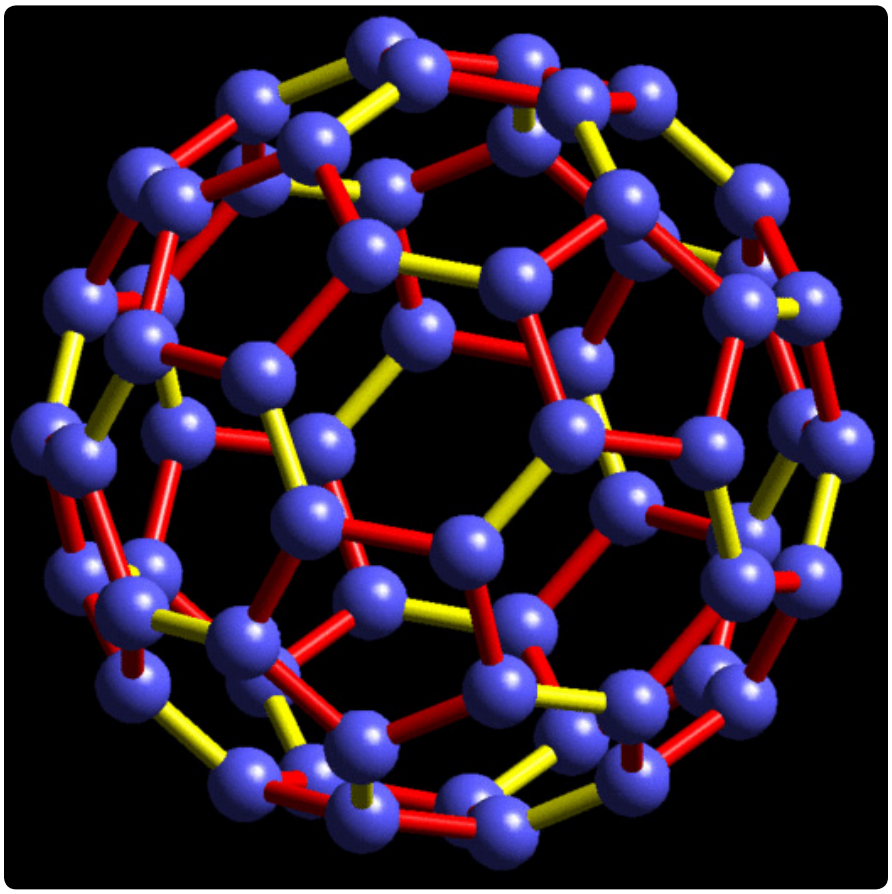
FDA Continues Dialogue on 'Nano' Regulation

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."



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.

Fifty years later, "nano" (small) technology 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 continuing a dialogue on nanotechnology begun in 2011 by publishing proposed guidelines on the evaluation and use of nanomaterials in FDA-regulated products.

The first draft guideline, "Draft Guidance for Industry, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology", was published in the Federal Register in June, 2011. The FDA is still reviewing and receiving comments on this document from the public.

In April 2012 the FDA is issuing two new draft guidelines for manufacturers of food substances and cosmetics, which are also open for public comment.

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."

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.

Possible Uses

The draft guidelines issued in June, 2011 list things that might be consid-

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ered when deciding if nanotechnology was used on a product regulated by FDA—including the size of the nanomaterials that were used, and what their properties are.

Nanotechnology—the science of manipulating materials on a scale so small that they 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 altering the look and feel of a cosmetic.

"Nanotechnology is an emerging technology that has the potential 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 larger counterparts, 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, Ph.D., 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 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.

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.

New Draft Guidelines

"Guidance for Industry: Safety of Nanomaterials in Cosmetic Products" describes issues that manufacturers should consider to ensure that cosmetic products made with nanomaterials are safe. Nanomaterials may be used in lotions and moisturizing creams for a smoother feel. They may also be used in makeup to create a more natural look.

"Right now, we don't have any information to make us believe that use of nanotechnology in cosmetics would cause a safety issue," says Linda Katz, M.D., director of FDA's Office of Cosmetics and Colors. "We will continue to monitor cosmetic products, and if safety issues arise, we will follow up to make sure that the products are safe for consumer use." Cosmetics do not require FDA approval before being sold.

"Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes" describes factors industry should consider when determining whether a significant change in the manufacturing of a food substance affects its identity, safety or regulatory status (such as whether a substance is covered by an existing food additive regulation). A food substance is one that is added to food or to food packaging for purposes that include improving taste, texture, or shelf life.

This guidance covers "any manufacturing process change that might affect a food substance's identity, intended uses, or the way it behaves in the body after it is eaten," says Dennis Keefe, Ph.D., director of the Office of Food Additive Safety.

Keefe added that nanotechnology now is being studied in food packaging to combat bacteria and detect spoilage, and to improve the bioavailability (the degree and rate at which a substance is absorbed into one's system) of nutrients, among other applications. FDA

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