FDA Research - The Foundation for Sound Regulatory Decisions

FDA *Consumer* magazine
The Centennial Edition/January-February 2006

The National Center for Toxicological Research conducts peer-reviewed studies to develop a scientifically sound basis for the FDA's regulatory decisions. The 504-acre facility, located in Jefferson, Ark., houses state-of-the-art research laboratories, animal facilities, and Biosafety Level 3 laboratories

The National Center for Toxicological Research (NCTR) plays a critical role in the Food and Drug Administration's mission to promote and protect public health.

The NCTR grew out of the conversion of the Army's Pine Bluff Arsenal to a unique facility for improving consumer protection. President Richard M. Nixon announced in January 1971 that the FDA would establish and administer the NCTR at the plant formerly used to produce biological warfare agents.

Located in Jefferson, Ark., about 30 miles south of Little Rock, the facility occupies 504 acres and includes 33 buildings with 1 million square feet of floor space. About 700,000 square feet of that space has been renovated to provide state-of-the-art research laboratories, animal facilities, and Biosafety Level 3 laboratories.

The center, which is the fundamental research arm of the FDA, provides the FDA and other regulatory agencies with the knowledge required to make decisions concerning toxic substances and their effects on human health.

The NCTR conducts peer-reviewed research targeted to develop a scientifically sound basis for regulatory decisions and to reduce risks associated with FDA-regulated products. This research is aimed at evaluating the biological effects of potentially toxic chemicals or microorganisms and developing methods to improve assessment of human exposure, susceptibility, and risk.

The FDA's research arm also is developing and standardizing new technologies, such as

genomics, proteomics, metabonomics, imaging, and nanotechnology, to identify and characterize early biomarkers of toxicity in traditional toxicological models.

Rats and mice are used to initially test the safety of FDA-regulated products and there often is uncertainty concerning the value of these predictions using available technology. The application of these new tools in animals and humans will help to more confidently predict the safety of medical products.

In addition, the NCTR is using data collection, interpretation, and storage of information about gene and protein expression (toxicoinformatics) to manage and integrate data from these new technologies to predict an adverse event prior to its occurrence.

The NCTR benefits significantly from collaborations with other FDA centers and other government agencies, academia, and industry.

One example is the use of ArrayTrack, an NCTR-developed tool used to store, analyze, and interpret DNA microarray data. This software is being used by the Center for Drug Evaluation and Research to assess pharmacogenomic data voluntarily submitted by the regulated industry. In this collaboration, the FDA is a catalyst creating new standards for drug development to promote and protect the public health.

A group of government, academic, and industry scientists meeting near Stanford University in December 2005 concluded that the NCTR is the "engine" moving the application of pharmacogenomics to improve health care. According to Raj Puri, M.D., Ph.D., of the FDA's Center for Biologics Evaluation and Research, tools such as ArrayTrack further the concept that the FDA is a catalyst for product development. ArrayTrack also is being considered as a regulatory tool for use by other agencies.

"Providing these tools and approaches is an important role for NCTR researchers," says William Slikker, Ph.D., acting director of the NCTR. "We anticipate that this analytical infrastructure will help in the transformation of the nation's health care system toward personalized medicine and the goal of proving the best treatment for each individual patient."

An important FDA function is to use risk management to provide taxpayers the greatest amount of health promotion and protection at the least cost. Today, that goal is accomplished by safety assessment of FDA-regulated products in substitute organisms and, to a lesser extent, in humans.

Ultimately, researchers believe researchers can use a systems biology approach to identify new disease markers and drug targets that will help design products to prevent, diagnose, and treat disease. In addition, the new approach also is essential to the field of nutrition and related issues such as obesity, dietary supplements, and essential nutrients, according to Slikker.

A systems biology approach to the assessment of the safety of FDA-regulated products enhances the mission of the NCTR and is aligned with Health and Human Services Secretary Mike Leavitt's goals of transforming health care, advancing medical research, and securing the homeland.