

Advisory Committee for Pharmaceutical Science

April 13-14, 2004

Nanotechnology: An Awareness Topic

Nanotechnology is a very rapidly growing area of science and is anticipated to lead to the development of many novel and sophisticated applications in drug delivery systems. Historically, nanometer sized materials (e.g., silver and gold colloids) have been used in medicine for many years. Additionally, many current pharmaceutical materials and drug delivery systems (e.g., micro-emulsions, liposomes) have dimensions in the nanometer range. The safety and efficacy of these products are currently being addressed adequately within the established regulatory system. However, the extensive research and development activities in nanotechnology are expected to lead to the development of more complex drug delivery systems, drug-device combination products, and other products regulated by the FDA. To ensure that FDA is ready to meet this responsibility, a multi-disciplinary discussion group has been assembled at the Agency level, within the Office of Commissioner. This group is proactively gauging the growth of nanotechnology so as to anticipate the complexity of future submissions to the FDA. As such, the Agency needs to have in place adequate regulatory procedures to deal with the challenges of the nascent technology.

The purpose of the brief discussion at the April 2004 Advisory Committee is to share information on CDER/FDA activities and emerging plans to address the regulatory needs of nanotechnology based products. At a future meeting of the Advisory Committee we will plan to discuss and seek advice on our approach to address nanotechnology based products.