DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993

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

Dear Drs. Carome and Wolfe:

We are writing in follow-up to your letter dated March 10, 2015. You requested a response to three questions asked in your August 2, 2013 letter and two additional questions about the outcome of our review. Please understand that FDA does not usually notify individuals or organizations about the status of complaint review or actions taken regarding a complaint.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT study) was not conducted by a device manufacturer to determine the safety or effectiveness of their device. It was coordinated by the National Institutes of Health and designed to evaluate different care options. This study was designed over ten years ago. Since that time, awareness of regulatory responsibilities has received attention across HHS agencies. We encourage study sponsors under our regulatory authority, usually medical device manufacturers, to enter into discussions with us early in the planning process. We continue to educate and advise other government agencies as well.

Typically, studies evaluating the safety and effectiveness of pulse oximeters do not require FDA approval of a separate Investigational Device Exemption (IDE). We encourage Institutional Review Boards to consult FDA if there is any question about whether or not a device study requires an IDE. Guidance is also available on that topic at: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

The disclosure of study risks via the informed consent document is a vital part of the clinical research process. As you know, on August 28, 2013, the Department of Health and Human Services (HHS) held a meeting to receive public input and comment on how an IRB should assess the risks of research involving randomization to one or more treatments within the standard of care for particular medical conditions, and what reasonably foreseeable risks of the research should be disclosed to research subjects in the informed consent process. Information is available at: http://www.hhs.gov/ohrp/newsroom/rfc/Public%20Meeting%20August%2028,%202013/aug28public.html

The meeting proceedings, the public comments made at the meeting, and written comments from the public submitted to HHS were carefully considered during the development of a draft guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care by the Office of Human Research Protection that was published in the *Federal Register* on October 24, 2014. Information is available

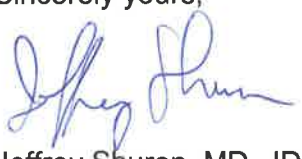
at: http://www.gpo.gov/fdsys/pkg/FR-2014-10-24/pdf/2014-25318.pdf and http://www.hhs.gov/ohrp/newsroom/rfc/comstdofcare.html#

We refer you to this document for any further questions related to the SUPPORT informed consent.

FDA takes protection of human subjects very seriously, especially when a vulnerable population such as premature infants is involved. After carefully considering all information available, we have no plans for additional investigation.

Thank you again for taking the time to bring this important matter to our attention.

Sincerely yours,



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