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For Immediate Release: June 9, 2011

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FDA takes 'first step' toward greater regulatory certainty around nanotechnology

Agency outlines roadmap for discussion on nanotechnology in regulated products

The U.S. Food and Drug Administration today released draft guidance to provide regulated industries with greater certainty about the use of nanotechnology, which generally involves materials made up of particles that are at least one billionth of a meter in size. The guidance outlines the agency's view on whether regulated products contain nanomaterials or involve the application of nanotechnology.

Nanotechnology, the science involving manipulation of materials on an atomic or molecular scale, is an emerging technology with a broad range of potential applications, such as increasing bioavailability of a drug, improving food packaging and in cosmetics.

The draft guidance, "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," is available online and open for public comment. It represents the first step toward providing regulatory clarity on the FDA's approach to nanotechnology.

Specifically, the agency named certain characteristics – such as the size of nanomaterials used and the exhibited properties of those materials – that may be considered when attempting to identify applications of nanotechnology in regulated products.

"With this guidance, we are not announcing a regulatory definition of nanotechnology," said Margaret A. Hamburg, M.D., Commissioner of Food and Drugs. "However, as a first step, we want to narrow the discussion to these points and work with industry to determine if this focus is an appropriate starting place."

For products subject to premarket review, the FDA intends to apply the points contained in the draft guidance, when finalized, to better understand the properties and behavior of engineered nanomaterials. For products not subject to premarket review, the FDA will urge manufacturers to consult with the agency early in the product development process so questions related to the regulatory status, safety, effectiveness or public health impact of these products can be adequately addressed.

In 2006, the FDA formed the Nanotechnology Task Force, charged with identifying and addressing ways to better enable the agency to evaluate possible adverse health effects from FDA-regulated nanotechnology products.

The agency issued a report by the task force in 2007 that recommended that the FDA issue additional guidance and take steps to address the potential risks and benefits of drugs, medical devices and other FDA-regulated products using nanotechnology.

FDA will develop additional guidance documents related to specific products or product categories in the future, as needed.

It is critical for FDA to understand how changes in physical, chemical or biological properties seen in nanomaterials affect the safety, effectiveness, performance or quality of a product that contains such materials.

The FDA has a robust regulatory science agenda to develop the tools, methods and expertise necessary to evaluate products that contain nanomaterials or otherwise involve the use of nanotechnology. The FDA's regulatory science portfolio focuses on generating data needed to ensure the safety and effectiveness of products using nanomaterials, with an emphasis on products the use of which could present the greatest potential risk to public health.

FDA is releasing its document in coordination with the "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials" issued on June 9, 2011, jointly by the Office of Science and Technology Policy, Office of Management and Budget, and the United States Trade Representative:

(<http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>)

For more information:

Draft Guidance for Industry:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm>

Questions and Answers:

<http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm258391.htm>

FDA's Nanotechnology Web Page:

<http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm>

National Nanotechnology Initiative:

<http://www.nano.gov/>

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