FDA Opens Dialogue on 'Nano' Regulation

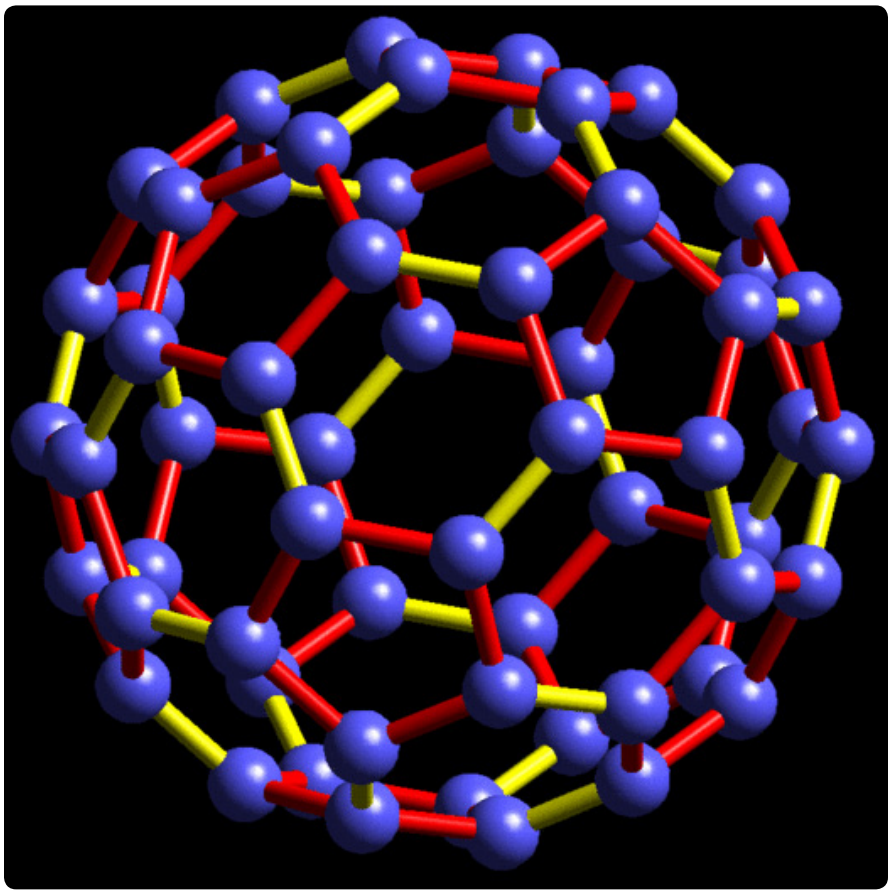
In 1959, a Nobel Prize-winning physicist challenged his colleagues to use submicroscopic particles to manufacture a wide range of products—an idea that captivated the imagination of scientists and inspired the science fiction movies "Fantastic Voyage" and "Innerspace."

Fifty years later, nanotechnology has moved from the science fiction realm to scientific fact, and federal regulators are laying the groundwork for monitoring a new generation of medical devices, drugs, cosmetics, and other products.

The Food and Drug Administration is now opening a dialogue on nanotechnology by publishing proposed guidelines on how the agency will identify whether nanomaterials have been used in FDA-regulated products.

The guidelines—"Draft Guidance for Industry, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology"—were published in the Federal Register Tuesday.

FDA Commissioner Margaret A. Hamburg, M.D., says the guidelines provide a starting point for the nanotechnology discussion. "Our goal is to regulate these products using the best possible science," Hamburg says. "Understanding nanotechnology remains a top priority within the agency's regulatory science initiative and, in doing so, we will be prepared to usher science, public health, and FDA into a new, more innovative era."



Buckyballs—strong, rigid molecules forming structures that resemble soccer balls—are a major subject of research in nanotechnology. Some are being investigated for their potential use in FDA regulated products.

Possible Uses

The guidelines list things that might be considered when deciding if nanotechnology was used on a product regulated by FDA—including the size of the "nano" (small) materials used and what the properties of the nanomaterials are.

And FDA wants industry leaders and the public to weigh-in.

Nanotechnology—the science of manipulating materials on a scale so small that it can't be seen with a regular microscope—could have a broad range of applications, such as increasing the effectiveness of a particular drug or improving the packaging of food or cosmetics.

"Nanotechnology is an emerging technology that has the potential

"...because materials in the nanoscale dimension may have different chemical, physical, or biological properties from their larger counterparts, FDA is taking a closer look."

to be used in a broad array of FDA-regulated medical products, foods, and cosmetics," says Carlos Peña, director of FDA's emerging technology programs. "But because materials in the nanoscale dimension may have different chemical, physical, or biological properties from their counterparts on the more conventional foot or meter scales, FDA is monitoring the technology to assure such use is beneficial."

In other words, using nanotechnology can change the way a product looks or operates, Peña says.

Although the technology is still evolving, it's already in use as display technology for laptop computers, cell phones, and digital cameras. In the medical community, a number of manufacturers have used nanotechnology in:

- Drugs
- Medical imaging
- Antimicrobial materials
- Medical devices
- Sunscreens

Ritu Nalubola, FDA's senior policy advisor and expert on nanotechnology, says FDA-regulated industries are also exploring new uses for nanotechnology. The agency's goal is to protect and promote public health while supporting innovation.

FDA will continue to monitor advancements in nanotechnology and its use in regulated products. The agency encourages industry consultation and will offer technical advice and guidance to manufacturers, as needed, to enhance product development, benefit, and safety.

"FDA has experience with regulating emerging technologies. Challenges of regulating nanotechnology are not unlike those related to other emerging and cross-cutting scientific and policy issues," Nalubola says.

Agency experts haven't identified specific safety concerns involving nanotechnology in FDA regulated products, but nanomaterials can, in some cases, raise safety issues. Because of this, FDA scientists continue to examine data to decide if and when additional studies are needed.

FDA Task Force

Peña says it's critical for FDA to understand how the changes in physical, chemical, or biological properties that have been documented in nanomaterials affect the safety, effectiveness, performance, or quality of a product that contains nanomaterials. Because of this, the agency has a robust science and research agenda to help us answer these questions, he says.

In 2006, FDA formed the Nanotechnology Task Force with an eye toward identifying and addressing ways to evaluate the potential effects on health from FDA-regulated nanotechnology products.

A year later, the task force recommended that FDA issue guidelines to industry and take steps to address the potential risks and benefits of drugs, medical devices, cosmetics, and other FDA-regulated products that incorporate nanotechnology. The proposed guidelines are the first step toward developing policies that guide regulation of products using nanotechnology. The agency plans to develop additional guidelines for specific products in the future.

FDA is working with the White House, the National Nanotechnology Initiative, other U.S. government agencies, and international regulators to focus on generating data and coordinating policy approaches to ensure the safety and effectiveness of products using nanomaterials.

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