FDA Issues Guidance on Drug and Biological Products Containing Nanomaterials

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Food and Drug Administration (FDA) has recently released guidance for the development of human drug products, including biological products, in which a nanomaterial is present in the finished dosage form. The guidance document is one of several FDA guidance documents related to FDA-regulated products that may involve the use of nanotechnology.

Nanotechnology may be used to create drug products in which nanomaterials serve a variety of functions, as active or inactive ingredients, including carriers loaded with an active ingredient. This document provides guidance on the development of human drug products, including those that are biological products, which include nanomaterial in the finished dosage form.

FDA has not established regulatory definitions of “nanotechnology”, “nanomaterial”, “nanoscale” or any other related terms. As described in FDA’s nanotechnology considerations guidance (issued in June 2014), at this time, when considering whether an FDA-regulated product involves the application of nanotechnology, FDA will ask:

1– Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm).

In addition, because materials or end products can also exhibit related properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm that might be relevant to evaluations of safety, effectiveness, performance, quality, public health impact, or regulatory status of products, they will also ask:

2– Whether a material or end product is engineered to exhibit properties or phenomena,

including physical or chemical properties or biological effects that are attributable to its dimension, even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).

This guidance does not apply to biological products composed of proteins, cells, viruses, nucleic acids, or other biological materials that naturally occur at particle sizes ranging up to 1 micrometer (1,000 nm), such as gene therapy or vaccine products, unless material that has been deliberately manipulated to have dimensions between 1-100 nm or to exhibit dimension-dependent properties or phenomena up to 1 micrometer, is also present in the product.

It discusses both general principles and specific considerations for the development of drug products containing nanomaterials, including considerations for developing products through abbreviated pathways. Considerations for quality, nonclinical, and clinical studies are discussed as they relate to drug products containing nanomaterials throughout product development and production. It also includes recommendations on the specific content of premarket applications for products containing nanomaterials where the nanomaterial is present in the finished dosage form.

The guidance has been prepared by the CDER Nanotechnology Working Group in the Center for Drug Evaluation and Research (CDER) with participation from the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.