FDA issues guidance to support the responsible development of nanotechnology products

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Three final guidances and one draft guidance have been issued by the U.S. Food and Drug Administration providing greater regulatory clarity for industry on the use of nanotechnology in FDA-regulated products.

One final guidance addresses the agency's overall approach for all products that it regulates, while the two additional final guidances and the new draft guidance provide specific guidance for the areas of foods, cosmetics and food for animals, respectively.

Nanotechnology is an emerging technology that allows scientists to create, explore and manipulate materials on a scale measured in nanometers - particles so small that they cannot be seen with a regular microscope. The technology has a broad range of potential applications, such as improving the packaging of food and altering the look and feel of cosmetics.

"Our goal remains to ensure transparent and predictable regulatory pathways, grounded in the best available science, in support of the responsible development of nanotechnology products," said FDA Commissioner Margaret A. Hamburg, M.D. "We are taking a prudent scientific approach to assess each product on its own merits and are not making broad, general assumptions about the safety of nanotechnology products."

The three final guidance documents reflect the FDA's current thinking on these issues after taking into account public comment received on the corresponding draft guidance documents previously issued (draft agency guidance in 2011; and draft cosmetics and foods guidances in 2012).

The FDA does not make a categorical judgment that nanotechnology is inherently safe or harmful, and will continue to consider the specific characteristics of individual products. All four guidance documents encourage manufacturers to consult with the agency before taking their products to market. Consultations with the FDA early in the product development process help to facilitate a mutual understanding about specific scientific and regulatory issues relevant to the nanotechnology product, and help address questions related to safety, effectiveness, public health impact and/or regulatory status of the product.

The guidances are:

**Final Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology**  
The guidance outlines overarching considerations for all FDA-regulated products, identifying points to consider when determining whether a product involves the use of nanotechnology. It is intended to help industry and others identify when they should consider potential implications for regulatory status, safety, effectiveness or public health impact that may arise with the application of nanotechnology in FDA-regulated products.

**Final Guidance for Industry: Safety of Nanomaterials in Cosmetics**  
Theguidance describes the FDA's current thinking on the safety assessment of nanomaterials when used in cosmetic products and encourages manufacturers to consult with the FDA on test methods and data needed to support the substantiation of a product's safety.

**Final Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives**  
The guidance alerts manufacturers to the potential impact of any significant manufacturing process change, including changes involving nanotechnology, on the safety and regulatory status of food substances. This guidance also describes considerations for determining whether a significant manufacturing process change for a food substance already in the market affects the identity, safety, or regulatory status of the food substance, potentially warranting a regulatory submission to the FDA.

**Draft Guidance for Industry: Use of Nanomaterials in Food for Animals**  
This draft guidance addresses issues related to the use of nanotechnology in food ingredients intended for use in food for animals. Public comments on this draft guidance are requested by September 10, 2014.

The FDA will continue to pursue ongoing scientific research and regulatory efforts and will consider new studies and data, as they become available, to determine future actions. Science is a critical component of the agency's ongoing review of products. FDA has invested in a nanotechnology regulatory science program that will enhance the agency's scientific capabilities. Additional guidances for industry will be developed as needed.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.