Safety of Nanoscale Materials in Personal Care Products

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Good afternoon. My name is Annette Santamaria and I am a board certified toxicologist with ENVIRON International Corporation. I am speaking here today on behalf of the Cosmetic, Toiletry, and Fragrance Association (CTFA). First I would like to thank the FDA for this opportunity to discuss the use and safety of nanotechnology in the area of cosmetics and personal care products. Nanotechnology offers distinct and well-recognized benefits for consumers of personal care products. Moreover, it has done so safely and effectively for many years. This presentation is based on the extensive comments that CTFA submitted to the FDA public docket on September 19, 2006. Those comments provide documentation that supports the safety and continued use of nanoscale materials in personal care products.

Today, I will discuss four main points regarding the use of nanoscale materials in personal care products, specifically:

- There is no evidence of a toxicity profile common to the various nanoscale materials;
- The safety of nanoscale ingredients should be evaluated, just as any other ingredient;
- Available toxicological methods are appropriate for evaluating the safety of all ingredients, regardless of size; and,

- Nanoparticles have been safely used in cosmetics and sunscreens for many years.

The suggested enhanced toxicity of nanoscale materials has not been confirmed by competent and reliable toxicological studies for most nanoscale materials. An *a priori* assumption of greater risk from nanoscale materials does not have a sound scientific basis. Particle size may have an impact on toxicity in some cases, however, generalizations about an increased toxicological potential of smaller-sized particles are not appropriate. In fact, there are conflicting results in the scientific literature about the impact of size on toxicological potential. Most information about the toxicological effects of nanoparticles, including nanoparticles of titanium dioxide and zinc oxide, comes from respiratory studies. However, it is essential to note that these studies have been conducted to evaluate the pulmonary toxicity of nanoscale materials. Furthermore, the results from these studies are equivocal – in some studies, smaller size was reported to be associated with enhanced toxicity, while in other studies, larger sized particles induced greater toxicity or there were no differences observed. Importantly, few toxicological studies have been conducted to systematically examine the role of particle size and surface area in producing toxicity. Furthermore, studies have not reported differences in toxicity following the dermal administration of chemical substances due to particle size.

To assess the safety of an ingredient, cosmetic companies evaluate the potential of the ingredient to induce adverse effects by reviewing existing scientific studies, conducting structure-activity studies, and by performing toxicological studies when necessary. For example, studies may be conducted to evaluate reproductive, developmental, respiratory, dermal, ocular, or carcinogenicity endpoints. Safety assessments consider level of exposure, route of exposure, and duration of exposure, which are all essential for characterizing risk. Once the information is obtained, recommendations are made, including the identification of data gaps to ensure that all toxicological endpoints and/or concerns have been addressed. If testing is deemed necessary to fill a critical data gap, then appropriate *in vitro* or *in vivo* studies will be conducted. By combining results from the toxicological evaluation and the exposure assessment, a risk characterization can be developed to determine whether an ingredient is safe for use in personal care products. The risk characterization of an ingredient includes an adequate margin of safety to protect against unexpected toxicity or adverse effects if the product is misused or abused.

The scientific methods that are currently used to ensure the safety of existing and new substances that may be used as cosmetic ingredients are equally appropriate for evaluating the safety of ingredients developed in the nanoscale range. In fact, panels of scientists have concluded that traditional approaches and

study protocols for the toxicological evaluation of chemical substances are appropriate and sufficiently robust to provide meaningful characterization of nanoscale materials. Cosmetic companies typically use state-of-the-art scientific methods for evaluating the safety of ingredients. Just as our understanding of science continues to evolve, so too will toxicological testing of all ingredients, including nanoscale ingredients, and new study methods will be implemented as necessary.

The regulatory processes that the FDA currently has for evaluating ingredients used in personal care products are more than adequate for ensuring their safety, regardless of their size or how they are manufactured. Cosmetic companies are responsible for the safety of their products and are committed to ensuring that consumers have access to safe products that not only improve health, but also promote personal care and enhance beauty. The industry uses established processes and programs, and recognized testing protocols to ensure the safety of personal care products.

Concerns have been expressed about nanoscale ingredients because of their small size and the possibility that they may be absorbed through the skin. Cosmetic ingredients in solution consist of discrete molecules which have the potential for dermal absorption. Personal care product companies approach the safety evaluation of an ingredient by focusing on the route of application and

duration of potential exposure. Therefore, dermal absorption is routinely taken into account in the safety evaluation of cosmetic and sunscreen ingredients and formulations. In addition, the available studies for evaluating dermal absorption are appropriate for evaluating nanoscale materials as ingredients.

The use of materials with dimensions in the nanoscale range in personal care products is not new. Nanoparticles of titanium dioxide and zinc oxide have been used in sunscreens for almost two decades and their safety has been thoroughly demonstrated. In addition, *in vitro* and *in vivo* studies provide compelling evidence that nanoscale particles of titanium dioxide remain on the surface of the skin and do not penetrate the skin. The use of nanoscale particles of titanium dioxide and/or zinc oxide in sunscreen products allows for greater protection against the harmful ultraviolet rays from the sun – including UVA radiation. Furthermore, the use of small particles in the formulation results in a clear protective barrier that is easier to apply. Consumers find these sunscreen products more aesthetically pleasing, thus leading to increased consumer acceptance. Both of these factors contribute to a greater impact of sunscreens on public health by protecting individuals from the harmful effects of the sun, including skin cancer. Clearly, sunscreens are an example of the improvement of a consumer product because of the addition of nanoscale materials.

In conclusion:

- Nanoparticles have been safely used in sunscreens for many years with no relevant evidence of adverse effects
- Existing test methods are appropriate for evaluating the safety of nanoscale materials
- Safety assessments are performed on nanoscale materials as they are developed for use in personal care products
- Current regulations ensure the safe use of nanoscale materials in cosmetic and sunscreen products

Again, thank you very much for this opportunity to speak on such an important matter.