FDA Releases Draft Guidance on Nanotechnology

June 13, 2011 by Sean Wajert

The U.S. Food and Drug Administration last week released draft guidance designed to move the process forward of providing its regulated industries with greater certainty about the use of nanotechnology (which generally involves materials made up of particles that are one billionth of a meter in size). The guidance outlines the agency's current view on certain issues about regulated products that contain nanomaterials or involve the application of nanotechnology.

FDA has not to date established regulatory definitions of "nanotechnology," "nanoscale" or related terms. The term is perhaps most commonly used to refer to the engineering (i.e., deliberate manipulation, manufacture or selection) of materials that have at least one dimension in the size range of approximately 1 to 100 nanometers. For example, theNational Nanotechnology Initiative Program defines nanotechnology as the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Other factors such as function, shape, charge, the ratio of surface area to volume, or other physical or chemical properties have also been mentioned in various published definitions.

Our readers know that 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 bio-availability of a drug, improving food packaging, and in cosmetics.

The draft guidance document, "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," represents a first step toward providing some regulatory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.

For products subject to premarket review, the FDA intends to apply the points contained in the draft guidance, when finalized, to better understand the properties and behavior of engineered nanomaterials.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.