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

March 29, 2021

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

From: Drs. Donna Mendrick and William Slikker, Jr.

Dear Science Advisory Board Members,

We welcome participation of the Science Advisory Board (SAB) in the review of the research conducted at the National Center for Toxicological Research (NCTR) that will occur on May 11-12, 2021. 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 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 (because these studies are reviewed by a multi-government panel in great detail, they will not be 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 current and proposed research programs?
- 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 provided in an open session except for those areas that impact personnel. That feedback will be given in closed sessions.)

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

Sincerely,

Original Digitally Signed

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

Original Digitally Signed

William Slikker, Jr, Ph.D.
Director