FDA U.S. FOOD & DRUG ADMINISTRATION
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

July 18, 2018

To: Science Advisory Board Members to the National Center for Toxicological Research

From: Drs. Donna Mendrick and Daniel Acosta

Dear Science Advisory Board Subcommittee Members,

We welcome participation of the Scientific Advisory Board (SAB) in the review of the research conducted at the National Center for Toxicological Research (NCTR) that will occur on December 4-5, 2018. The SAB is comprised of eminent scientists in their fields and NCTR requests that the Board conduct external reviews of its research programs to provide independent scientific guidance, technical advice, and recommendations on strategic direction and mission relevance to the NCTR leadership and program staff. It is anticipated that the SAB will provide objective advice to the NCTR Director, researchers and senior staff on strengths and perceived weaknesses of each aspect of the research program. Because there is insufficient time to present all the ongoing and planned research being conducted at NCTR, summaries of research programs will be provided with some examples of individual projects.

Research projects at NCTR are conducted by senior scientists with the assistance of staff fellows and postdoctoral fellows. These projects may arise in several ways including:

- In response to requests from FDA regulatory centers
- Initiated by NCTR Principal Investigators
- Requested from the National Toxicology Program (since there are reviewed by a multi-government panel in great detail, these studies are not covered in this SAB review)

These projects are critical to the success of NCTR's mission and goals, and the quality of the science must be state-of-the-art, able to withstand critical analysis and worthy of publication in peer-reviewed journals.

Tasks for the SAB:

- What is your evaluation of the research programs being conducted?
- One role for NCTR is to prepare the FDA for new technologies. Please evaluate how NCTR may improve horizon-scanning for emerging sciences and comprehensive safety assessment approaches

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- Identify and discuss critical regulatory, research, scientific issues, trends, and needs in relation to the research capabilities of the NCTR/FDA. (Feedback will be given in open session except for those areas that impact personnel. That feedback will be given in closed sessions.)

We look forward to your visit and review of NCTR's research.

Sincerely,

Donna L. Mendrick, Ph.D.
Designated Federal Official and Associate Director for Regulatory Activities

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Deputy Director of Research