

FDA Should Systematically Gather Basic Nanomaterial Information

by John C. Monica, Jr.

Numerous products regulated by the Food and Drug Administration (FDA), including drugs, medical devices, cosmetics, sunscreens, and dietary supplements, already contain nanoscale materials. The agency predicts that “[v]irtually any product category regulated by FDA might currently or in the future involve uses of nanotechnology somewhere in the manufacturing process. A somewhat smaller set of products can be expected to retain nanoscale structure in the finished products”

With this bright future, many advocacy groups have asked whether existing laws provide FDA with the authority and resources it needs to address any potential health and safety risks that may arise from the use of nanoscale materials or structures in FDA-regulated products. FDA believes the answer is “yes.”

FDA only regulates certain categories of products. Existing requirements may be adequate for most nanotechnology products that we will regulate. These products are in the same size-range as the cells and molecules with which FDA reviewers and scientists associate every day. In particular, every degradable medical device or injectable pharmaceutical generates particulates that pass through this size range during the processes of their absorption and elimination by the body. To date, FDA has no knowledge of reports of adverse reactions related to the “nano” size of resorbable drug or medical device products. If new risks are identified, arising from new materials or manufacturing techniques for example, new tests or other requirements may be needed.

The agency further notes that existing laws provide it with the legal authority to require information on particle size for FDA products requiring pre-marketing approval — assuming the agency deems that information appropriate and relevant. No such across-the-board determination has yet been made. FDA products that do not require pre-marketing approval present a slightly different issue. For some of these products, FDA can require that pre-market notices contain nanoscale particle size information if deemed appropriate. Again this has not yet occurred. For products requiring neither pre-marketing approval or notice, the issue is more complicated. FDA may need new legal authority to require the meaningful disclosure of nanoscale information in these instances.

But such issues of agency authority are overshadowed by an even more basic question of agency oversight. To illustrate, try this: Place a general telephone call or email inquiry to FDA and ask whether the agency keeps a list of FDA-approved products employing nanoscale materials. Then dig deeper and call each of the six FDA centers (CDER, CFSAN, CBER, CVM, CDRH, and NCTR) and ask the same question. Unfortunately, no such list exists. In fact, FDA freely admits that it does not currently track this information.

Thus, the larger question becomes whether the agency can appropriately react if a future problem is discovered related to the “nanoness” of one of its regulated products.

For example, one high-profile implant manufacturer recently advertised that it has obtained FDA approval for a new line of implants that employ nanoscale material surfaces to promote better osseointegration and to reduce the chances of infection and implant rejection. The manufacturer’s advertising and press releases tout the “nanoness” of the new implant surfaces as a holy grail of adhesion and acceptance. The manufacturer’s 510(K) application, however, does not mention the term “nanotechnology” or reference new nanoscale features of the

product. Because the manufacturer's prior version of the implant used an FDA-approved bulk version of the nanoscale material, the company was not required to mention the "nanoness" of the new version on its 510(K) application. This is not an isolated incident. Several nano-enabled products regulated by FDA have used this same loop hole.

None of this means the "nano-sky" is falling. Nor are many instances of adverse health consequences likely to be caused by the use of nanoscale materials in FDA-approved products. Nonetheless, a slight risk still exists. Until the science is in, products using nanotechnology should be tracked and specifically monitored. If no problems ever result, great. If, however, a problem develops in a nano-enabled product, FDA must be prepared to investigate whether other approved products might be susceptible to similar problems. The public will demand nothing less. Right now, unfortunately, FDA does not even know which products contain nanoscale materials and has no definitive way of quickly making this determination. FDA's credibility will be severely hampered and the tremendous health benefits promised by nanotechnology may be stymied by public backlash if this information gap is encountered in a real time of need.

** John C. Monica, Jr., is a partner with the law firm of Porter Wright Morris & Arthur LLP, in Washington, D.C. He is a recognized national authority on nanotechnology legal issues, head of the firm's nanotechnology practice group and publisher of the firm's website Nanotechnology Law Report at www.nanolawreport.com*