

March 4, 2005

Philip A. Ludbrook, MD
Associate Dean, Washington University Medical Center
Chair, Washington University Medical Center Human Studies Committee
660 S. Euclid Avenue
Box 8089
St. Louis, MO 63110

Subject: **“Precursor Preference in Surfactant Synthesis of Newborns”**

Re: Notification of FDA regulatory authority

Re: Notification of intent to seek public comment

Dear. Dr. Ludbrook:

This letter is to notify you that the Office of Human Research Protection (OHRP) at the Department of Health and Human Services forwarded the above-referenced protocol to the Food and Drug Administration (FDA) to make a determination as to whether the above-referenced study is regulated by FDA, and therefore whether it is subject to 21 CFR Part 50, Subpart D, “Additional Safeguards for Children in Clinical Investigations.” FDA has completed its assessment and determined that the study is a clinical investigation regulated by the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act. Accordingly, it must be conducted in compliance with the requirements set forth in 21 CFR Parts 56 and 50, including Subpart D of Part 50.

Your February 7, 2005 letter to OHRP stated that the institutional review board that reviewed the above-referenced protocol concluded that the protocol presented an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, but was not otherwise approvable. Therefore, in accordance with 45 CFR 46.407 and 21 CFR 50.54, OHRP and FDA will be seeking public comment on and consulting with a panel of experts regarding the protocol.

FDA believes that the public cannot provide meaningful comment on the proposed clinical investigation without having access to sufficiently detailed information regarding the research. Therefore, FDA intends to make publicly available, in a docket on FDA’s website, all information that we believe to be necessary for the public’s consideration and comment on the proposed clinical investigation. This includes, but is not limited to, the protocol and all institutional review board materials sent to FDA and OHRP as part of the referral for review. If you have any questions regarding this public availability, please contact me as soon as possible so we can discuss the matter. We are aware that OHRP is sending you a similar letter regarding the planned public availability of these materials.

Your participation, and the participation of Dr. Kimberly Spence, Principal Investigator, will be critical to this process, and we will be communicating with you in the near future about the process and the timing of the expert panel review. In the past we have found it

very beneficial and informative to have the IRB Chair and the Principal Investigator present for the expert panel meeting.

In the course of FDA's consideration of whether this protocol is subject to FDA regulation, the issue was raised of whether an investigational new drug application (IND) is required for this protocol. Accordingly, I have forwarded the protocol to Dr. Robert Meyer, the director of the Office of Drug Evaluation II at FDA's Center for Drug Evaluation and Research. He or someone on his staff will be in contact with you regarding whether an IND is required.

Should you have any questions or wish to discuss the Subpart D process in the meantime please contact Dr. Sara Goldkind at 301-827-0428.

Sincerely,
Dianne Murphy, MD
Director
Office of Pediatric Therapeutics
Office of the Commissioner

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cc: Dr. Kimberly Spence, Principal Investigator
Dr. Murray Lumpkin, OC, FDA
Dr. Steven Galson, CDER, FDA
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