ABSTRACT for Talk on Cosmetics and Nanotechnology
"Nano labeling and consumers: Understanding or confusion/ FDA regulation or labeler's discretion? The cosmetic case study"

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Before the problem of melamine from China in dog foods, I would have stated that pet foods and pet supplements are lowest in FDA enforcement priority. But now I would say that cosmetics are the category with the lowest FDA enforcement priority—with the compliance issues being an unsafe ingredient found in the product, or a cosmetic product making drug claims. This is why nanoscale cosmetics will pose a growing regulatory challenge to the FDA in the coming years.

Cosmetics are "1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and 2) articles intended for use as a component of any such articles; except that such term shall not include soap." Cosmetics are intended to alter the appearance of the body, not alter the structure or function of the body—which is the central definition of a drug.

Over the past four or five years, FDA has been striving to understand the health benefits, safety risks, and regulatory implications of products made with these tiny particles. FDA has held several public meetings to discuss a regulatory strategy for oversight of nanotech products, both before and after issuing its Nanotechnology Task Force Report on July 25, 2007. In that Report dietary supplements and cosmetics are product categories singled out repeatedly as posing particular regulatory problems—given that new drugs, medical devices, biologics, and combination products require some form of FDA premarket approval. The central regulatory problem for nanotech cosmetics is that unless an ingredient is a new color additive, or unless a cosmetic is making a drug claim (in which it then is treated as a drug), then there is no premarket approval or even premarket notice required. For the vast majority of cosmetics, FDA has post-market oversight powers only.

Yet the use of nanoparticles in cosmetics has been widespread since the beginning of this still emerging technology, and is now increasing. Major companies such as Estee Lauder and L'Oreal have been testing and using nanoparticles (especially in anti-wrinkle creams) for years. As of 2007, PEN determined that over 320 consumer products on the market used a variety of nanomaterials, and of these, cosmetics was the largest category in the survey with 58 products. As of March 2010, the number of patents with the words nano and cosmetics in the text is 562. The benefits are clear and numerous. For example, a nanotech cream can make the skin tense and taut, and thus reduce the appearance of wrinkles, and even of deep lines. What is not clear are the risks of nanoparticles applied topically, which may work transdermally, and which may travel to other parts of the body.

Now, 2010 may be the year in which FDA decides that it is proper and prudent to initiate rulemaking (proposing new regulations) for nanotech products, in particular for cosmetics, or to issue guidance documents. FDA recognizes that special safety issues arise when scientists add sub-microscopic particles to otherwise safe products like foods, supplements, cosmetics, and even packaging. The agency is now struggling to find a balance between encouraging innovation in this

nascent, revolutionary, and promising technology without putting the public health at risk. In addition to premarket review, another large question for the FDA, and soon for the FTC, is labeling and advertising claims. Should claims about the presence of nanoparticles in cosmetics be permitted? Required? Subject to premarket review and approval? And these questions in turn depend on consumer understanding of nanotechnology—which currently is vague.

Beyond safety issues, there are challenging questions about nanotech labeling and advertising. Both label and promotional claims regarding nanoparticles are proliferating for cosmetics products, causing consumer confusion and regulatory concern. "Should product labeling declaring the presence or amount of nanoscale materials be either required or permitted?" (the Report, p. 21; emphasis added.) FDA's position as of July 2007 was that the use of nanotechnology in a product does not mean that its safety or effectiveness is necessarily increased or decreased. Of course, all labels must be truthful and not misleading, and must disclose all material information, including any risks. Based on the current science, in general the Nanotechnology Task Force is not recommending that the agency require specific nanotech labeling, but rather recommends that FDA "Address on a case-by-case basis whether labeling must or may contain information on the use of nanoscale materials." (The Report, p. 35). Randall Lutter, the agency's deputy commissioner for policy, stated in an interview near the release of the Report, "At this point, we lack an ability to say that nanoscale alone raises safety concerns worthy of putting on the label." (Technology Review, July 27, 2007). Although there has been a public meeting of stakeholders since this July 2007, the FDA's official policy has not changed.

Therefore, under current law, while nanotech claims and disclosure are not required, they are permitted for cosmetics, provided that the labeler meets FDA's standards for label claims of true, accurate and not misleading, and that the marketer meets the Federal Trade Commission's (FTC's) standard of "competent and reliable scientific evidence" for all claims about the special properties of nanoparticles (e.g., penetrates to the deepest layer of skin). Of course, permitting nanotech claims can also in effect allow possible misuse of the nano "buzzword" on products that do not truly use nanotechnology, e.g., "microparticles"—and this takes us back to the issue of consumer confusion, and perhaps even deception.