CHPA Comments on Draft FDA Guidance on Nanotechnology

August 25, 2011 by Sean Wajert

Last week, the Consumer Healthcare Products Association (CHPA) submitted comments on the FDA's draft guidance on nanotechnology, "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, " which we posted on before.

CHPA is the not-for-profit association representing the makers of over-the-counter medicines and dietary supplements, and the consumers who rely on these healthcare products. CHPA is one of the oldest trade associations in the United States. Nanotechnology holds great promise for this industry.

CHPA agreed with the FDA that proposing a "definition" for nanotechnology is not a straight forward process; applying a strict, universal definition of nanotechnology to the fields of drug research, drug product development and drug manufacturing would not be, in CHPA's view, an appropriate science-based approach.

Defining a nanomaterial as a structure between 1 and 100 nm, and using this definition to establish new regulations on products containing nano-sized materials, would, they asserted, erroneously group drug products together to form a new category based on size of ingredients. Nanotechnology is not a separate drug category, but a technology used to, among other things, generate nanometer-sized ingredients and excipients. Inclusion of nanometer-sized active ingredients or excipients in a drug product does not by itself determine a product's safety and efficacy (i.e. size alone is not itself an indicator of toxicity).

CHPA agreed that the agency should distinguish between engineered nanomaterials and those naturally occurring at the nanoscale. There exist common pharmaceutical ingredients with a long history of use that should not be considered as "engineered nanomaterials" or as agglomerates of nanomaterials but which may have particles whose size naturally falls within this range.

CHPA also noted that NIOSH accurately refers to nanotechnology as the manipulation of matter on a near-atomic scale to produce new structures, materials, and devices. Nanomaterials are mainly engineered for their novel chemical, physical, and quantum mechanical properties; at the nanometer size, many materials exhibit such unique beneficial properties that may not exist when at the micron size. CHPA argued it is appropriate to include in the description the notion of particles that are deliberately manipulated and controlled at the nanoscale, which also exhibit changes in physical, chemical, or electromagnetic properties, the existence of unique phenomena to enable novel applications.

For example, milling, a beneficial process for the manufacturing of many individual pharmaceutical ingredients, may create particles with a portion of the particle size distribution under 1 micron; however, the chemical properties of the milled ingredient usually do not differ drastically from that of the bulk ingredient.

The agency should give further consideration, said CHPA, to the possibility that not all materials should be considered equal; each material must be evaluated on a case-by-case basis. For example, soluble nanomaterials might not be treated the same as insoluble ones.