NANODERMATOLOGY SOCIETY
Where DERMATOLOGY and NANOTECHNOLOGY meet

**President**
Adnan Nasir, MD PhD
president@nanodermsociety.org

**Vice President**
Adam Friedman, MD
vicepresident@nanodermsociety.org

**Secretary**
Steven Wang, MD
secretary@nanodermsociety.org

**Treasurer**
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treasurer@nanodermsociety.org

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4414 Lake Bone Trail, Suite 408
Raleigh, NC 27607
Fax: 919-781-3909
administrator@nanodermsociety.org

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Food Safety and Applied Nutrition**

Office of Cosmetics and Colors

Phone: (240) 402-1130

Email: industry.cosmetics@fda.gov

5/14/2012

In response to both the recently FDA released new draft guidelines on the use of nanotechnology in food and cosmetics, and subsequent dissatisfaction of the several non-profits working on nanotechnology oversight—Center for Food Safety (CFS), Friends of the Earth (FoE), Institute for Agriculture and Trade Policy (IATP)and the International Center for Technology Assessment--the Nanodematology Society (NDS) is issuing the following response:

- The NDS applauds and welcomes the FDA's interest in nanotechnology in food and cosmetics. Nanotechnology is an important area of innovation and developers in this area are looking to the agency for clarity in safety and regulatory policy.
- Of importance, the FDA acknowledges that there are distinct differences between nanomaterials and their bulk counterparts, that new properties emerge at the nanoscale and therefore and may require new testing. The FDA agrees with the scientific consensus that these

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nanomaterials have the capacity to be fundamentally different, and therefore can create not only new and novel materials and devices, but potentially new risks, necessitating innovative testing.

- For now, the FDA has only taken a voluntary rather than mandatory regulatory approach, meaning industry is encouraged to consult with the FDA early in the product development process to address questions related to the regulatory status, safety, effectiveness, or public health impact of products that involve the use of nanotechnology. During the draft guidance period, the FDA is accepting pubic feedback in order to help guide future efforts, which we encourage.

- The FDA officially has the authority to dictate safety and characterization standards under the Federal Food Drug and Cosmetic Act (FFDCA). The FDA's goal is to develop transparent and predictable regulatory pathways grounded in the best scientific practices. A current limitation is that there is no general consensus on the most appropriate and effective means to evaluate nanotechnology safety, and this is a key aim of this ongoing mission. The FDA made it clear that they do not consider all products containing nanomaterials or otherwise involving the application of nanotechnology as intrinsically benign or harmful. This neutral attitude does not appear to be shared by the aforementioned non-profits which in addition to filing a lawsuit against the FDA in December 2011 regarding the agency's failure to respond to their longstanding 2006 petition demanding oversight action, were unimpressed by what they described the draft guidance as "marginal progress." These foundations suggest that there is existing research indicating that nanomaterials have the ability to enter the bloodstream through contact with the skin, often based on *in vitro* or cell culture data. For sunscreens, the most recent data show minimal penetration of nanoparticles in the skin and no systemic absorption (1,2).

- The Nanodermatology Society still maintains its position in line with the its public announcement statement released in April 2011, that all data to date specifically evaluating the safety of nanosunscreens have yet to demonstrate any true threat to human health and instead offer extraordinary benefits in the fight against skin cancer (3,4).

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- The NDS strongly believes that the FDA has a responsibility to ensure that nanomaterial use in cosmetic, over the counter as well as prescription products be evaluated under consensus guidelines.

- The NDS believes that guidelines regarding nanomaterial safety, labeling, and regulation should be derived from expert evaluation and testimony. Contributors for guidelines should come from ranks of individuals of varying background with an interest in nanotechnology including physicians, scientists, industry, academics, consumers, and policy makers, each selected by leaders of their appropriate representative societies and groups, and conforming to Institute of Medicine (IOM) and FDA guidelines on conflict of interest (as modeled in 5).

- The preponderance of the basis of the guidelines should be rigorous, critical, and up-to-date scientific data. The NDS believes that guidelines should not be based on controversial evidence, weak evidence, or pure conjecture.

- The NDS believes that the guidelines should have an expiration period, as an acknowledgement of the evolution of science and technology. The rate of nanotechnology growth is rapid, and changes in guidelines are expected to occur as new techniques, materials, and devices are developed.

- The NDS believes that the guidelines and any updates should be made available to the public as soon as they are finalized.

With respect to additional comments regarding the FDA guidelines, the NDS would like to clarify the definition of biopersistence for TiO2 as mentioned in guideline 2b. For example, TiO2 can accumulate in tissues such as kidneys, but can also be eliminated, for example in the liver in some animal models (6). We recommend that this statement be removed from the guidelines or modified. We also see that the FDA recommends in guideline 2c that penetration studies be conducted on intact and impaired skin (for example, psoriatic skin or eczema or sunburn). The FDA may wish to waive this guideline for

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manufacturers who clearly indicate that the product is solely to be used on intact skin and to be avoided on damaged or diseased skin. The FDA may also consider the need for data on impaired skin on a case-by-case basis and, for example, accept data from a peer-reviewed published precedent showing lack of penetration of a particular nanoparticulate moiety in damaged skin (i.e., 7)

With the proper attention to consumer and patient safety, an emphasis on the most current available scientific data, with a sunset date, and with clear adherence to the ethical principals promulgated by the FDA and the IOM, the FDA can develop consensus guidelines regarding nanotechnology in foods and cosmetics.

Sincerely,

Adnan Nasir, MD PhD, FAAD, President

Adam Friedman MD, FAAD, Vice-President

The Nanodermatology Society

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