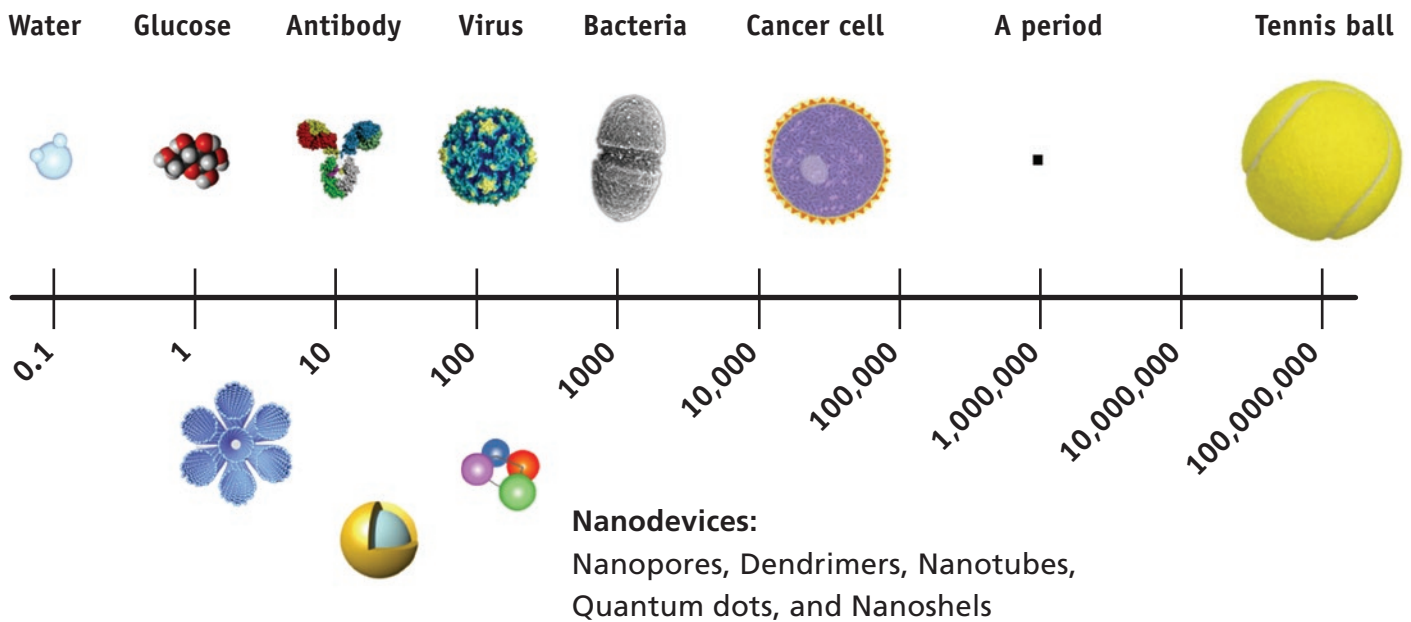


FDA Ready for More 'Nanoscale' Challenges

Nanometers



Source: National Cancer Institute

Nanotechnology is changing the way many FDA-regulated products will be made. In the interest of promoting and protecting the public health, FDA will work to clarify what information will be needed in its efforts to oversee products that contain nanoscale materials—those created at sizes as small as 100,000th the width of a human hair.

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For the most part, FDA experts believe that nanotechnology products present challenges similar to those FDA faces for products of other emerging technologies.

FDA's Nanotechnology Task Force released a report on July 25, 2007, that recommends the agency consider developing guidance and taking other steps to address the benefits and risks of drugs and medical devices using nanotechnology.

Commissioner of Food and Drugs Andrew von Eschenbach, M.D., endorsed the Task Force Report and its recommendations.

"Nanotechnology holds enormous potential for use in a vast array of products," he said. "Recognizing the emerging nature of this technology and its potential for rapid development, this report fosters the continued development of innovative, safe and effective FDA-regulated products that use nanotechnology materials."

Nanotechnology Today

Nanotechnology is currently used in such fields as display technology for laptop computers, cell phones, and digital cameras, and in water filtration.

And nanomedicine is an area of biomedical research that seeks to use nanoscale tools to improve health.

Current medical uses of nanotechnology include

- burn and wound dressings
- a dental-bonding agent
- sunscreens
- protective and glare-reducing coatings for eyeglasses

Nanotechnology Tomorrow

Some day, you may see nanotechnology used in food packaging to further extend shelf life or used medically to

- provide new drugs that are able to reach sites in the body more effectively and at safer doses.
- create tiny sensors that detect diseases in the body far earlier than existing diagnostic tools.
- manufacture incredibly small pumps that can be implanted to deliver lifesaving medications precisely to the cells and tissues that need them.

Regulation Strategies

For the most part, FDA experts believe that nanotechnology products present challenges similar to those FDA faces for products of other emerging technologies. FDA experts recognize, however, that product safety and effectiveness can change as size goes up or down within the nanoscale, adding additional complexity to the product review. It's also possible that nanotechnology will be used in a wide variety of products, such as foods, drugs, cosmetics, and medical devices.

The agency expects that many of the nanotechnology products it will regulate will span the regulatory boundaries between drugs, medical devices, and biologics. These, then, would be

regulated under the rules established for "combination products." [FDA](#)

For More Information

FDA's Main Nanotechnology Web Page
www.fda.gov/nanotechnology/

FDA's July 25, 2007
 Nanotechnology Press Release
www.fda.gov/bbs/topics/NEWS/2007/NEW01671.html