DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue.
Silver Spring, MD 20993-0002

AUG 20 2013

Michael A. Carome, M.D.
Director
Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen's Health Research Group
1600 20th Street, NW
Washington DC 20009

RE: The Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT)

Dear Drs. Carome and Wolfe:

Thank you for sharing your concerns about the SUPPORT study that involved treatment of premature infants with different oxygen levels. Your letter dated August 2, 2013 raises important questions about the language used in the informed consent documents and about the use of modified fetal pulse oximeters during research on a vulnerable population.

The Office of Human Research Protection is closely examining current guidelines for disclosing study risks during the informed consent process, based on their review of the SUPPORT study and broader ethical issues related to the conduct of research in standard of care contexts.

The Food and Drug Administration (FDA) is assessing the information you have provided as well as other available information on and surrounding this study. FDA's mandate is to protect and promote public health. We take protection of human subjects very seriously, especially when a vulnerable population such as premature infants is involved. FDA device experts will carefully consider all the information available, and identify an appropriate course of action if we determine that FDA regulations were violated during the conduct of the SUPPORT study.

Thank you again for contacting us about this important matter. If you have further questions or concerns, please contact Albert Rodriguez at (301) 796-6336.

Sincerely yours,

Jeffrey Shuren M.D., J.D
Director
Center for Devices and
Radiological Health