NCTR/FDA and NCL/NCI Announce Continuation of their Partnership to Study Nanotechnology Safety

In 2006, the National Cancer Institute (NCI) and the Food and Drug Administration (FDA) entered into a formal partnership (Memorandum of Understanding) to study the safety of nanotechnology-derived products and established NCI's Nanotechnology Characterization Lab (NCL). This successful interaction is being continued by collaboration between FDA's National Center for Toxicological Research (NCTR) and the NCL.

The National Center for Toxicological Research (NCTR) is the FDA's internationally recognized research center. Its mission is to develop science-based best-practice standards, guidance, and tools and to incorporate toxicological advancements into the regulatory process. NCTR has state-of-the-art facilities and expertise for conducting toxicological studies in a variety of animal species.

The NCI Alliance for Nanotechnology in Cancer is a major NCI program aimed at accelerating the translation of nanotechnology-derived cancer treatments into clinical applications. The Alliance supports the research of hundreds of investigators who are using nanotechnology as the basis of new products for imaging, early detection, and cancer therapy. The safety-testing arm of the Alliance is the Nanotechnology Characterization Laboratory (NCL), which is itself a longstanding collaboration between NCI and the FDA. The NCL is operated through the NCI's Federally Funded Research & Development Center (FFRDC) at NCI-Frederick and performs nanomaterial safety and toxicity testing *in vitro* (in the laboratory) and in animal models. To date, the NCL has evaluated more than 180 different nanoparticles.

NCL and NCTR/FDA share common goals related to nanotechnology safety," said Dr. Piotr Grodzinski, the Director of NCI's Alliance for Nanotechnology in Cancer. "NCTR and NCL have an interest in understanding mechanisms of nanoparticle toxicity, and exploring nanoparticle biological behavior. This collaboration allows the medical and regulatory communities to benefit from the scientific expertise of both the NCI and the FDA".

NCL is partnering with NCTR/FDA in a way that leverages both NCTR and NCL core expertise and resources to facilitate nanotechnology studies in large animals (nonhuman primates). "The goal of these studies is refinement of a framework for effective risk identification, assessment, and regulatory evaluation of nanotech products," said Dr. William Slikker, the Director of NCTR.

The aim of the continuing collaboration under the MOU is to understand how nanoparticles interact with the immune system, and to further evaluate the capabilities of nanotechnology to reduce adverse drug effects. NCL and NCTR also plan to conduct GLP-quality pharmacokinetic studies that will provide nonhuman primate data for interspecies pharmacokinetic comparisons. Measures of toxicity, specifically immunotoxicity, that are amenable to blood analysis will also be included.

NCL and NCTR/FDA expect these collaborative studies will facilitate development and regulatory review of new nanotech clinical products and aid in the development of nanotechnology-based platforms and tools for medical research and clinical applications.-----

For more information about the FDA's National Center for Toxicological Research (NCTR), go to http://www.fda.gov/AboutFDA/CentersOffices/nctr/default.htm. For more information about nanotechnology's use in the diagnosis and treatment of cancer, visit the NCI Alliance for Nanotechnology in Cancer at http://nano.cancer.gov/.