

Consumer Healthcare Products Association

Position Statement on Engineered Nanomaterials (Nanotechnology)

The Consumer Healthcare Products Association (CHPA) and its members, the U.S. manufacturers and distributors of over-the-counter (OTC) medicines and nutritional supplements, recognize the efforts of the U.S. Food and Drug Administration (FDA) to further develop methodologies and techniques for characterization of nanomaterials for drug applications. In addition, CHPA applauds the approach for creating a public forum to collect current research from academia, industry, and other government agencies to advance the science of engineered nanomaterials.

Consumers rely on safe and effective OTC medicines to treat their symptoms and those of their family members. Importantly, OTC medicines are accessible to all consumers and remain the most cost-effective preparations currently in the healthcare environment. The consumer healthcare industry is continuously striving to develop new innovative medicines to enhance the science and the efficacy of available products. Although engineered nanomaterials do not appear to be widely used in OTC therapies presently, CHPA does feel it is a promising and important technology that has the potential to deliver innovative products with increased benefit to the consumer.

The FDA currently maintains a selection of guidance documents for specific drug categories and also requires adequate toxicology testing to clearly ensure drug safety. Each new drug application is considered on a case-by-case basis to determine safety and efficacy. CHPA considers that current FDA-approved test procedures for establishing safety and efficacy for a drug product are also adequate for products containing engineered nanomaterials.

Nanotechnology is not a separate drug category, but a technology used to generate nanometer sized ingredients and excipients. Inclusion of nanometer sized active ingredients or excipients in a drug product does not automatically determine a product's safety and efficacy (i.e. size alone is not in itself an indicator of toxicity); the drug product should be held to the same stringent standards as any other drug product to prove both safety and efficacy. At this time, we do not consider it necessary that products containing engineered nanomaterials should be approved through a different set of regulations. There is no established risk for the use of nanomaterials in OTC drug products

In addition, CHPA does not agree with the current proposed "definitions" of nanotechnology; applying a strict, universal definition of nanotechnology to the fields of drug research, drug product development and drug manufacturing is not, in our 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 nanosized materials will erroneously group drug products together to form a new category based on size of ingredients. National Institute for Occupational Health and Safety (NIOSH) accurately refers to "nanotechnology (as) the manipulation of matter on a near-atomic scale to produce new structures, materials, and devices" and here, does not limit the classification to a specific size range. Certain elements of this terminology may be considered. Nanomaterials are mainly engineered for their novel chemical, electronic, and quantum mechanical properties; at the nanometer size many materials exhibit such unique beneficial properties that may not exist when at the micron size.

On that note, all materials should not be considered equal under a single guidance for “nanotechnology” of drug products and each material must be evaluated on a case-by-case basis. There exist many categories under the main umbrella of engineered nanomaterials; for example, soluble nanomaterials should not be treated the same as insoluble ones. In addition, properties of “soft” nanomaterials differ greatly from that of “hard” nanomaterials. Criteria that are considered important, but not limited to, are as follows: shape and size (how many dimensions are on the nanoscale), agglomeration/aggregation, distribution of particles, functional properties such as mobility, flow, hydration, desiccation, surface charge (hydrophobicity/hydrophilicity), and zeta potential.

Each drug application should be examined on a case-by-case basis in light of the different properties of the nanomaterials that may be utilized and the route of administration of the finished product. If a drug product containing nanomaterials is thoroughly tested for safety and efficacy with the current rigorous drug evaluation processes, further testing should not be necessary.

CHPA does recognize FDA’s efforts to create guidance documents to facilitate proper characterization of nanomaterials in the final drug product. CHPA recommends when developing a guidance document related to nanotechnology for the drug industry, the construction of several different guidance documents should be considered rather than one that encompasses all materials, i.e. “soft” versus “hard” nanomaterials.

Lastly, CHPA considers it unnecessary for OTC drug products containing nanomaterials to be required to contain any “nano” labeling unless desired by the OTC drug manufacturer. The “nano” wording alone would not inform the buyer of any additional safety or efficacy information. However, a drug product not containing engineered nanomaterials should not be misleading through inappropriate use of the prefix “nano”.

In conclusion, CHPA and its member companies consider that while further development of characterization methodologies is clearly needed in all areas of nanotechnology, the current regulations and required toxicology testing to support the safety of OTC drug products are adequate for products which may be formulated with engineered nanomaterials.