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

Comments on Docket No. 2006N-0107

Greetings

I have grave concerns about the FDA's regulatory oversight of nanomaterials in consumer products. Many consumer products containing engineered nanomaterials are already available on U.S. market shelves, including many cosmetics, sunscreens, and other personal care products. 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.

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. There are many more unknowns than knowns about the dangers of nanomaterials, due to the severe lack of federal funding for health and safety studies. Nonetheless, 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. For example, nanoparticles of titanium dioxide and zinc oxide used in large numbers of cosmetics, sunscreens and personal care products are photoactive, producing free radicals and causing DNA damage to human skin cells when exposed to UV light. Carbon fullerenes, another type of nanoparticle used in cosmetics, have been found to case brain damage in fish and be toxic to human liver cells at low levels.

Nanoparticles can gain assess to the blood stream following inhalation or ingestion. And, even though these nano-cosmetics and nano-sunscreen products are smeared in large amounts directly on the skin, the jury is still out on the ease of their skin penetration. 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.

The FDA's failure 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.

Moreover, the unregulated commercialization of these products poses unknown dangers to the environment once they are released into the waste stream. The same unique mobility and toxicity concerns that apply to human health apply to environmental risks. Even simply detecting these engineered substances in the environment is a new challenge.

For these reasons, I strongly request that FDA use its upcoming Public Meeting and its new Nanotechnology Task Force to discuss the human health and environmental risks presented by nanomaterials in consumer products. While this meeting is a good, albeit late, start, FDA should also 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.

Currently, FDA's reliance on manufacturers' assurances of safety make me and my family act 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 and into the environment. Until such actions are taken, I fully support a moratorium on the release of nanomaterial consumer products and the recall of products currently on the market.

Sincerely

Paul David Tuff
19394 Acclaim Dr
Salinas, CA 93908