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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FDA's Nanotech Safety Rules May Not Help Cos. Avoid Risk

By **Greg Ryan**

Law360, New York (April 24, 2012, 8:40 PM ET) -- The U.S. Food and Drug Administration recently published long-awaited safety guidelines for nanotechnology in food and cosmetics products, but the recommendations are so ambiguous that companies may need to rely on consultations with the agency to protect themselves in future litigation, attorneys say.

The FDA demonstrated it would remain flexible toward nanotechnology in two draft guidance documents released Friday regarding the safe use of the technology in food ingredients, food contact substances and cosmetics, according to attorneys. While the agency laid out certain areas of nanotechnology it believed needed more study, such as the use of nanomaterials in cosmetic products in spray cans, it refrained from issuing new policy directives.

But the middle-of-the-road approach might leave companies in the lurch, attorneys said. While the guidance lays out the FDA's recommendations for safe nanotechnology use, those recommendations are vague enough that companies will find it difficult to determine whether they comply with the agency's standards, they said.

“From a litigation perspective, these safety assessments seem to impose a lot of new burdens without the benefit of protection,” said Shook Hardy & Bacon LLP attorney Lori McGroder.

In light of that ambiguity, companies should consider heeding the FDA's offer to consult with agency officials on nanotechnology use in products under development, attorneys said. A company's cooperation with the agency now may prove essential to emerging victorious in litigation later, they said.

“Documents like these can end up being significant factors in terms of evidence in a product liability lawsuit down the road,” said David Wallace of Chadbourne & Parke LLP.

Federal agencies often encourage companies to consult with them during product development, but nanotechnology may prove a special case, attorneys said. The promising technology is in an early stage of development, but consumer and environmental groups have already likened it to asbestos and other toxic torts, they said.

Companies are sometimes reluctant to voluntarily huddle with federal agencies for fear it will leave them no choice but to follow officials' potentially costly advice. Small companies in particular could meet with the FDA on a food or cosmetics product that incorporates nanotechnology, only to find they do not have the funding to follow through on the testing recommended by the agency, attorneys said.

“Whether you're a manufacturer or not, you hear someone say, 'We're from Washington, and we're here to help you,' and there's a natural reluctance,” Wallace said.

Still, in this case, companies need to overcome any reluctance they have about working with regulators, attorneys said.

“In the long run, there's more to gain than there is to lose,” Wallace said.

Building up a track record of working with the FDA is important, given that plaintiffs' attorneys might use the various responsibilities laid out in the draft guidance as a way to attack companies in litigation down the road, attorneys said.

“What we may hear from the plaintiffs bar is that maybe there's an evolving duty here in what companies need to do in terms of testing the safety of nanomaterials," said James Mizgala of Sidley Austin LLP.

Still, the decision to consult with the FDA on nanotechnology will likely depend on a company's circumstances, McGroder said.

“A cosmetics manufacturer should go talk to the FDA if they really have a concern, but from a litigation perspective, other than being in a position to say in a lawsuit, 'Well, we talked to the FDA,' no real protection is given to the manufacturer to informally consult with the FDA,” McGroder said.

In addition, for all of the FDA's talk about additional tests and new regulatory submissions, it is not clear how much additional work the agency could handle if a large number of companies chose to seek consultations on the guidance, according to attorneys.

“We all know the FDA doesn't have infinite resources,” Mizgala said. “I think they would get flooded if that was their approach, and they wouldn't have enough manpower to address those filings.”

In the mean time, companies hoping for more guidance from the FDA might be waiting awhile. It might take a seismic event, such as a high-profile incident in which a nanomaterial harmed human health, for the FDA to take a more intricate stance on nanotechnology, attorneys said.

“I think we see this long, slow dance continue to play out, with the FDA not wanting to do anything too drastic at this point,” Wallace said.

--Editing by Lindsay Naylor.