DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 9, 2006

Andrew Kimbrell
Executive Director
The International Center for Technology Assessment
660 Pennsylvania Avenue, S.E., Suite 302
Washington, DC 20003

Re: Docket No. 2006-0210/CP1

Dear Mr. Kimbrell:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received May 16, 2006.

The petition requests that FDA take the following actions:

"Petitioners request that the Commissioner undertake the following actions with regard to all nanomaterial products:

1) Amend FDA regulations to include nanotechnology definitions necessary to properly regulate nanomaterial products, including the terms "nanotechnology," "nanomaterial," and "engineered nanoparticle."
2) Issue a formal advisory opinion explaining FDA's position regarding engineered nanoparticles in products regulated by FDA.
3) Enact new regulations directed at FDA oversight of nanomaterial products establishing and requiring, inter alia, that: nanoparticles be treated as new substances; nanomaterials be subjected to nano-specific paradigms of health and safety testing; and that nanomaterial products be labeled to delineate all nanoparticle ingredients.
4) Any currently existing or future regulatory FDA programs for nanomaterial products must comply with the requirements of the National Environmental Policy Act (NEPA), including, inter alia, that FDA conduct a Programmatic Environmental Impact Statement (PEIS) reviewing the impacts of nanomaterial products on human health and the environment.

Petitioners request that the Commissioner undertake the following actions with regard to nanomaterial sunscreen drug products:

5) Reopen the Administrative Record of the Final Over-the-counter ("OTC") Sunscreen Drug Product Monograph for the purpose of considering and analyzing information on engineered nanoparticles of zinc oxide and titanium dioxide currently used in sunscreens.
6) Amend the OTC Sunscreen Drug Monograph to address engineered nanoparticles, instructing that sunscreen products containing engineered nanoparticles are not covered under the Monograph and instead are "new drugs" for which manufacturers must complete a New Drug Application in accordance with 21 U.S.C 355.
7) Declare all currently available sunscreen drug products containing engineered nanoparticles of zinc oxide and titanium dioxide as an imminent hazard to public health and order entities using the nanoparticles in sunscreens regulated by FDA to cease manufacture until FDA's Sunscreen Drug Monograph is finalized and broader FDA nanotechnology regulations are developed and implemented.
8) Request a recall from manufacturers of all publicly available sunscreen drug products containing engineered nanoparticles of titanium dioxide and/or zinc oxide until the manufacturers of such products complete new drug applications, those applications are approved by the agency, and the manufacturers otherwise comply with FDA's relevant nanomaterial product testing regulations."

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials, and in relation to which the Agency is seeking public input. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your requests.

The requests you make in the petition call for the Agency to take a variety of actions relating to its regulatory approaches in all product areas and relating to the regulation of over-the-counter (OTC) sunscreens in particular. Both the general and sunscreen-specific actions requested involve the Agency's making determinations as to what, if any, changes to existing regulatory approaches may be appropriate for purposes of regulating products of nanotechnology.

FDA has formed an internal task force, the FDA Nanotechnology Task Force, to consider issues related to the safety and effectiveness of FDA-regulated products that use nanotechnology materials. As you know, the Task Force chaired a public meeting on nanotechnology on October 10, 2006, for which the Agency opened a docket for public comments. You and other interested persons presented information and views on scientific and regulatory issues related to use of nanotechnology for FDA-regulated products..

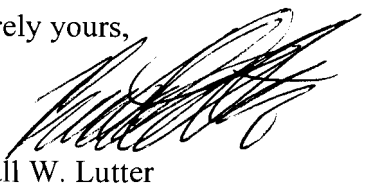
With respect to petition requests 5 and 6 in particular, the Agency is currently working on a rulemaking to amend the OTC Sunscreen Drug Product Monograph. FDA intends to publish the Federal Register notice for this rulemaking in the near future. The rulemaking process will provide stakeholders an opportunity to comment on sunscreen

drug issues, including the regulatory status of small particle size titanium dioxide and zinc oxide.

FDA is also actively engaged in health effects and materials characterization research that is relevant to some of the questions you raise. For example, in collaboration with National Institute of Environmental Health Sciences and the Environmental Protection Agency through the National Toxicology Program, FDA's National Center for Toxicological Research is conducting evaluations of dermal penetration of nanomaterials. In addition, FDA's Center for Drug Evaluation and Research is collaborating with the National Institute of Standards and Technology to measure particle size in sunscreen products. Furthermore, FDA has chaired the National Science and Technology Council's Work Group on Nanotechnology Environmental Health Implications and has through this effort lead development of a recently released evaluation of environmental, health, and safety research needs for engineered nanomaterials (http://www.nano.gov/NNI_EHS_research_needs.pdf).

As these examples of FDA efforts reflect, the Agency takes these issues seriously and is considering them actively. We look forward to participation by you and other stakeholders throughout this process.

Sincerely yours,



Randall W. Lutter
Associate Commissioner for Policy and Planning