

E-ALERT | Food & Drug

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FDA ISSUES DRAFT GUIDANCE ON THE APPLICATION OF NANOTECHNOLOGY

On June 9, 2011, the Food and Drug Administration (“FDA”) released a draft guidance entitled “Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology.”¹ The draft guidance provides manufacturers, suppliers, and importers of FDA-regulated products with FDA’s current view on whether products² contain nanomaterials or otherwise involve the application of nanotechnology. Nanotechnology has the potential to be used in a broad array of FDA-regulated products including, for example, medical products (e.g., to increase bioavailability of a drug), foods (e.g., to improve food packaging), and cosmetics (e.g., to change reflectivity).³

The limited scope of the draft guidance suggests that FDA continues to approach the regulation of products containing nanomaterials cautiously. The draft guidance does not establish regulatory definitions for nanomaterials, nanotechnology, or related terms. Nor does it attempt to categorize the regulatory status of nanotechnology products. Instead, it enumerates “points to consider” to help industry determine whether an FDA-regulated product contains nanomaterials or involves the application of nanotechnology. These points are intended to help identify when to consider the potential implications for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology.

POINTS TO CONSIDER

According to the draft guidance, FDA will ask two questions when considering whether a product contains nanomaterials or otherwise involves the application of nanotechnology:

1. Whether an engineered material or end product has at least one dimension in the nanoscale range (approximately 1 nm to 100 nm); or
2. Whether an engineered material or end product exhibits properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer.

¹ <http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm>. In conjunction with the draft guidance, FDA also published a Q & A. FDA, “Q & As – Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology,” <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm258391.htm> (June 9, 2011). The draft guidance was released in coordination with the “Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials,” also issued on June 9, 2011, jointly by the Office of Science and Technology Policy, Office of Management and Budget, and the Office of the United States Trade Representative (<http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>). FDA’s draft guidance was subsequently published in the Federal Register on June 14, 2011. 76 Fed. Reg. 34715 (June 14, 2011).

² FDA’s draft guidance notes that the use of the word “products” in the guidance is meant to include products, materials, ingredients, and other substances regulated by FDA. Draft Guidance, at n.2.

³ See FDA, Q & As, at Q.1.

FDA'S RATIONALE FOR ELEMENTS WITHIN THE POINTS TO CONSIDER

Having set out these two "points to consider," the draft guidance goes on to discuss FDA's rationale for several of the "elements" contained in the "points to consider." These include:

- **Engineered material or end product:** FDA is particularly interested in the *deliberate* manipulation and control of particle size to produce specific properties, because the emergence of these new properties or phenomena may warrant further evaluation. FDA distinguishes engineered materials or end products from products that contain incidental or background levels of nanomaterials or those that contain materials that naturally occur in the nanoscale range (e.g., microorganisms or proteins).
- **At least one dimension in the nanoscale range (approximately 1 nm to 100 nm):** FDA notes that it chose the 1 nm to 100 nm size range for its "points to consider" because (a) it is "commonly used" in the scientific community, and (b) materials in this range can exhibit new or altered physicochemical properties which enable novel applications.
- **Exhibits properties of phenomena . . . that are attributable to its dimension(s):** FDA is interested in how materials at nanoscale can affect the safety, effectiveness, performance, quality, and, where applicable, public health impact of products. For example, it notes that dimension-dependent properties or phenomena may be used for functional effects such as increased bioavailability, decreased dosage, or increased potency of a drug product; decreased toxicity of a drug product; better detection of pathogens; enhanced protection offered by improved food packaging materials; or improved delivery of a functional ingredient or a nutrient in food.
- **Size range of up to one micrometer (1,000 nm):** In the absence of a bright line upper limit, FDA considers an upper bound of 1,000 nm as a reasonable parameter for screening materials with dimensions beyond the nanoscale range to determine whether these materials exhibit properties or phenomena attributable to their dimension(s) and relevant to nanotechnology.

APPLICABILITY OF THE POINTS TO CONSIDER

FDA intends its "points to consider" to be applicable to all products, materials, ingredients, and other substances regulated by FDA (e.g., drugs, devices, biologics, foods, and cosmetics). Further, they apply not only to new products, but also may apply when manufacturing changes alter the dimensions, properties, or effects of a product or any of its components. For products subject to premarket notice or review, FDA intends to incorporate attention to nanomaterials into its product-specific review procedures. For products not subject to premarket review, manufacturers are encouraged to consult with FDA early in the product development process. Future guidance may be articulated for specific product areas.

PUBLIC COMMENT

The draft guidance is open for public comment until August 15, 2011.

Covington is closely tracking important developments in the regulation of emerging nanotechnologies across numerous industry sectors, and the firm is available to advise on the resulting implications for businesses engaged in this fast-developing area.

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