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Reaction is mixed to petition asking FDA to recall sunscreens that use nanotechnology

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May 30, 2006 - Reaction is mixed to a petition filed by consumer, health and environmental groups that asked the Food and Drug Administration to recall sunscreens that contain nanoparticles unless they are proven safe. The petition, filed May 16, also called for premarket safety testing of nano sunscreens, and for nano-specific toxicity testing and mandatory labeling of nano products.

An industry representative said that sunscreens are safe. Academic experts said there is not enough evidence for harmful effects to justify a recall of sunscreens, but some called for labeling of the products and for more public access to information about safety studies done by industry. The FDA, for its part, said it will respond to the petition, but declined to comment any further.

Already, consumers seem to be worried: Friends of the Earth, one of the petitioners, received dozens of calls from consumers asking about products without nanomaterials, said Lisa Archer, a senior campaigner for the group. The calls came in response to a report the group published, also on May 16, with a list of 116 personal care products, cosmetics and sunscreens that contain nanomaterials. "We are in the process of trying to create a list of companies that are currently not using nanomaterials," Archer said.

The sunscreen ingredients the petitioners warned about are nanoparticles of titanium dioxide and zinc oxide smaller than 100 nanometers, the upper size limit of what is usually called nanoparticles. It's unclear whether such particles can enter intact skin, Friends of the Earth say. But the group says studies suggest that particles as large as 7,000 nanometers can enter skin that is broken, for example as a result of shaving wounds or acne.

The FDA said through a spokesperson that it has "previously classified 16 sunscreen ingredients as safe and effective, and particle size does not affect the classification of these ingredients." But the petitioners argue that size does matter, in that nanoparticles are likely more harmful than larger particles of the same material, and products that contain them should therefore be recalled and tested for safety. "We shouldn't assume that nanoparticles don't cross the skin until we have robust research to demonstrate this," Archer said.

Still, Kristen Kulinowski, director of the international council on nanotechnology at Rice University, said a recall would be premature. "If no complaints have been filed, if no health risks have manifested themselves yet, then I don't necessarily agree with a recall," Kulinowski said. That doesn't mean Kulinowski thinks everything is just fine.

Kulinowski said she wants to see more of the safety data from companies. "When I talk to my friends in industry, they say 'oh we tested that'," she said. "Well, that's great, but I'd like my scientific friends to make their own assessment."

Exact labeling of what's in a 'nano' product is also important, said Vicki Colvin, who studies nanoparticle toxicity at Rice University. "We can't comment on it, we can't even design our tests to reflect what's commercially available because we don't actually know what's in there," Colvin said. "There is nothing that anybody loses by having very open and explicit labeling."

Meanwhile, the Cosmetic, Toiletry and Fragrance Association, an industry group, issued a statement that sunscreens using "small microfine particles [¿] have been affirmed to be safe by the FDA." John Bailey, the association's Executive Vice President for Science, said that sunscreens don't even contain nanoparticles, but particles larger than 100 nanometers. "That's what the industry is telling us," he said. "I don't much use the term nanotech. I think these are more microfine particles."

Asked why the Friends of the Earth report found that some manufacturers call their products 'nano,' he said that may be for promotional reasons. He also cited a study that shows that these particles don't penetrate intact skin. And if someone has a skin injury, Bailey said, "they should make sure it heals before applying any type of product other than medicines."

The Friends of the Earth report also warns that some face creams and moisturizers contain carbon spheres called fullerenes that, the group says, have been shown to cause "brain damage" in fish and can also damage human liver cells.

But Colvin, who did the study on human liver cells, said it was done with cultured cells, and that there is a "big leap" between such a study and an actual animal. And the fish study didn't really show brain damage, she said, but elevated so called reactive oxygen species in the brain as a reaction to the particles. Otherwise, she said, the fish were still swimming around, "doing their thing."

George Kimbrell, staff attorney for the International Center for Technology Assessment, one of the groups that filed the legal petition with the FDA, hopes the petition will at least force the FDA to take a stance on nanotechnology. If the agency responds that no additional regulations for nanotechnology are required, "then we can go to court and say they are not fulfilling their statutory obligation of protecting health and safety," said Kimbrell, who is the main author of the petition. The FDA has 180 days for an initial response, he said.

The FDA, meanwhile, is participating in studies of skin absorption of "nano-sized titanium dioxide and zinc oxide preparations used in sunscreens," according to its Web site. The agency has also announced a public meeting this fall to discuss developments in nanotechnology.

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