/i09/abs/nl801323y.html. Accessed Sep 22, 2008.

[13] Id.

[14] Pisanic, T. R. et al (2007). "Nanotoxicity of iron oxide nanoparticle internalization in growing neurons." Biomaterials, 28:2572–2581.

[15] Rogers, EJ (2008). "A high throughput in vitro analytical approach to screen for oxidative stress potential exerted by nanomaterials using a biologically relevant matrix: Human blood serum." Toxicol In Vitro, Sep, 22(6):1639-1647. Epub Jun 13. As noted, the nanomaterials shown to cause oxidative stress are all now in common use. For example: Nano-silver is used in literally hundreds of consumer products, including dietary supplements, primarily for its antibacterial properties; nano-carbon black is used by industry in a range of manufacturing processes, from making tires to plastics to pigments; fullerene, or "buckyballs," is an ingredient in many cosmetics and creams; and nano-titanium dioxide is the miniaturized version of titanium dioxide, which along with zinc oxide is used in sunscreens to block the sun's UV rays.

Indeed, the FDA's position that there is not enough evidence to conclude that nanomaterials must be treated differently appears increasingly in the minority. The European Commission's (EC) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concludes that: "Experts are of unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics." [16] The Royal Society and Royal Academy of Engineers similarly assert that nanomaterials need to be differentiated from other materials "to take account of the enhanced or different properties that some nanoparticles (and nanotubes) may have compared with larger particles of the same chemical species." [17] In their report, the two British groups call for "treating nanoparticulates as new substances" to fill the gap in UK and European regulations that currently allows producing existing substances in nanoscale form without additional testing. [18]

EPA Consent order issued for nanomaterial

A notable recent development toward categorizing nanomaterials as "new" substances comes from a decision by the Environmental Protection Agency (EPA). In September, the EPA issued the first known consent order for a nanomaterial. The order was issued to Swan Chemical Inc. of Lyndhurst, NJ for the company's "Elicarb® MW product – a multi-walled carbon nanotube that has potential in many new applications including ultra-strength composites and high performance electronics."[19]

The order, which has not been made public, reportedly sets out conditions for the company regarding nanotubes, including conducting a 90-day inhalation test for rats; giving EPA a 1-gram sample of the material, along with a safety data sheet; and requiring workers to wear protective gear.[20] The order was issued following the agency's review of the Elicarb® MW pre-manufacturing notice (PMN).

The order is noteworthy because it demonstrates the EPA's recognition that carbon nanotubes in question were not adequately covered by existing guidelines regarding bulk forms of carbon, such as graphite.[21] More importantly, it may indicate broader controls

[16] SCENIHR (2005). "Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies." European Commission. Adopted Sep 28-29: 6. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_cons_01_en.htm. Accessed Oct 23, 2008.
[17] RA/RAE (2004). "Nanoscience and Nanotechnologies." [report] Jul 4:72. http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf. Accessed Oct 19, 2008.
[18] RA/RAE (2004). "Nanoscience and Nanotechnologies." [report] Jul 4:71. http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf. Accessed Oct 19, 2008.
[19] Thomas Swain & Co. (2008) "Swan pioneers nanomaterial controls with EPA." Press release, Sep. http://www.thomas-swan.co.uk/ASP/News_Events/News_Events.asp?Type=News&ID=195&Arc=&DLT=Swan%20pioneers%20nanomaterial%20controls%20with%20EPA. Accessed Oct. 15, 2008.
[20] Greenwire (2008). "EPA issues consent order for company planning to develop carbon nanotubes." E&E Publishing, LLC, Sep 10. http://www.eenews.net/Greenwire/2008/10/10/archive/12?terms=nanotechnology. Accessed Oct 15, 2008.
[21] Franco points out that the Material Safety Data Sheet (MSDS) that Thomas Swan submitted for its previously developed Elicarb® Single-wall product classified the carbon nanotubes as graphite. This was

to come. We hope that the EPA will follow up their consent order to Swan Chemical Inc. by issuing a Significant New Use Rule (SNUR)[22] under TSCA section 5(a)(1)(B) to bind *all* nano-manufacturers and processors to terms and conditions calling for comprehensive nanomaterial-specific information, including full characterization and data substantiating the environmental and safety impacts of the product.

Consent decrees are only binding to the PMN submitter (Swan Chemical Inc.) and do not apply to other nanotechnology manufacturers, even if they are producing carbon nanotubes using exactly the same methods. The SNUR, on the other hand, is wide reaching and should apply conditions that go beyond those negotiated in the consent order to Swan Chemical Inc.

Support from broad coalition of NGOs for treating nanomaterials as new materials

While the EPA's consent order provides no assurance that the agency will soon move to recognize that nanomaterials deserve special scrutiny, this is exactly what we and many other nongovernmental organizations are calling on the EPA, the FDA and other regulatory agencies to do. Other groups that share our view that nanomaterials should be categorized as "new" substances for legal and regulatory purposes include: the Center for Genetics and Society (CGS), Consumers Union (CU), the Edmonds Institute, the Environmental Defense Fund (EDF), the ETC Group, Friends of the Earth (FoE), Food and Water Watch (FWW), the Institute for Agriculture and Trade Policy (IATP), the International Center for Technology Assessment (ICTA), the Loka Instute, the Natural Resources Defense Council (NRDC), the Wilson Center's PEN, and the Silicon Valley Toxics Coalition (SVTC), among others.[23] Many of the organizations have called on the federal regulatory agencies for years to recognize and address the need for specific and effective oversight of nanomaterials.

In the first legal action of its kind, the International Center for Technology Assessment and a coalition of consumer, health and environmental groups petitioned the FDA in 2006 to develop formal definitions for nanotechnology terms and enact new regulations requiring that "nanoparticles be treated as new substances" requiring their own specific safety testing procedures and assessments. They also called for the labeling of all FDA-regulated products containing nanomaterials.[24]

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clearly inappropriate. See: Franco A. et al., (2007). "Limits and prospects of the 'incremental approach' and the European legislation…" Reg Tox and Pharm. 48: 176.

[22] As of September 30, 2005, SNURs had accompanied consent orders for PMN chemicals 734 times. See: Schierow L. (2007). "The Toxic Substances Control Act (TSCA): Implementation and New Challenges." CRS Report RL34118, Aug 7: 10. http://www.cnie.org/NLE/CRSreports/07Aug/RL34118.pdf. Accessed Oct 15, 2008.

[23] A number of these organizations (CSRL, CGS, the Edmonds Institute, FoE, FWW, IATP, ICTA, the Loka Institute, and SVTC) co-signed a June 24, 2008 letter to Sen. John Kerry (MA-D), subcommittee chair on the Senate Commerce, Science and Transportation Committee. The letter demanded a number of changes to draft National Nanotechnology Initiative reauthorization legislation written by his subcommittee, including the insertion of a provision instructing "federal regulatory agencies to immediately begin developing regulations, standards and guidelines specific to nano-engineered particles and materials."

[24] ICTA (2006). "Petition Requesting FDA Amend Its Regulations…" May 16. http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf. Accessed Sep 29, 2008.

Also emphasizing the importance of defining the terms of debate, former FDA Deputy Commissioner Michael R. Taylor wrote: "The single most important step that FDA should take immediately is to establish criteria and provide guidance to the industry for classifying some nanoscale materials as 'new' for legal, regulatory and safety purposes." The recommendations in Taylor's 2006 report, "Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?"[25] have been reiterated in report by J. Clarence Davis, a leading authority on environmental research and policy. In his 2008 report, "Nanotechnology Oversight: An Agenda for the Next Administration," also for the Project on Emerging Nanotechnologies, Davies states his first priority for the FDA: "Establish criteria for determining which nanomaterials are 'new' for regulatory purposes."[26]

The Natural Resources Defense Council, like the Environmental Defense Fund[27] and many other organizations, has similarly argued that nanomaterials should be treated as new chemicals. Nanomaterials should be assessed "as new substances, since their unique physical properties impart unique hazard profiles," writes Natural Resources Defense Council senior scientist Jennifer Sass. [28]

The most effective definition may focus on the most important difference: added risk

The way nanotechnology terms are formally defined will have a significant impact on the effectiveness, or failings, of the rules and regulations they modify. The most effective definition of nanomaterials for regulatory and oversight purposes would focus on the added EHS risks they represent compared to larger scale entities.[29] In this way, the agency would focus on the most important factor and avoid getting bogged down in simply trying to determine the precise—and potentially arbitrary—rigid physical parameters and configurations that constitute a nanomaterial or nanoparticle.

Any physical parameters referenced in a definition should be flexible so as to not exclude materials that exhibit special properties due to their small size and shape (and, thus, clearly qualify as nanomaterials) yet are larger, for example, than 100 nanometers. It has

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[25] Taylor M. R. (2006). "Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?" PEN, Oct 06. http://www.nanotechproject.org/process/assets/files/2705/110_pen5_fda.pdf. Accessed Sep 23, 2008.

[26] Davies J. C. (2008) "Nanotechnology Oversight: An Agenda for the Next Administration," PEN, 23 July 08. http://www.nanotechproject.org/process/assets/files/6709/pen13.pdf. Accessed Sept 29, 2008.

[27] EDF (2007). "EDF Activities on Nanotechnology," Jul. http://www.edf.org/documents/6594_nano_summary.pdf. Accessed Oct. 20, 2008.

[28] Sass J. (2006). "Nanotechnology's Invisible Threat," NRDC *Health Facts* pub, Dec: 2. http://www.nrdc.org/health/science/nano/fnano.pdf. Accessed Oct 16, 2008.

[29] Andrew Maynard credits Bernd Sachweh of BASF for his definition of "nano" as something that adds value to an existing entity. See: Bernd Sachweh of BASF, "Integrated Process Technology for Nanomaterial Production," (PP presentation), Nanotechnology Occupational and Environmental Health Conference, Environmental Health, Taipei, Taiwan, Aug 29 - Sep 1, 2007.
See: Maynard A. (2008). "Value-Added Nanotechnology." Andrew Maynard Blog, SafeNano Community, Sep 3. http://community.safenano.org/blogs/andrew_maynard/archive/2008/09/03/value-added-nanotechnology.aspx. Accessed Sept 22, 2008.

been suggested that particles up to 300nm should be treated as nanomaterials.[30] Dr. Andrew Maynard of PEN suggests Taylor's definition of nanotechnology might provide a starting point, although it references the range 1-100nm:

> *For regulatory and oversight purposes, nanotechnology is the control of matter at dimensions between approximately 1 and 100 nm, where the behaviour of the resulting material or product differs sufficiently from the component materials to lead to significant changes in potential risks to human health and the environment."* [31]

While the National Nanotechnology Initiative (NNI), the government nanotechnology coordinating program of which the FDA is a participant, has defined nanomaterials as "materials with dimensions at the nanoscale which ranges roughly from 1 to 100 nanometers,"[32] it's clear that there is no "bright line" at 1 nm or 100 nm in terms of where nanotechnology starts or ends. Buckyballs are considered nanoparticles although they can be smaller than 1 nm, while nanoparticle reinforced polymers exhibit unique properties at 200-300nm.[33]

2. SEPARATE -

- **Remove nanoscale ingredients or components from all FDA listings of approved substances (e.g., generally recognized as safe (GRAS) foods, drugs included inn over-the-counter drug monograph)**

The nanotechnology definitions and criteria developed by the FDA should clearly differentiate nanomaterials from traditional materials. We believe that this differentiation should be reflected immediately among all lists of FDA-approved substances—as called for by the Consumers Union, ICTA, Friends of the Earth, the Woodrow Wilson Center's Project on Emerging Nanotechnologies, and many other groups and experts. This would mean the removal of nanomaterials from GRAS food ingredients and GRAS/E OTC drugs; approved food additives, color additives and (non-OTC) human and animal drugs; and from any materials that have been approved through the Cosmetic Ingredient Review (CIR). Affected listings would also include the OTC sunscreen monograph.

As nanomaterials are characterized and their proper health and safety testing data thoroughly reviewed, they would have the potential to be admitted onto FDA approved lists of substances on a case-by-case basis.

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[30] "All particles up to 300nm in size must be considered to be 'nanomaterials' for the purposes of health and environment assessment, given the early evidence that they pose similar health risks as particles less than 100nm in size which have to date been defined as 'nano.'" See: FoE Australia, Europe and USA (2008). Report, Mar:7. http://nano.foe.org.au/node/219. Accessed Oct 22, 2008.

[31] Taylor

[32] NNI (undated)."What Is Nanotech?" NNI Facts webpage. http://www.nano.gov/html/facts/whatIsNano.html. Accessed Oct. 20, 2008.

[33] NSF (2000). "Nanotechnology definition," NSF website, Feb. http://www.nsf.gov/crssprgm/nano/reports/omb_nifty50.jsp. Accessed Oct 22, 2008.

Hyped as new and acts like new, then: categorize and assess as new

Simply put, if nanomaterials are considered "new" substances for legal and regulatory concerns—as they clearly should be—then using them in FDA-regulated products should require new applications/petitions, new data and new assessments that are specific to the nanomaterial and application in question.

The European Food Safety Authority (EFSA) has already agreed to such an approach, announcing this year that, "Any new nanomaterials would need to undergo safety assessments by EFSA before they can be included on the relevant [approved list of approved food additives, colours, sweeteners or smoke flavourings] and so be permitted to be used in foods."[34]

We believe that allowing nanoscale materials to be covered in the assessments of conventional materials, as has been the case, contravenes scientific evidence and violates agency's mandate to ensure the safety and effectiveness of the products it regulates.

Furthermore, by failing to differentiate nanomaterials and flag them for assessment, the agency leaves it in the hands of the manufactures to decide whether particular nanoscale versions of approved conventional materials differ markedly enough to warrant a separate premarket review by the FDA. The market for nanomaterials is expanding rapidly and becoming increasingly competitive. Manufacturers have disincentives to initiate a process that could delay deployment of their products, particularly when it's not clear what situations would call for such a review in the first place.

As noted before, if the manufacturer judges the nanotechnology version to be the same as the approved traditional substance, "FDA may not become aware of the product until after it enters the market."[35] Once a product is in the market—and there is the risk of human and environmental exposure—the burden of responsibility falls upon the FDA to show that the product/material raises sufficient new regulatory and safety concerns to necessitate action.

Defining nanomaterials and explicitly excluding them from FDA lists of approved conventional materials clears up the current ambiguous situation. It ensures consistent treatment of nanomaterials for legal and regulatory purposes. The clarity and consistency will be good for the agency, manufacturers, investors and public health and safety.

[34] FSAI (2008). "The Relevance for Food Safety of Applications of Nanotechnology in the Food and Feed Industries," Report, Sep 21: 50. http://www.fsai.ie/publications/reports/Nanotechnology_report.pdf. Accessed Oct 10, 2008.
[35] Taylor

3. DISCLOSE

- **Require the presence of nanomaterials to be fully disclosed and characterized**
- **Require premarket notifications of nanoscale dietary supplement ingredients as "new dietary ingredients"**
- **Mandate nanomaterial labeling**

As the Task Force report points out, a broad spectrum of agency-regulated products requires premarket authorization (i.e., approval, clearance, licensing or listing). These products include: drugs, biological products, medical devices, food ingredients and food and color additives.[36] The FDA should require mandatory disclosure of nanomaterials used in any products. Disclosure, along with nano-specific characterization and safety assessments—which is discussed in more detail in the next section— should be integral parts of all premarket authorization processes.

Specifically, nanotechnology disclosure, characterization and assessment should, at a minimum, be inserted into the authorization process for:

- new drug applications (NDAs)
- biologics license applications (BLAs)
- new animal drug applications (NADAs)
- new sunscreen monograph applications
- GRAS/E drug ingredient listing
- GRAS food ingredient listing
- food additive listing
- color additive listing
- medical device approval

The FDA should make appropriate adjustments to regulations and guidelines to assure that additional untested nanomaterials do not enter the market. The FDA should, for example, clarify that modifying an approved product with the nanoscale version of an ingredient or component requires notifying the agency and receiving a new review and authorization before remarketing the product.

In the same vein, all medical devices that include nanomaterials, regardless of their normal ("non-nano") categorization, should be categorized by *default* as Class II (higher risk) devices [37] and should be subject to a thorough premarket approval (PMA) process—as suggested as an option by the Task Force. The report suggests that PMAs could "be required for a product otherwise…considered Class I or Class II if the inclusion of nanoscale material [in the devices] raises questions of safety or effectiveness warranting

[36] FDA Task Force, "Nanotechnology: A Report of the U.S. Food & Drug Administration Task Force," FDA, 25 Jul 06, 19. http://www.fda.gov/nanotechnology/taskforce/report2007.pdf. Accessed Sept 23, 2008.

[37] Devices that contain categorized as Class II medical devices receive greater scrutiny than Class I devices, including premarket notification under section 510(k) of the FFDCA and "special controls" under the Comprehensive Medical Device Improvement Act of 1990, which allows the agency to require performance standards, post-market surveillance, patient registries and other measures deemed appropriate to "provide reasonable assurance of the safety and effectiveness of a class II device." *See*: L. No. 101-629, Sec. 5(a), 104 Stat. 4517-18 (1990); *see* 21 USC Sec. 360c(a)(1)(B).

clinical studies."[38] The body of scientific evidence associated with nanoscale materials has clearly raised many serious questions about their safety and effectiveness. At present, PMAs have generally been reserved only for the highest risk (Class III) devices, and even then, unfortunately, the vast majority of these have received PMA exemptions.

Declare nanoscale dietary supplement ingredients: "new dietary ingredients"

In the cases of dietary supplements and cosmetics, unlike medical devices or drugs, the FDA does not have the authority to require premarket safety testing. However, the agency can declare nanoscale dietary supplement ingredients "new dietary ingredients" (NDIs), thus requiring manufacturers to provide premarket notification[39] at least 75 days before they plan to market the supplements.[40] In the premarket notification, manufacturers would need to supply the safety data they used to substantiate the safety of the nanoscale ingredients.

Rather than being forced to prove a product is unsafe after it is already on the market, the premarket notification process allows the FDA to keep nano-enhanced supplements off the market if it decides the safety data provided is not sufficient to prove nano-ingredients' safety. To do so, however, the agency would have to respond within the 75-day period.

Nanoscale dietary supplement ingredients should be considered "new dietary ingredients," as defined in 21 USC 350b, requiring premarket notification, as they were not marketed in the United States before October 15, 1994.

Mandatory nanomaterial labeling and disclosure

We strongly disagree with the Task Force's conclusion, endorsed by the Secretary, that current science does not provide "a basis for saying that…a product containing nanoscale materials must be labeled as such."[41] It is now well established that nanomaterials have unpredictable and sometimes very pronounced differences in their properties compared to their bulk forms. The Task Force itself references these important differences, and their potential impacts, throughout the report—undermining many of its own arguments. On the same page that it recommends against labeling nanomaterials, the Task Force recognizes the FDA's authority to do so.[42]

These differences between nanomaterials and bulk materials constitute "material facts" that labels, as defined by law, are expected to relate to consumers. In fact, to *not* label ingredients as nanoscale should qualify as misbranding and misleading under Sec. 201(n)

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[38] FDA Task Force: 25
[39] See: 21 USC 350b(a)(2) and 21 CFR 190.6
[40] Schultz W. B. (2008). 8 Sep 08. "Nanotechnology and Dietary Supplements," presentation on behalf of the W. Wilson Int'l Center for Schlrs, PEN. FDA Nano. Public Meetg, Rockville, MD. http://www.nanotechproject.org/process/assets/files/7037/shultz1.pdf. Accessed Oct 10, 2008.
[41] FDA, 2007. Nanotechnology Task Force Report: 35.
[42] FDA, 2007. Nanotech. Task Force Report: 35.

and Sec. 403(a)(1) of the FD&CA, since the labeling would "fail to reveal facts that are material" and suggest that the ingredients are perhaps safer than has been demonstrated.

Mandatory labeling of nanomaterials, which would extend to dietary supplements and cosmetics, has been criticized as being costly and cumbersome, and because it could instill needless anxiety among consumers without providing a public benefit. We believe that labeling can be instituted quickly and inexpensively, and that it provides a number of important benefits, such as greater transparency and public awareness. Rather than causing public anxiety, consumer confidence in the technology should actually *improve* with labeling.[43] We believe that labeling would allow consumers to make more informed decisions about whether to use products containing nanomaterials.

Additionally, labeling initiatives have historically had strong public support—because consumers value them. A poll last year found 82 percent of respondents in favor of country of origin labeling of food.[44] A poll conducted in 2001 by the Center for Science in the Public Interest found that 62 to 70 percent of consumers wanted genetically modified food labeled, while 76 percent wanted labeling for food that had been sprayed with pesticide.[45] While not a measure of American attitudes, an Australian public poll on nanotechnology reported that 68 percent of respondents "strongly agreed" that food companies should label any food products in the form of manufactured nanoparticles. [46] In the same poll, 96 percent favored safety testing for nanofoods.

Furthermore, some of FDA's counterparts have come to a different conclusion about nanotechnology labeling. Last month, the Food Safety Authority of Ireland (FSAI) called for EU-wide regulations mandating the labeling of all food products and food packaging that includes nanotechnology to allow consumers to make informed purchasing decisions.[47] The FSAI report echoed the earlier endorsement of nano labeling by the UK's Royal Society and Royal Academy of Engineers, "based on a desire for transparency of information," as well because of their belief "that chemicals in the form

[43] Inappropriate and misleading uses of nano terms can damage the credibility of nanotechnology in the eyes of the public and contribute to reduced consumer confidence in products that may contain nanoscale materials. "Magic Nano" is probably the most well known misuse of a nano terms. The protective glass and tile sealant that was voluntarily recalled in 2006 for causing severe breathing problems in some consumers was tested by the Federal Institute for Risk Assessment in Berlin and found to contain no nanoscale particles. To use an example of an FDA-regulated product, the dietary supplement marketed as "nanoSLIM" uses the nano prefix but describes its key ingredients as "pulverized into micron-sized particles." Micron-sized particles are hundreds to a thousand times the size nano-sized particles. Mandating nanotechnology labeling would help prevent and identify the misuse of nano terms.

[44] Lake Research Partners, 2007. Public Opinion Survey on Country of Origin Labeling. Poll conducted for Food & Water Watch, Mar 25. http://www.foodandwaterwatch.org/press/releases/food-labeling-82-percent-support-cool-article03252007. Accessed Oct 23, 2008.

[45] CSPI, 2001. U.S. consumer survey on labeling of genetically engineered foods. http://www.cspinet.org/new/labeling_gefoods.html. Accessed Oct 23, 2008.

[46] EMC, 22 Oct 08. "Australian Public Perceptions of Nanotechnology." http://nano.foe.org.au/node/273. Accessed Oct 22, 2008.

[47] "The Relevance for Food Safety of Applications of Nanotechnology in the Food and Feed Industries," FSAI report, Sep 08. 58. http://www.fsai.ie/publications/reports/Nanotechnology_report.pdf. Accessed Oct 19, 2008.

of nanoparticles should be treated as new chemicals" due to their unique properties and risks.[48]

Labeling provides greater disclosure and transparency, which, like third-party premarket testing and public engagement, are important if we want to assure long-term consumer confidence in the FDA. Consumers are currently getting mixed signals. While nanotechnologies' benefits and wide-ranging applications have been heavily promoted by the private sector and government officials, some researchers warn about nanotechnology's hazards and the absence of safeguards protecting the public and the environment.

Actively engaging and involving the public on the issue has been a low government priority. A poll released in September found that only 51 percent of American adults surveyed knew anything about nanotechnology, and half of those knew too little to predict any future benefits or risks from the technology.[49] Without greater transparency and public engagement it will be difficult for consumers—nanotechnology's largest stakeholder group—to participate in the debate about the proper regulatory framework for nanotechnology and nanomaterials.

Regarding the effect on manufacturers, labeling may lead some to be more sensitive about safety, perhaps encouraging manufacturers/processors to opt for using the most thoroughly tested nanomaterials that may be more broadly accepted by consumers.[50]

4. ASSESS

- **Develop nano-specific standard risk assessment and testing procedures**
- **Require characterization to include all known safety impacts**
- **Re-evaluate toxicity thresholds for all nanomaterials**

Facing a rapidly expanding technology whose potential applications are almost innumerable, and considering a chronically under-resourced agency and the substantial difficulties of removing products (even dangerous ones) once they have entered the market, it is important that we change the current model and ensure that the presence of nanomaterials in products is not only disclosed, but that they are also comprehensively *evaluated* before they enter commerce.[51] Evaluations should be nano-specific by taking into account the full range of properties associated with nanomaterials.

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[48] "Nanoscience and Nanotechnologies," RA/RAE report, Jul 04. 73. http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf. Accessed Oct 19, 2008.

[49] "Awareness Of And Attitudes Toward Nanotechnology And Synthetic Biology," [report on findings from national tel. survey] Peter D. Hart Research Associates, Inc. on behalf of PEN, 16 Sep 08.

[50] A 2003 study by FDA on the affects of implementing trans fat labeling for food estimated that the labeling's impact on consumer behavior would be modest, while it is having an significant impact on manufacturers' behavior. (U.S. FDA, CFSAN. 2003. "Food Labeling: Trans Fatty Acids in Nutrition." Federal Register68, no. 133, 41433-506. July 11, 2003.)

[51] It is informative to consider the results of the U.S. regulatory approach to managing chemicals without mandating premarket toxicological testing. According to *Toxic Ignorance*, a 1997 report by the Environmental Defense Fund, nearly 75 percent of large-volume chemicals still lacked even minimal data on chronic toxicity. Basic health stats were publicly unavailable for two-thirds of the 3,000 top-selling

Standardized characterization, risk assessment procedures and testing

We strongly disagree with the FDA's assertion that existing tests are, at least for now, "probably adequate" for assessing nanomaterials. To the contrary, the European Commission's Scientific Committee on the Emerging and Newly Identified Health Risks suggests that the current animal and *in-vivo* testing used for safety assessments may be wholly inadequate for assessing nanomaterials. Nanomaterials, they conclude, "may have different (eco-) toxicological properties than the substances in bulk form and therefore their risks need to be assessed" differently.[52]

Contradicting the FDA's contention even more directly, the UK's Office of Science and Technology notes: "Safety testing on the basis of a larger form of a chemical cannot be used to infer the safety of the nanoparticulate form of the same chemical." Regulations, therefore, needed "to be reviewed to reflect the possibility that nanoparticulate material may have a greater toxicity than material in the larger size."[53]

We believe characterization should include measurements of all nanomaterial features known to impact health and safety. At least *sixteen* physicochemical parameters have been identified—far more features than the two or three that are traditionally measured.[54] Nanomaterial toxicity is multifactorial and characterization—like testing—should take account of the different factors that can have an impact to assure you arrive at a comprehensive description that can be used in calculating an accurate risk profile.

Descriptions should use a standardized terminology, nomenclature and metrology to ensure that measurements are consistent and comparable. Such standards are already being developed by the Organization for Economic Co-operation and Development (OECD) and the Technical Committee 229 of the International Organization for Standards (ISO TC229).[55]

The FDA should also develop standard risk assessment and testing procedures to ensure that tests are reliable and reproducible, and that assessments are comprehensive and

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chemicals in the U.S. And this approach doesn't come without significant dangers, as we've discovered with chemicals like PCBs, CFCs and dioxins, which are extremely toxic and persistent even in extremely small quantities—characteristics that have caused some to compare to nanomaterials. Clearly a more precautionary approach is necessary, as is in the case of nanotechnology.

[52] "Opinion on the Appropriateness of the Risk Assessment Methodology…," SCENIHR, Jun 07, p.20-21. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf. Accessed Sept. 16, 2008.

[53] "Response to the Royal Society and Royal Academy of Engineering Report: Nanoscience and Nanotechnologies," OST Office, UK Government, Feb 05. http://www.nano-and-society.org/NELSI/documents/resopnsetoroyalsociety0205.pdf. Accessed Sept 29, 2009.

[54] Andrew Maynard (2006). *Nanotechnology: The Next Big Thing, or Much Ado about Nothing?* Annals Occupatnl Hygiene, 7 September: 7.

[55] For information on ISO/TC 229, see its webpage on the ISO website: http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983. Accessed Oct 10, 2008.

accurate. Assessments should take into consideration direct and indirect impacts, and reflect the true conditions in which products will be used. [56]

To help develop the standard procedures, the FDA should coordinate with other agencies and join on-going initiatives, such as the recently announced International Alliance for NanoEHS Harmonization (IANH) formed "to establish protocols for reproducible toxicological testing of nanomaterials in both cultured cells and animals." Federal agencies that are already partners of IANH include the Centers for Disease Control (CDC), the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Standards and Technology (NIST), and the National Characterization Laboratory.[57]

We understand that the FDA is already working on defining safety testing methods and protocol through its membership on the Nanoscale Science and Engineering Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC) Committee on Technology, and through its co-chairmanship of the NSET Working Group on Nanomaterials Environmental and Health Implications (NEHI). We hope these efforts can be accelerated.

Unique properties call for nano-specific assessments

As SCENIHR, the European Commission's committee of scientists, points out in its 2007 report, current animal and in vitro testing methods used to assess safety may be entirely inadequate to assess nanomaterials.[58] Testing methods and thresholds must be tailored to nanomaterials as their small size and unique properties undermine the effectiveness of traditional risk assessment procedures that have generally correlated potential risk with the amount of material present. Nanomaterials' increased surface area to volume ratio increases the potential chemical and biological reactivity of the materials and may increase toxicity.

For example, a spherical particle with a diameter of $2x10^{-6}$ meters (2 micrometers, roughly the width of the smallest cell in the human body) has a surface area to volume ratio of 3 million. However, a spherical particle with a diameter of $2x10^{-9}$ meters (2 nanometers) has a surface area to volume ratio of 3 billion. This one-thousand-fold difference means that when a given mass of material is represented as nanoscale particles rather than microscale particles, a vastly larger surface area of the material is exposed to the environment and available for potential reactions – such as toxic reactions in the human body.

[56] Michael Hansen, CU senior scientist, "Comments of Consumers Union at FDA Nanotechnology Public Meeting: Breakout session on Food and color additives, including food contact substances," [written comments from presentation] Sep 8, 2008. Rockville, MD.
[57] "Partners and Collaborators," IANH website, http://nanoehsalliance.org/sections/PartnersCollaborators. Accessed Oct. 20, 2008.
[58] "Opinion on the Appropriateness of the Risk Assessment Methodology…," SCENIHR, Jun 07, p.20-21. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf. Accessed Sept. 16, 2008.

If toxicity corresponds with surface area, the current safety standards for exposure to conventional forms of many materials may be woefully inadequate for protecting individuals exposed to the same materials in nanoparticle form. For example, one hundred microliters of a substance that would normally represent a harmless dose could be lethal when constituted of nanoparticles of the same substance.

The agency must take into account physical shape, size, surface area and chemical structure – and all other known characteristics that could affect safety – when developing new safety standards for nanomaterials.

Implementation needed now

After more than a year and another public meeting since the FDA's Nanotechnology Task Force issued its report, the agency has yet to implement changes recommended in the report or by groups that have commented on the need for adequate regulation of nanotechnology. We strongly urge the agency to promptly act before the unregulated use of nanotechnology advances.

Nanotechnology is quickly becoming one of the biggest areas of public and private investment in the world, and already $147 billion in nano-enabled products were produced in 2007. By 2015 that figure is expected to grow to $3.1 trillion worldwide.[59] Nanomaterials have been incorporated into at least 800 consumer products already on the market, according to the Consumer Products Inventory kept by the Project on Emerging Nanotechnologies (PEN). And, with FDA-regulated products representing about 20 percent of domestically purchased consumer goods, many of the nano-enhanced products fall under the FDA's purview. Of the inventory's over 800 products, 502 are categorized under "Health and Fitness" and 80 under "Food and Beverage"—product category areas that the FDA oversees. Of the products listed under "Health and Fitness," 153 were personal care products, 123 were cosmetics and 33 were sunscreens. [60]

By instituting labeling and requiring premarket nano-specific assessment and testing, the FDA will also be far better informed and in a much better position to fulfill its responsibilities to ensure the safety and effectiveness of products. The improved tracking that would be possible of nanomaterials in commerce would allow the agency to react much more quickly and comprehensively if it needs to—an important capability given the fact that many FDA-regulated products are high-exposure and high-risk. [61]

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[59] "Nanomaterials State of the Market Q3 2008: Stealth Success, Broad Impact,"Lux Research report, Sep 08. http://www.luxresearchinc.com/press/RELEASE_Nano-SMR_7_22_08.pdf. Accessed Oct. 21, 2008.

[60] "Consumer Products," Project on Emerging Nanotechnology. http://www.nanotechproject.org/inventories/consumer. Accessed Sept 23, 2008.

[61] The recent salmonella outbreak linked to tomatoes and jalapeño and serrano peppers highlighted how highly valuable a tool a good tracking system is for FDA. The lack of one for fresh produce is blamed with the agency's inability to conclusively locate the outbreak's source, while the resulting "tomato scare" has been blamed for $100 million in food industry loses. (Mike Nizza, "Salmonella Outbreak Ends with Questions," [blog entry] The Lede, NYTimes.com, 28 Aug 08.)

We would urge the FDA to place the data collected on nanomaterials—including testing procedures, characterization and risk assessment results—in the public domain, with the limited exceptions for proprietary business information. The data will increase transparency and safety; boost consumer confidence; enable more effective policies and assessment strategies; and encourage manufacturers to take a more responsible, balanced approach to using this new technology.

Thank you for considering our comments.

Submitted by,

Adam Tapley
Consumer Nanotechnology Project
Center for the Study of Responsive Law
P.O. Box 19367, Washington, DC 20036
Tel. (202) 387-8030, Fax (202) 234-5176
atapley@csrl.org