

FDA Needs To Systematically Collect Vital Nanotech Data, Attorney Says

FDLI Conference Feb. 28-29 Focuses on Nanotechnology Law, Regulation and Policy

Hundreds of nanotech products, including foods, medicines and medical devices, now have reached the market, and their number will grow exponentially in the years ahead. But the main regulatory body, the Food and Drug Administration, is not yet systematically collecting basic nanomaterial information, says John C. Monica, Jr., a partner at the law firm of Porter Wright Morris & Arthur LLP, in Washington, D.C, and head of the firm's nanotechnology practice group.

In an *Insighter* article, posted on the Food and Drug Law Institute's website, www.fdpi.org, Monica notes that FDA maintains that current laws and rules are probably adequate for most nanotechnology products regulated by the agency. But such issues of authority are overshadowed by an even more basic question of agency oversight, according to Monica, who writes: "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, Monica asserts, 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. Until the science is in, products using nanotechnology should be tracked and specifically monitored, concludes Monica. "FDA must be prepared to investigate whether other approved products might be susceptible to similar problems. The public will demand nothing less," says Monica, adding: "Right now, unfortunately, FDA does not even know which products contain nanoscale materials and has no definitive way of quickly making this determination."

The Food and Drug Law Institute's 1st Annual Conference on Nanotechnology Law, Regulation and Policy, co-sponsored by Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies, in partnership with Burdock Group and Arizona State University, Feb. 28-29 in Washington, D.C., will focus on this and other important legal and regulatory issues concerning nanotechnology.

For more information on the conference, visit www.fdpi.org/conf or contact Michael Levin-Epstein, Editor-in-Chief, (202) 222-0897 or mdl@fdli.org

The full text of the *Insighter* piece is posted at www.fdpi.org

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