Share Your Opinions

Complex drugs such as nanomedicines and nanosimilars hold great promise for addressing some of the most challenging issues in nearly every medical specialty. The safety and efficacy of nanomedicines can be influenced by minor variations in the drug’s composition. Therefore, many experts believe appropriate characterization of these medicines may, in some cases, require clinical trials to ensure the safety of patients.

The U.S. Food and Drug Administration (FDA) reviews products containing nanomaterials and/or whether they involve nanotechnology on a case-by-case basis through the currently established regulatory pathways. Yet, suggestions have been made that additional guidance is necessary to provide clarity and legal certainty to manufacturers, policymakers, healthcare providers and the consumer.

As engaged and active members of the nanomedicine community, your perspectives are instrumental to establishing flexible and science-based regulatory guidelines and shaping policy for the future needs ahead. If you would like to share your experiences or express your opinions regarding the regulatory pathway for nanomedicines and nanosimilars, please send your comments to:

Office of Pharmaceutical Science
U.S. Food and Drug Administration
WO Building 51, Room: 4184 10903 New Hampshire Ave. Silver Spring, MD 20993, USA

Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993, USA

The U.S. Patent and Trademark Office (PTO) has created an internal working group and developed a rudimentary classification system for nanotechnology patents. In the past, the PTO has held nanotechnology customer partnership meetings to share unique experiences and patent law issues pertaining to nanotechnology. According to the PTO website such interaction and feedback is encouraged: “We value our customers in obtaining feedback from individual participants as important in our efforts to continuously improve the quality of our products and services.” Accordingly, you may send comments to:

Office of the Under Secretary and Director
U.S. Patent and Trademark Office
Alexandria, VA 22313-1450