Q & As - Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology

1. Why is FDA interested in nanotechnology?

Nanotechnology, the science involving manipulation of materials on the nanoscale, is an emerging technology that has the potential to be used in a broad array of FDA-regulated products, including medical products (e.g. to increase bioavailability of a drug), foods (e.g., to improve food packaging) and cosmetics (e.g. to change reflectivity). Materials at the nanoscale can have different chemical, physical, or biological properties compared to their conventionally-scaled counterparts.
For general information about nanotechnology science and applications, see www.nano.gov.

2. What is FDA announcing?

The agency is issuing a draft guidance on considering whether an FDA-regulated product contains nanomaterials or otherwise involves the use of nanotechnology. FDA's issuance of this guidance is a first step toward providing regulatory clarity on FDA's approach to nanotechnology. Over time, the agency plans to issue more specific guidances tailored to particular products or classes of products. These actions are consistent with the 2007 FDA Nanotechnology Task Force's science and policy recommendations to the Commissioner.

3. How does one comment on the draft guidance?

The "Draft Guidance for Industry, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology" is available at regulations.gov (search for the docket number FDA-2010-D-0530). Comments will be accepted for 60 days after publication in the *Federal Register* of the notice announcing the availability of the draft guidance.

4. What is FDA's current thinking regarding identifying products that involve the use of nanotechnology?

Based on FDA's current scientific and technical understanding of nanomaterials and their characteristics, the agency is proposing certain points to consider by which it will determine whether an FDA-regulated product contains nanomaterials or otherwise involves the use of nanotechnology (Draft Guidance for Industry, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology). Industry is encouraged to consult with the FDA early in the product development process to address questions related to the regulatory status, safety, effectiveness, or public health impact of products that involve the use of nanotechnology.

5. Is FDA announcing a regulatory definition of nanotechnology?

No. FDA's draft guidance presents points that the agency intends to consider in determining whether a product contains nanomaterials or otherwise involves the use of nanotechnology. Those considerations are related to the likelihood that the products will exhibit properties that pose questions about the regulatory status, safety, effectiveness, or public health impact of products. The draft guidance does not establish a regulatory definition of the term "nanotechnology" or any related vocabulary.

6. What is FDA's regulatory approach toward nanotechnology-enabled products and their uses?

FDA's goal is to develop transparent and predictable regulatory pathways grounded in the best science. FDA intends to do this with a regulatory approach that is iterative, adaptive and flexible.

FDA does not categorically judge that all products containing nanomaterials or otherwise involving the application of nanotechnology as intrinsically benign or harmful.
FDA is maintaining its product-focused, science-based regulatory policy that allows for variations among product classes and over time as the science evolves. Products regulated by FDA are subject to different statutory standards for safety, efficacy, or public health impact. Therefore, acceptable levels of uncertainty and risk may vary among product-classes, even where objective measures of risk are similar.

For products subject to premarket notice or review, FDA intends to incorporate attention to nanomaterials into its product-specific review procedures and apply certain considerations (see Draft Guidance above) to better understand the properties and behavior of engineered nanomaterials. For products not subject to premarket review, manufacturers are encouraged to consult with FDA to reduce the risk of unintended harm to human or animal health.
Industry is encouraged to consult with the agency early in the product development process to address questions related to the regulatory status, safety, effectiveness, or public health impact of products that involve nanotechnology. FDA will offer technical advice and guidance to manufacturers, as needed, so that they can improve pre-market product development and safety assessments.

7. What are the key scientific considerations related to nanotechnology as relevant to FDA-regulated products?
Properties of a material may change as the size of the material enters or varies within the nanoscale range. It is critical for FDA to understand how such changes in physical, chemical, or biological properties affect the safety, effectiveness, performance or quality of a product.
The potential risks and benefits to human and animal health of the diverse array of nanotechnology applications are not yet completely identified or understood. Of particular importance to FDA are the biological interactions of products containing nanomaterials. FDA's regulatory science research portfolio focuses on understanding interactions of nanomaterials with biological systems; and on the adequacy of testing approaches for assessing safety, effectiveness, and quality of products containing nanomaterials.
FDA needs a robust regulatory science agenda to develop the tools, methods, and expertise necessary to evaluate submissions from industry. For more information about our regulatory science program, please see our presentation to the FDA Science Board.

8. What has FDA done within the Agency to ensure that products that involve nanotechnology are regulated in a coordinated fashion across all product types?
The Office of the Commissioner established the FDA Nanotechnology Task Force (NTF) in 2006 which continues to operate to date. The Task Force functions to identify and recommend ways to address gaps in science and policy to enable the agency to ensure the safety and effectiveness of FDA-regulated products that involve the use of nanotechnology.

9. Does the FDA coordinate its research and policies related to nanotechnology with other US government agencies?
Yes. Coordination of FDA's nanotechnology regulatory science research is facilitated by FDA's participation in the National Science and Technology Council's Subcommittee on Nanoscale Science, Engineering and Technology (NSET) and its Nanotechnology Environmental and Health

Implications (NEHI) working group. FDA also engages in policy dialogue with other U.S. government agencies on various topics of mutual interest, including policies relevant to nanotechnology. FDA's approach facilitates the responsible transfer of nanotechnology to applications in FDA-regulated products, consistent with the strategic goals of the U.S. National Nanotechnology Initiative as well as the White House's guidance on principles for regulation of emerging technologies and nanotechnology.
See also: Nanotechnology National Activities

10. Does FDA participate in nanotechnology related activities in the international arena?
Yes. FDA participates in international forums (see Nanotechnology International Activities). FDA also works with its foreign regulatory counterparts to share perspectives and information on the regulation of nanotechnology products and uses.